Journal of Law, Market & Innovation

ISSUE 3/2025

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Journal of Law, Market & Innovation

3/2025

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Journal of Law, Market & Innovation
Vol. 4 - Issue 3 - 2025
ISSN 2785-7867
Journal of Law, Market & Innovation
Editors-in-Chief:
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FOREWORD TO ISSUE 3/2025

ECODESIGN & SUSTAINABLE PRODUCTS INITIATIVES

The Special section of the present Issue 3/2025 (Vol. 4) of the *Journal of Law, Market & Innovation* (JLMI) is dedicated to Ecodesign and Sustainable Products Initiatives, a topic that has become central to contemporary regulatory debate[1]. The shift from a linear to a circular economic model is reshaping legal frameworks, market practices, and technological development across jurisdictions. This transformation raises broader questions about the role of private law, particularly contract law, in integrating sustainability and environmental objectives into commercial relationships[2], and about how traditional market mechanisms can reconcile profit-driven incentives with public-interest goals such as climate protection and sustainable development[3].

In Europe, the Ecodesign for Sustainable Products Regulation (ESPR) (Regulation (EU) 2024/1781) marks a decisive step toward integrating environmental considerations into product design, production, and lifecycle governance. Its introduction of the Digital Product Passport, performance and information requirements, and sustainability-oriented responsibilities signals a profound rethinking of how environmental impacts are evaluated and managed across value chains. Complementary instruments such as the CSRD (Directive (EU) 2022/2464 on corporate sustainability reporting) and the CSDDD (Directive 2024/1760 on corporate sustainability due diligence) further embed transparency, accountability, and due diligence in corporate behaviour, reinforcing the vision of sustainable products as the new normal for the internal market.

The reflections provided in this Special Issue resonate strongly with the Innovation Letter by Prof. Ann Tischner, "*Circular design and environmentally-centered design thinking in law*", which opens the volume. Drawing from Victor Papanek's early warnings

[1] Jacopo Ciani Sciolla, Ecodesign. Le sfide filosofico-giuridiche della progettazione sostenibile, Mimesis, Milano / Udine, 2024.
[2] Cristina Poncibò, 'The Contractualisation of Environmental Sustainability' (2016) 12 (4) European review of contract law 335-355 and Id, 'The Contract Governance of Sustainable Development' (2022) 1 Isaidat law review 35-56.
[3] Riccardo De Caria, 'Regole di sostenibilità socio-ambientale e principi del libero mercato: verso un nuovo paradigma?' in Federico Riganti (ed), *Sostenibilità e mercati vigilati: regolatori e operatori nella "galassia" ESG* (Giappichelli, Torino 2024) 11-36.

in *Design for the Real World*, Prof. Tischner illuminates the paradox of design: once implicated in wastefulness and environmental degradation, design is now expected to serve as a catalyst for societal and ecological wellbeing[4]. Her analysis of circular design—its methodologies, its lifecycle-based perspective, and its alignment with the EU Circular Economy Action Plan—provides the conceptual bridge between product innovation and legal transformation. Crucially, she underscores that designers do not operate in isolation: markets, infrastructures, cultural norms, and the legal system itself determine whether circularity can become a lived reality rather than an aspirational blueprint.

Prof. Tischner invites us to rethink the legal system as an ecosystem, one that must be reoriented through what she calls an "environment-centred ethos." Her argument that law should adopt the iterative, holistic and interdisciplinary mindset characteristic of design thinking mirrors the questions explored by the authors of this issue. How can legal norms support durability, repairability, and modularity? How can rules remain both flexible and future-proof, without succumbing to the risks of legislative overload? And how can legal incentives be structured to reward sustainable creativity—whether through intellectual property, alternative incentive mechanisms, or "green" reinterpretations of existing frameworks?

The contributions assembled here take up these challenges across a wide range of domains.

The transformation of consumer law through ecodesign obligations is examined by Alberto Jaci in *"Ecodesign and consumer law"*. It explores how Regulation (EU) 2024/1781 links sustainability criteria at the design stage with the substance and scope of consumers' contractual rights—reshaping product conformity, information duties, anti-greenwashing safeguards, and the role of national contract law and private international law in operationalising these new obligations.

The regulatory, competitive, and governance challenges arising from the new ecodesign framework is analysed by Armando Alvares-Garcia Júnior in *"Regulatory Challenges in Sustainable Markets: The Impact of Regulation (EU) 2024/1781 on European Competitiveness"*. His article assesses how the Regulation interacts with technical standards and overlapping legal regimes, the differentiated burdens it places on SMEs, its effects on global supply chains, and the risks that implementation gaps pose to innovation and competitiveness—offering policy recommendations for adaptive, inclusive regulatory pathways.

Alexandra Papageorgiou explores the evolving judicial landscape of ecodesign through the landmark case *BSEF v Commission* (T-113/20). This article argues that the judgment crystallises the shift from the energy-efficiency-focused approach of the Ecodesign Directive to the broader sustainability paradigm embodied in the ESPR. By upholding the

[4] Jacopo Ciani Sciolla, 'Industrial Design Protection and Ecodesign Innovation: In-terplays and Interferences' Annali Italiani di diritto d'autore (2025, forthcoming).

Commission's competence to impose material restrictions for recyclability and improved end-of-life outcomes, and by clarifying the interplay between ecodesign, chemicals, and waste regimes, the General Court validated the proportionality and legitimacy of a more expansive regulatory scope.

Valerio Giovannini examines the cumulative regulatory burdens arising from the intersection of ESPR and the Carbon Border Adjustment Mechanism (CBAM). The article analyses how concurrent application of these instruments may generate de facto extraterritorial effects, through granular emissions reporting, traceability obligations, and product redesign requirements, while raising questions of proportionality, legal coherence, and cost-effectiveness for international producers and EU consumers.

The role of Life Cycle Assessment (LCA) and eco-design as bridges between technological innovation, environmental responsibility, and consumer protection is analysed by Martina Mastrodomenico and Remigio Graziani in *"LCA and eco-design between innovation and responsibility"*. Their contribution shows how LCA provides the scientific foundation for responsible production and consumption policies, how eco-design operationalises durability, repairability and recyclability, and how these tools underpin key instruments—from the ESPR and Directive 2019/771 to the proposed Green Claims Directive, ISO 14040/14044 standards, and the emerging right to repair.

The tensions between intellectual property protection and the EU's evolving right to repair is examined by Manon Vanderhaeghe in *"The impact of intellectual property protection on the EU's right to repair"*. Her article analyses how IP rights can create barriers to accessing essential repair commodities such as spare parts, diagnostic tools, software, and repair information. Against the backdrop of Directive (EU) 2024/1799 on the right to repair, the ESPR, and the Data Act (Regulation (EU) 2023/2854), she examines how these instruments jointly articulate a "right to repair sensu lato," while identifying limits and frictions arising from their interaction with IP rights.

The role of the Digital Product Passport (DPP) in empowering consumers and other economic actors under the ESPR is at the core of the contribution by Anna Katharina Suzuki-Klasen. Her article investigates how the DPP—together with complementary labels and information requirements—supports product traceability, facilitates sustainable consumer choice, and strengthens circularity by providing data relevant to repairers, refurbishers, and waste operators, while also highlighting potential limitations such as accessibility challenges and information overload.

Authors engage these themes from doctrinal, empirical, normative, and interdisciplinary perspectives. In doing so, they echo Prof. Tischner's call for a renewed methodological lens—an emerging "ecological analysis of law"—that evaluates legal rules not only for efficiency or coherence but for their environmental and societal impact.

We express our deep gratitude to the scholars who contributed to this issue, to the reviewers for their careful and generous evaluations. We hope that this issue will support policymakers, practitioners, and researchers in navigating the transformative legal and

economic shifts now underway. As the frameworks governing sustainable products continue to evolve, JLMI remains committed to fostering the interdisciplinary dialogue needed to understand their implications and to shape a more resilient, sustainable, and equitable future.

J.C.S., R.d.C., S.M., C.P.

Anna Tischner *

INNOVATION LETTER

CIRCULAR DESIGN AND ENVIRONMENTALLY-CENTRED DESIGN THINKING IN LAW

Abstract

Circular design is essential for transitioning from the harmful linear "take-make-dispose" model—diagnosed by Victor Papanek as producing "permanent garbage"— to a circular economy focused on extending product lifecycles, ensuring durability and repairability, and closing resource loops. Achieving this requires lawyers and legislators to move past fragmented, linear thinking and adopt an "environment-centred ethos," using design-thinking methods to reconceive the legal system as an ecosystem capable of generating resilient and adaptable solutions. To address major legal barriers—such as the tension between IP rights aimed at short-term exclusivity and the long-term needs of circularity—there is an urgent need for an "ecological analysis of law" that evaluates existing norms and develops alternative incentives that make ecodesign both economically viable and environmentally beneficial.

JEL CLASSIFICATION: K320

SUMMARY

1 Design for the Real World

More than fifty years ago, design educator and advocate for responsible design Victor Papanek opened his seminal book *Design for the Real World* (1971)[1] with a stark diagnosis: "There are professions more harmful than industrial design, but only a very few of them." Papanek accused design of "persuading people to buy things they don't need, with money they don't have, in order to impress others who don't care." He further lamented that, "by creating whole new species of permanent garbage to clutter up the landscape, and by choosing materials and processes that pollute the air we breathe, designers have become a dangerous breed."[2]

* Anna Tischner is a professor of intellectual property law at the Jagiellonian University in Krakow, Poland.
[1] Victor Papanek, *Design for the Real World* (Bentham Books 1971).
[2] Ibid. Preface, 14.

10.13135/2785-7867/12843

Papanek's oeuvre inspired the environmental turn in design as an opposition to planned obsolescence, mass consumerism, and short-term profitability.[3] The idea of circular design emerged in close connection with the broader project of economic transformation—from a linear economy, based on the take-make-dispose model, to a circular economy.[4] The EU Circular Economy Action Plan,[5] a cornerstone of the European Green Deal,[6] focuses on improving product design to support long-term use. It highlights key criteria such as durability, modularity, ease of part replacement, repairability, and recyclability. The overarching aim is to extend product lifecycles and ensure that all components can be reused, thereby closing resource loops. As the European Commission (EC) rightly observes, current product design often overlooks environmental impacts across the lifecycle—particularly aspects of circularity—which leads to frequent product replacement and greater energy and resource consumption in manufacturing, distribution, and disposal.[7]

As a discipline, circular design provides specific knowledge and methodologies to translate the principles of this new economic system into practice.[8] It requires designers to consider all stages of a product's lifecycle, ensure sustainability from manufacturing to disposal, and create solutions that facilitate reuse, repair, recycling, redesign, remanufacture, and recovery[9]. To design out waste effectively and to keep products and materials in use as long as possible, circular business models are required. Building on circular design, circular business models preserve value by recovering, refurbishing, and recycling products and materials. They often rely on services, leasing, or sharing platforms to keep resources in use, transforming them into new products and closing the loop.

Paradoxically, design—once partly responsible for environmental damage—is now expected to play a world-bettering role.[10] The power of design is no longer "as a link in a chain but as the hub of a wheel ".[11] With its capacity to shape both individual and collective behaviour, design holds the power to influence societies globally and to help

[3] William McDonough and Michael Braungart, *Cradle to Cradle: Remaking the Way We Make Things* (Farrar, Straus and Giroux 2010).
[4] Ellen MacArtthur Foundation, *Towards the Circular Economy. Vol 1: Economic and Business Rationale for an Accelerated Transition* (2013) <https://ellenmacarthurfoundation.org/topics/circular-economy-introduction/overview> accessed 15 September 2025.
[5] European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions — A new Circular Economy Action Plam for a cleaner and more competitive Europe COM/2019/640 final (11 March 2020, COM/2020/98) <https://ec.europa.eu/environment/pdf/circular-economy/new_circular_economy_action_plan.pdf> accessed 15 September 2025.
[6] European Commission, Communication on The European Green Deal COM/2019/640 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52019DC0640> accessed 15 September 2025.
[7] European Commission, EcoDesign for Sustainable Products Regulation: Executive Summary of the Impact Assessment (30 March 2022) <https://ec.europa.eu/environment/publications/proposal-ecodesign-sustainable-products-regulation_en> accessed 15 September 2025.
[8] Ellen MacArthur Foundation, Circular Design Overview (webpage) <https://www.ellenmacarthurfoundation.org/topics/circular-design/overview> accessed 15 September 2025.
[9] Donald A Norman, *Design for a Better World: Meaningful, Sustainable, Humanity Centered* (MIT Press 2023).
[10] Bernd E Bürdek, *History, Theory and Practice of Product Design* (Birkhäuser, Basel 2015) 14.
[11] Tim Brown, *Change by Design: Revised and Updated* (Harper Business, New York 2019) 11.

reshape our economy.[12] Although design "is about envisioning change",[13] a shift in designers' approaches alone is not sufficient to realize the ambitious ideals of the circular economy. Designers do not operate in a vacuum: the market and society are just as important as their ambitious plans. Numerous barriers remain, including financial obstacles (such as the absence of tax incentives, state subsidies and circular procurement), limited infrastructure and technical expertise, supply chain challenges, and cultural resistance. Among these, legal barriers play a particularly important role. European legislation in this area is becoming increasingly extensive and complex, yet it often remains overly general and inconsistent.

2 Law for the Real Problems

According to the European Commission, making sustainable products should become the norm.[14] Achieving this objective naturally requires a reconsideration of the legal environment—including not only legal standards but also the individuals and authorities responsible for their implementation. As the principle attributed to Albert Einstein reminds us, "we cannot solve our problems with the same thinking we used when we created them." Circular design, which acknowledges and engages with the complexity and interconnectedness of the world while often drawing inspiration from nature, provides a useful model.[15] Synergy and thoughtful multidisciplinary cooperation are therefore essential. This mindset should likewise be adopted by lawyers and legislators, who are expected to play a central role in driving economic transformation.

The design thinking methodology "uses the designer's sensibility and methods to match people's needs with what is technologically feasible and what a viable business strategy can convert into customer value and market opportunity".[16] It should also become a standard in legal education and practice.[17] Design thinking emphasises innovative solutions that are desirable, feasible, and viable. In the context of circular design and economic transformation, however, it is not so much user needs but rather an "environment-centred ethos" that should guide the assessment of desirability. What is

[12] Dana Beldiman, Stina Telimann-Lock and Anna Tischner, 'Designing for the European Green Deal : a supplementary protection regime for circular designs' in the EU in Dana Beldiman (ed), *Design Law : Global Law and Practice* (Edward Elgar 2024) 661.
[13] John Heskett, *Design and the Creation of Value* (Bloomsbury 2017) 135.
[14] European Commission, Communication on Making Sustainable Products the Norm COM/2022/140 final <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022DC0140> accessed 15 September 2025.
[15] Joe Iles, 'Head of Design Activation at the Ellen MacArthur Foundation' (The Circular Economy Show Podcast) <https://www.youtube.com/watch?v=2eZlpwOXk2Y> accessed 15 September 2025.
[16] Tim Brown, "Design Thinking" (*Harvard Business Review*, June 2008) 2.
[17] See, for instance, the Legal Design Lab based out of Stanford Law School's Center on the Legal Profession and Stanford University's Institute of Design <https://www.legaltechdesign.com/> accessed 30 September 2025. See also Rim Razzouk & Valerie Shute, "What is Design Thinking and Why Is It Important?" (2012) 82(3) Review of Educational Research 330; Susan Ursel, "Building Better Law: How Design Thinking Can Help Us Be Better Lawyers, Meet New Challenges, and Create the Future of Law" (2017) 34 Windsor Yearbook of Access to Justice 28, 58; Marshall Lichty, "Design Thinking for Lawyers" (*Lawyerist*, 18 October 2019) <https://lawyerist.com/blog/design- thinking-for-lawyers/> accessed 20 September 2025.

required is a comprehensive, empathetic, and in-depth reflection on the root causes of the problems, together with a shift away from fragmented and linear approaches toward a perspective that conceives of the legal system as an ecosystem.

Normative and judicial support cannot rely on a one-size-fits-all approach; instead, future-proof solutions must be both universal and adaptable to specific needs and challenges. A resilient legal framework for circularity should therefore strike a balance between flexibility and legal certainty. This balance can be achieved by combining broad and general provisions—such as standards and principles—with detailed, concrete rules.[18] Ecodesign for Sustainable Products Regulation (ESPR)[19], as the cornerstone of the Commission's approach to more environmentally sustainable and circular products, is a great example of the need for a mixed regulatory approach.

The desire to implement rapid change may lead to legislative hyperactivity and excessive regulation. Lawyers could take inspiration from an old principle in design: *less is more*.[20] Rather than producing vast bodies of new and uncoordinated legislation that contribute to informational and regulatory overload, it is often more effective to explore the potential of a "green" interpretation of existing rules. Frequently, instead of introducing measures that disrupt systemic coherence, it may be sufficient to shift interpretive perspectives so as to incorporate the public interest in a healthy environment. This observation is particularly relevant in the field of intellectual property law, where rights often create barriers to repair, reuse, refurbishment, and upcycling. In many cases, existing legal frameworks already provide sufficient flexibility to develop solutions that balance the private interests of rights holders with the broader common good.[21]

In the context of circular design, it is also important to examine whether the legal system provides adequate incentives for this type of design. Traditionally, such incentives have been offered through intellectual property law, granting creators or investors the opportunity to recoup their investments via legally secured market exclusivity. However, the existing design protection regime was developed within a linear economy model. EU design law, in particular, tends to prioritise short-term gains over long-term sustainability, favouring profits from increased sales volume rather than value creation—i.e., design that benefits both people and the planet.[22] Design protection should move beyond its

[18] Annette Kur, Nari Lee and Anna Tischner, *Fairness in Intellectual Property Law* (Edward Elgar Publishing 2024) 251.
[19] Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products OJ L 2024/1781.
[20] Ludwig Mies van der Rohe (1886–1969), principle attributed to the architect, one of the pioneers of modernist architecture.
[21] In this spirit, see for example Ansgar Ohly, 'A right to repair in European patent law in: 'The Future of IP: Stimulating Creativity and Inclusivity' in Amandine Léonard, Arina Gorbatyuk & Esther van Zimmeren (eds), *The Future of IP: Stimulating Creativity and Inclusivity* (Intersentia 2025) 122.
[22] Directive (EU) 2024/2823 of the European Parliament and of the Council of 23 October 2024 on the legal protection of designs (recast)) [2024] OJ L 2024/2823 which replaced Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs [1998] OJ L 289/28 and Council Regulation (EC) No 6/2002

marketing function—which has historically been the primary aim of the EU sui generis design protection system—and embrace a broader societal and ecological purpose. This raises another question of whether the intellectual property rights system is the most effective mechanism for generating incentives for circular design. Perhaps alternative incentive schemes are needed to make ecodesign both economically viable and practically feasible.

In the context of circular design, what is needed are not only incentives to foster socially desirable creativity and innovation in the form of exclusivity, but also a strategy for the rapid dissemination of circular design, so that it becomes a norm not only in books but, above all, in action. The balance between access and incentive requires careful reconsideration.[23] Academia plays a crucial role in this and related matters. Just as, years ago, economic analysis of law[24] examined the effectiveness of legal incentives, the efficiency of legal rules, and the comparative merits of different legal structures (such as property versus liability rules), today we likewise need a methodology focused on ecological issues—one that evaluates the effectiveness of legal norms.[25] We need tools to assess legal rules by asking what impact they have on behaviour and whether those effects are socially and environmentally desirable. In this respect, the call for an "ecological analysis of law,"[26] which would examine the functioning of the legal system from an ecological perspective, is not only timely but also urgently necessary.

of 12 December 2001 on Community designs (CDR) [2002] OJ L 3/1 as amended by Regulation (EU) 2024/2822 of the European Parliament and of the Council of 23 October 2024 [2024] OJ L, 2024/2822.

[23] Dana Beldiman, Søren Teilmann-Lock & Anna Tischner, 'Designing for the European Green Deal : a supplementary protection regime for circular designs in the EU' in Dana Beldiman (ed), *Design Law : Global Law and Practice (*Edward Elgar Publishing 2024) 667.

[24] Richard A Posner, *Economic Analysis of Law* (Boston: Little, Brown and Company 1973); Ronald H Coase, 'The Problem of Social Cost' (1960) 3 Journal of Law and Economics 1–44; Guido Calabresi and Douglas Melamed, 'Property Rules, Liability Rules, and Inalienability: One View of the Cathedral' (1972) 85(6) Harvard Law Review 1089–1128.

[25] Sharanya Basu Roy, 'The Use of Economic Analysis of Law in the Context of Environmental Regulations' (2018) 18 Global Jurist <https://doi.org/10.1515/gj-2017-0019> accessed 15 September 2025.

[26] Ansgar Ohly, Reparatur, 'Neuherstellung und der Erschöpfungsgrundsatz im europäischen Patentrecht' in C Harmsen & A Verhauwen (eds), *Festschrift für Thomas Kühnen* (Hürth: Carl Heymanns 2024) 797, 792.

*Alberto Jaci**

SPECIAL SECTION

ECODESIGN AND CONSUMER PROTECTION

Abstract

This contribution explores the evolving relationship between ecodesign and consumer protection within the EU legal framework, in light of the adoption of Regulation (EU) 2024/1781. By introducing binding sustainability criteria at the product design stage, the Regulation not only advances the environmental agenda of the Union but also reshapes the substance and scope of consumers' contractual rights.

The paper first outlines the regulatory foundations of ecodesign and of consumer law, analysing their respective sources, objectives, and mechanisms. It then investigates the points of intersection between the two fields — particularly in relation to the obligation to inform, the notion of product conformity, and the fight against greenwashing — as well as the areas of divergence, highlighting differences in regulatory logic, enforcement structures, and personal scope.

The study further considers how ecodesign strengthens consumer rights in both substantive and procedural terms, including the effectiveness of remedies and the empowerment of consumer choice. Particular attention is given to the role of national contract law in operationalising ecodesign obligations, as well as to the future implications for private international law, especially concerning overriding mandatory rules and jurisdictional coherence.

Two additional dimensions are examined in depth: first, the potential impact of ecodesign standards on producer liability, both contractual and tortious, especially where misleading environmental information or unsafe product features are involved; second, the progressive emergence of sustainability as a general principle of contract interpretation, potentially guiding the reconstruction of parties' intent and the integration of contractual duties in light of broader EU policy goals.

The article concludes that ecodesign is not merely a technical discipline, but a structural component of an emerging European law of sustainable contracts, requiring deeper integration between private law and regulatory governance.

JEL CLASSIFICATION: D18, K12, K13, K32

SUMMARY

* Italian/EU qualified lawyer. Ph.D. Student in "Private Law" at the Department of Political and Legal Sciences of the University of Messina.

10.13135/2785-7867/12829

and regulatory tensions – 2.2 How and to what extent ecodesign strengthens consumer rights - 3 The role of Italian contract law in the implementation of ecodesign obligations - 4 Producer liability between ecodesign and consumer protection – 4.1 Future prospects for harmonisation and implications for private international law – 4.2 Sustainability as an interpretative principle in contract law – 5 Conclusion

1 Introduction

In recent years, the European Union has undertaken a profound rethinking of its regulatory framework aimed at guiding the transition to a circular economy and ensuring greater environmental sustainability[1]. This rethinking has manifested itself most clearly in the adoption of Regulation (EU) 1781/2024, which enshrines ecodesign as a core principle of the European strategy on sustainable products[2]. According to the European legislator, ecodesign consists of 'integrating environmental sustainability considerations into product characteristics and processes throughout the entire value chain'[3], obliging manufacturers to assess the environmental impact of goods right from the design stage and to ensure the traceability of environmental information through tools such as the Digital Product Passport[4].

In parallel, consumer law has been consolidated as one of the pillars of the European single market[5], with the primary objective of rebalancing the information asymmetry between professionals and consumers and protecting them from abusive contractual practices and non-compliant products[6]. The regulatory evolution, starting from Directive 93/13/EEC[7] on unfair terms to the more recent Directive 2019/771/EU[8] on contracts for the sale of goods, has led to the affirmation of a protection framework based on the principles of safety, quality and transparency.

[1] Cocina Beltran Puentes, 'The New Ecodesign Regulations: Towards More Circular Products?' (2024) 33 (2) Revista Galega de Economia 1-23. For the author "The circular economy strategy of the European Union has undertaken one of its objectives, which is the need to reform ecodesign legislation, and has therefore approved several regulations for specific product categories that, for the first time, regulate material efficiency aspects such as product durability and repairability. The Commission's proposal for a new ecodesign framework regulation seeks to extend the scope of the current directive and generalize the use of durability and repairability requirements".
[2] Giacomo Furlanetto, 'Moda, sostenibilità e pubblicità' (2024) 4 Rivista giuridica dell'ambiente 1137.
[3] Regulation EU 1781/2024, [2024] *OJ L*, 2024/1781, art 2 no 6.
[4] Graziella Bernardo, Daiana Dall'Arche, Angelarosa Manicone, 'The new European Ecodesign Regulation: a holistic vision for sustainability' (2024) 2 5th International Congress on KHAZAR Scientific Research and Innovation 373-385.
[5] Stephen Weatherill, *EU Consumer Law and Policy* (2nd edn, Edward Elgar Publishing 2013) 352.
[6] Kati Cseres, 'The Controversies of the Consumer Welfare Standard' (2006) 3 (2) Competition Law Review 121.
[7] The purpose of this Directive is to approximate the laws, regulations and administrative provisions of the Member States relating to unfair terms in contracts concluded between a seller or supplier and a consumer. See: Hans Schulte-Nölke, 'The Objectives of Directive 93/13/EEC on Unfair Contract Terms: An Overview after 30 Years of Case Law' (2024) 32 European Review of Private Law 315. For the author, the main objective of the Unfair Contract Terms (UCTD), from a regulatory point of view, is to create a judicial or administrative fairness corrective to the unilateral power to draft contractual terms that private law grants to businesses towards consumers in the formation of a contract.
[8] This directive aims to create harmonisation across the EU for certain aspects of contracts for the sale of goods, including conformity of goods with the sales contract, remedies in the event of non-conformity (and how to exercise those remedies), and commercial guarantees. The regulations that EU Member States have adopted to comply with the Sale of Goods Directive will become effective starting January 1, 2022. Merchants must comply with their obligations under the Sale of Goods Directive. See: Elias Van Gool, Anaïs Michel, 'The New Consumer Sales Directive 2019/771 and Sustainable Consumption: a Critical Analysis' (2021) 10(4) Journal of European Consumer and Market Law 136.

The aim of this contribution is to examine the relationship between ecodesign and consumer law by investigating whether and to what extent the sustainability criteria imposed by recent legislation can be considered an integral part of consumer protection. In this investigation, the analysis of convergences and divergences between the two areas will be central, in order to assess whether ecodesign actually contributes to the strengthening of consumer rights or whether, on the contrary, it remains confined to an autonomous sectoral discipline[9].

1.1 Definition and regulatory sources of ecodesign in the EU legal order

With the adoption of Regulation (EU) 2024/1781, the European legislator has transformed ecodesign from a mere technical policy option into a binding legal requirement, mandating that environmental sustainability be integrated from the design phase into both the characteristics of products and the processes that govern their manufacture and distribution[10]. This approach reflects a systemic vision in which products are no longer considered in isolation, but as integral components of an economic and environmental cycle extending from production to end-of-life[11]. The stated objective is to reduce environmental impact throughout the entire product life cycle by promoting industrial models based on durability, reparability and recyclability, in accordance with the principles of the circular economy[12].

Within this framework lies the introduction of the Digital Product Passport[13], established by the core provisions of the Regulation, which obliges manufacturers to collect and disclose certified information on material composition, energy efficiency, ease

[9] Daniel Hinchliffe, Floris Akkerman, 'Assessing the review process of EU Ecodesign regulations' (2017) 168 Journal of Cleaner Production 16033. The author focuses the analysis on the "EU Ecodesign and Energy Labelling Directives that set regulations on the energy efficiency, environmental, and information requirements of energy related products entering the EU market. Each individual product regulation stipulates that the EU Commission must undertake a review after a certain number of years. This review stage is crucial to improve the effectiveness and ambition of regulations, and also presents an opportunity to include new resource efficiency aspects. The strength of a review depends on the review process, which has followed various approaches in each reviewed product group so far". In conclusion he based his study "on comparing the review processes to the standard Methodology for Ecodesign of Energy related Products (MEErP) used in preparatory studies to develop new Ecodesign regulations".

[10] Ludwig Krämer, 'EU Ecodesign and Product Policy: from Energy Efficiency to Circular Economy' (2024) 21 (3-4) Journal for European Environmental & Planning Law 343. For the author «product policy plays a central role in the integration architecture of the European Union. The need to protect the environment led in the beginning of the 21st century to a Commission initiative on an "Integrated Product Policy"».

[11] Anja Marie Bundgaard, Rikke Dorothea Huulgaard, Arne Remmen, 'Getting the Priorities Right in Material Efficiency: From the Ecodesign Directive to the Ecodesign for Sustainable Products Regulation' (2024) Electronics Goes Green 2024+ (EGG): From Silicon to Sustainability, EGG 2024 - Proceedings IEEE 7.

[12] Tejendra Singh Singhal, Jinesh Kumar Jain, Atchuta Ramacharyulu, Alok Jain, Dalael Saad Abdul-Zahra, Manjunatha, Arun Pratap Srivastava, 'Eco-Design of Products and Processes: A Review on Principles and Tools for Sustainable Manufacturing' (2024) 505 E3S Web Conf 9.

[13] Anna Gieß, Frederik Möller, 'Exploring the value ecosystem of digital product passports' (2025) 29 (2) Journal of Industrial Ecology 561. The Digital product passports (DPPs) are an emerging digital technology that advances the circular economy (CE) by facilitating inter-organizational data sharing and life-cycle management of products.

of disassembly, presence of hazardous substances and overall environmental footprint[14]. The passport is designed as a data repository accessible to consumers, market surveillance authorities and supply chain actors, and aims to promote full traceability of products[15]. The absence or incompleteness of such information constitutes a serious regulatory breach, subject to administrative sanctions at national level, thus ensuring the effectiveness of the newly established legal framework[16].

Regulation 2024/1781 represents a development in continuity with Directive 2009/125/EC, which originally introduced the first European legal framework for ecodesign, albeit limited to energy-related products[17]. That directive, still applicable in many sectors, laid the foundation for a harmonised technical regulation aimed at reducing market fragmentation and setting mandatory minimum environmental performance requirements[18]. The shift from a directive to a regulation, as enacted in the 2024 text, marks a significant change of regulatory paradigm[19]: no longer merely establishing minimum standards, but instead defining binding design, monitoring and environmental disclosure requirements directly applicable to economic operators[20].

The regulatory framework has been further reinforced by the Corporate Sustainability Reporting Directive (CSRD, 2022/2464)[21] and the Corporate Sustainability Due Diligence Directive (CSDDD, 2022/2463)[22], which impose far-reaching obligations on businesses to

[14] Konstantinos Voulgaridis and others, 'Digital product passports as enablers of digital circular economy: a framework based on technological perspective' (2024) 85 Telecommunication Systems. Modelling, Analysis, Design and Management 699.

[15] Foivos Psarommatis, Gökan May, 'Digital Product Passport: A Pathway to Circularity and Sustainability in Modern Manufacturing' (2024) 16 (1) Sustainability 396.

[16] Steffen Foldager Jensen, Jesper Hemdrup Kristensen, Sofie Adamsen, Andreas Christensen, Brian Vejrum Waehrens, 'Digital product passports for a circular economy: Data needs for product life cycle decision-making' (2023) 37 Sustainable Production and Consumption 242

[17] Nicolas Prignot, Grégoire Wallenborn, 'Standardisation of practices and representations of users in the ecodesign Directive' ECEEE 2009 SUMMER STUDY 9.

[18] Rosalind Malcolm, 'Ecodesign Laws and the Environmental Impact of our Consumption of Products'(2011) 23 (3) Journal of Environmental Law 487.

[19] Claudio Favi, Marco Marconi, 'Product Eco-Design in the Era of the Circular Economy' (2025) 17(1) Sustainability 487-503.

[20] Anne-Christin Mittwoch, 'The Digital Product Passport of the Ecodesign Regulation - Passport to a Successful Twin Transformation in Product Law?' (2024) 45 (3) Business Law Review 62-67.

[21] Tania Pantazi, 'The Introduction of Mandatory Corporate Sustainability Reporting in the EU and the Question of Enforcement' (2024) 25 European Business Organization Law Review 509. For the author the Directive "introduces mandatory sustainability reporting for all large undertakings in the European Union, as well as third-country undertakings active in the Union. The new rules were mandated by the increase in investor needs, as well as the interest of civil society actors". When the question turns to the question of public and private enforcement of the new sustainability reporting obligations, he observes "public enforcement is, to a certain degree, guaranteed by the amendment of existing rules. The new Directive is silent on private enforcement issues, although it may trigger private litigation, predominantly by shareholders. Other interested groups, such as consumers and civil society actors, will not be able to directly challenge breaches of the new rules, despite the intention of the legislator to foster sustainability reporting and responsible corporate behaviour to the benefit of civil societies".

[22] Nicolas Bueno, Nadia Bernaz, Gabrielle Holly, Olga Martin-Ortega, 'The EU Directive on Corporate Sustainability Due Diligence (CSDDD): The Final Political Compromise' (2024) 9 (2) Business and Human Rights Journal 294. The authors state that "The CSDDD is the first region-wide due diligence legislation, yet it is also a political compromise among EU member states, which civil society and business have been watching closely". But, obviously, "Member states are expected to implement the Directive in progressive stages, reaching the objective of covering all companies employing more than 1,000 employees and a net turnover of EUR 450 million only by 2029. The Commission will periodically assess

incorporate environmental and social factors into their governance and reporting strategies. The CSRD notably expands ESG (environmental, social and governance) disclosure requirements to a broader range of entities, including listed SMEs, demanding a systemic assessment of environmental risks, including those stemming from product design. The CSDDD, on the other hand, introduces positive obligations on companies to prevent and mitigate environmental harm throughout the supply chain, thereby generating a cascading effect that directly influences the design phase of goods.

Against this backdrop, ecodesign assumes a strategic function, no longer confined to technical compliance, but increasingly seen as a metric of corporate accountability[23] and a critical benchmark in evaluating sustainability performance[24]. Conformity with ecodesign standards now constitutes a key component of corporate social responsibility[25], with significant contractual, financial and reputational implications.

The legal architecture of ecodesign thus emerges as a multi-layered and multidimensional regulatory phenomenon, transcending the boundaries of industrial product law to permeate core domains of environmental regulation and market governance[26]. It necessitates an integrated approach capable of combining technical specifications, legal obligations, transparency mechanisms and enforcement tools in a coherent system aligned with the European Union's sustainability objectives and its broader innovation agenda for the single market.

1.2 Bacisc of consumer law

Consumer law constitutes one of the foundational pillars of the European Union's internal market[27]. Its normative evolution is based on the recognition of the structurally weaker position of consumers vis-à-vis professionals, a weakness that manifests itself both contractually and informationally. Within this context, the European legislator has sought

these thresholds and the need to cover high-risk sectors and will also submit a report on due diligence requirements tailored for financial undertakings".

[23] Pilar Portillo-Tarragona, Víctor Kuba-Khoury, Alfonso Aranda-Usón, Sabina Scarpellini, 'Environmental Management Accounting and Accountability for Circular Eco-Innovation Projects' (2025) 17 (6) Sustainability 2932. The findings of this paper show that companies consistently report sustainability issues and circular economy principles. Specific project information is disseminated punctually, but declines significantly over time, revealing different levels of accountability throughout the lifecycle of circular eco-innovation investments. This study advances circular accounting and the eco-innovation literature by equipping practitioners with tools to compare heterogeneous projects, even during budgeting, and introducing a novel temporal perspective on circular reporting.

[24] Filipe Mattos Batista de Moraes, Luiz Kulay, Andrea Trianni, 'Integrating life cycle assessment and ecodesign to improve product effectiveness and environmental performance: A novel approach' (2025) 55 Sustainable Production and Consumption 76.

[25] Krishnaveni Manubolu, Raveesha Peeriga, 'Ecodesign Principles' in Yingngam B, Aslam MS, Haghi AK (eds), *Sustainable Pharmaceutical Product Development and Optimization Processes* (Springer 2025) 21.

[26] Benjamin Goodwin, 'Analysis of the EU Ecodesign for Sustainable Products Regulation (ESPR)' (Environmental Coalition on Standards 2024) 12.

[27] Charles O'Mahony, 'The Legal Framework for Data and Consumer Protection in Europe' in Kuanchin Chen, Adam Fadlalla (eds), *Online Consumer Protection: Theories of Human Relativism* (IGI Global 2009) 21.

to redress the existing imbalances by ensuring transparency, access to remedies, and legal certainty in consumer relations.

Beginning with Directive 93/13/EEC, which prohibits the inclusion of unfair terms in contracts concluded with consumers, the Union has developed a progressively robust and structured body of legislation[28]. Directive 2011/83/EU established harmonised rules for distance and off-premises contracts[29], imposing extended pre-contractual information duties and guaranteeing the right of withdrawal. Most recently, Directive 2019/771/EU on contracts for the sale of goods has strengthened the consumer protection framework by imposing strict conformity obligations on sellers and introducing an expanded notion of non-conformity, encompassing the failure to meet public statements made about the product[30].

Within this legal framework, the right to information plays a pivotal role in ensuring the substantive protection of consumers[31]. They must be entitled to receive clear, accurate and comprehensive details regarding the essential features of the product — increasingly including its durability, reparability and environmental sustainability[32]. These aspects, once peripheral, have become central in light of the interaction with the ecodesign legislation, which elevates them to objective criteria for contractual assessment[33].

From a private international law perspective, Regulation (EC) No. 593/2008 (Rome I) is of particular importance in cross-border contractual relations[34]. Article 6 of the Regulation stipulates that, even in the presence of a choice-of-law clause, consumers may not be deprived of the protection afforded by the mandatory provisions of the law of their habitual residence. In the context of products designed in accordance with ecodesign criteria and sold across multiple Member States, this entails that sustainability requirements and information duties — even if formally defined by the seller's domestic

[28] Shpresa Alimi-Memedi, 'Consumer protection and freedom of contract in the Directive 93/13/ecc on unfair terms in consumer contracts' (2018) 6 (9) Justicia. International Journal of Legal Sciences 95.
[29] Anca Daniela Chirita, 'The impact of Directive 2011/83/EU on Consumer Rights' in Anne Keirse, Marco Loos and Ilse Samoy (eds), *Ius Commune Law Series* (Intersentia 2012) 27. The author affirms that «the scope of application of the directive shows how much of its substance, particularly on unfair contracts, has been left outside its scope». The article concludes with the need for European codification as to avoid the fragmentation of private law, but it questions the usefulness of such codes for later stages of European integration where 'borders' as trade barriers cease to exist.
[30] Ovidiu Ioan Dumitru, Andrei Viorel Tomescu, 'European consumer law in the digital single market' (2020) 10 (2) Juridical Tribune 222.
[31] Caroline Cauffman, Catalina Goanta, 'A New Order: The Digital Services Act and Consumer Protection' (2021) 12 (4) European Journal of Risk Regulation 758.
[32] Mark Armstrong, Jidong Zhou, 'Consumer Information and the Limits to Competition' (2022) 112 (2) American Economic Review 534.
[33] Karolina Vikingsson, Carl Dalhammar, Leonidas Milios, 'European Union Policy Developments Related to Ecodesign, Green Claims, and Eco-labeling: Implications for Voluntary Circular Labeling Initiatives' in Shinichi Fukushige, Tomomi Nonaka, Hideki Kobayashi, Chiharu Tokoro and Eiji Yamasue (eds), *EcoDesign for Circular Value Creation: Volume I* (Springer 2025) 14.
[34] John Ashley Kimbell, 'The Rome Convention on the Law Applicable to Contractual Obligations – Past, Present, and Future' in Barış Soyer (ed), *Commercial Disputes* (1st edn, Informa Law from Routledge 2024) 11.

law — must conform to the standards of the consumer's country if these are more protective.

On the procedural side, Regulation (EU) 1215/2012 (Brussels I bis) ensures that consumers may bring proceedings, or be sued, in the courts of their place of residence, even when the professional is domiciled in another Member State[35]. This rule significantly strengthens the enforceability of consumer rights and facilitates effective access to judicial protection, including in disputes relating to sustainability claims, non-conformity, or the absence of required environmental information, such as that contained in the Digital Product Passport.

Altogether, these provisions give rise to a multi-layered system of protection, within which the innovations introduced by ecodesign legislation can be meaningfully situated. They serve to reinforce pre-existing instruments such as the right to information, liability for lack of conformity, and protection against unfair commercial practices. However, as will be shown, the harmonisation between these two normative fields is not devoid of tensions: ecodesign and consumer law operate along partially distinct trajectories, with different aims and instruments, thus calling for careful normative and interpretative coordination[36].

2 Point of contact between ecodesign and consumer law

The incorporation of ecodesign into the European Union's regulatory framework on products does not merely concern environmental or technical matters; rather, it structurally affects the configuration of contractual relations between professionals and consumers[37]. The rules on sustainable product design intersect in multiple ways with consumer law, potentially enhancing pre-existing protection mechanisms[38]. This convergence is most apparent in three key areas: pre-contractual information duties, the definition of contractual conformity, and the prevention of misleading commercial practices.

[35] Stephanie Law, 'Lis Pendens – Related Actions' in Marta Requejo Isidro (ed), *Brussels I Bis. A commentary on Regulation (EU) No 1215/2012*, Sec. 9 (Elgar Commentaries in Private International Law 2022) 54.
[36] Peter Arnt Nielsen, 'Civil cooperation in the EU from 1960 to 2024' in Morten Midtgaard Fogt (ed), *Private International Law In An Era Of Change* (EAPIL 2024) 18.
[37] Victor Mehnert, Hans Wolfgang Micklitz, 'The Interplay between Ecodesign and Consumer Sales Law' in Marta Santos Silva and others (eds), *Routledge Handbook of Private Law and Sustainability* (1st edn, Routledge Handbooks 2024) 15. The authors in these papers argue that «supervisory authorities and consumers shall enforce ecodesign product standards, which can be integrated into the contractual relationship between private parties via the objective requirements. However, further adjustments regarding the legal guarantee period and the presumption period are needed to promote sustainable consumption».
[38] Please note a contribution highlighting the potential limits of consumer protections in the pursuit of sustainability: Felix Pflücke, 'The limits of consumer law in pursuing sustainability' in Julian Nowag (ed), *Research Handbook on Sustainability and Competition Law* (Edward Elgar Publishing 2024) 26. The study demonstrates that some consumer law provisions contradict consumer theories and scientific studies and provides targeted and actionable policy recommendations to address these deficiencies.

The first point of contact lies in the broadening of pre-contractual transparency obligations. Directive 2011/83/EU requires professionals to provide consumers, prior to the conclusion of the contract, with clear and comprehensible information regarding the essential characteristics of the goods, including their durability, reparability, and increasingly, their environmental credentials. The introduction of the Digital Product Passport under Regulation (EU) 2024/1781 fits squarely within this paradigm. It mandates that manufacturers produce a standardised and verifiable set of environmental data, accessible to the consumer[39]. Once disclosed, such information acquires legal significance and becomes part of the contractual content: any inaccuracy or omission may constitute a lack of conformity under Directive 2019/771/EU, triggering the relevant remedies[40].

The second area of convergence concerns the redefinition of the concept of conformity of goods[41]. Article 7 of Directive 2019/771/EU provides that a product must conform not only to the contract, but also to the legitimate expectations of the consumer, particularly in light of public statements made by the seller or manufacturer. Where such statements include sustainability-related aspects — such as ecological composition, material origin or expected durability — they acquire binding force. A discrepancy between these declarations and the actual features of the product constitutes a breach of conformity, entitling the consumer to invoke contractual remedies such as repair, replacement, price reduction, or termination[42].

A third point of intersection emerges in the regulation of unfair commercial practices, governed by Directive 2005/29/EC. The obligation to provide transparent and verifiable environmental information acts as a safeguard against greenwashing, namely, the dissemination of baseless sustainability claims aimed at unduly influencing consumer behaviour[43]. The ecodesign framework, by imposing the integration of verifiable sustainability standards into production processes and requiring their documentation through the Digital Product Passport, contributes to preventing misleading environmental advertising and aligning promotional claims with the actual characteristics of the good[44].

[39] Verónica Ruiz Abou-Nigm, Antonia Sommerfeld, 'Circular Fashion and Legal Design: Weaving Circular Economy Threads into International Contracts' Working Paper IE Law School AJ8-288-I (Cátedra Cervelló IE 2024) 37.
[40] Patrizia Giampieri, 'Legal Formulae in the National Legislations and in EU Directives on Consumer Contracts' in Patrizia Giampieri (ed), *Legal Formulae. Exploring Legal Multi-words in English, Italian and French* (Palgrave Macmillan 2025) 67. The comparative analyses between Italian, French, and British national legislation on consumer contracts carried out bring to the fore discrepancies in the use and in the frequencies of the legal formulae across the different corpora.
[41] Marzena Czarnecka, Grzegorz Zych, 'Consumer Protection in the European Union' in Tina Soliman Hunter, Marcin Kraśniewski, Jurgita Malinauskaite, Marzena Czarnecka (eds), *Routledge Handbook of Consumer Protection and Behaviour in Energy Markets* (1st edn, Routledge Handbooks 2024) 16.
[42] Evelyne Terrin, 'A Right to Repair? Towards Sustainable Remedies in Consumer Law' (2019) 27 (4) European Review of Private Law 22.
[43] Geraint Howells, Hans Wolfgang Micklitz, Thomas Wilhelmsson, 'European Fair Trading Law The Unfair Commercial Practices Directive' in Geraint Howells (ed), *Markets and the Law* (Routledge Handbooks 2016) 26.
[44] Krämer (n 10).

Finally, the convergence between ecodesign and consumer law is also evident in the promotion of durability as a core element of product quality[45]. Ecodesign encourages minimum standards of useful life, upgradability and maintainability, particularly in the technology sector. These features reinforce the consumer's right to reliable and sustainable goods, reducing the risk of premature obsolescence and mitigating future costs associated with frequent replacement[46]s or repairs[47]. Durability thus becomes not merely an environmental objective, but a crucial aspect of the consumer's economic protection.

Taken together, these points of convergence show that ecodesign, although conceived primarily as an instrument of environmental policy, has the potential to structurally enhance contractual guarantees for consumers, rendering the purchasing process within the internal market more transparent, reliable, and aligned with sustainability objectives.

2.1 Divergences, purpose, scope and regulatory tensions

Despite the substantial points of convergence with consumer law, the legal framework governing ecodesign maintains a distinct identity that is not fully overlapping with that of consumer protection. The two normative domains pursue different rationales, target different categories of subjects, and are structured through heterogeneous regulatory instruments, often operating at disparate levels of normativity. These divergences generate potential tensions which warrant a systematic reflection on the interplay between environmental protection and consumer rights.

A first and fundamental divergence concerns the different purposes pursued by each field. Consumer law is built around a protective function: it aims to rebalance asymmetric contractual relationships by conferring remedies, imposing information duties and regulating form requirements to enable informed consumer choice[48]. Ecodesign, by contrast, reflects a public environmental policy, oriented towards the protection of general interests such as sustainability, emissions reduction, ecological safety and resource efficiency[49]. As a consequence, consumer protection may constitute an indirect outcome of ecodesign regulation, but it is not its primary normative goal[50].

[45] For more on this topic, see: Rahul Jetti, Debayan Dhar, 'Product Durability: A Systematic Literature Review' (2024) 37 (5) Archives of Design Research 93

[46] Katarzyna Kryla-Cudna, 'Sales Contracts and the Circular Economy' (2020) 28 (6) European Review of Private Law 1207; Mireia Artigot Golobardes, 'Revisiting European Consumer Protection through the Lens of Sustainable Markets' in Marta Santos Silva and others (eds), *Routledge Handbook of Private Law and Sustainability* (1st edn, Routledge Handbooks 2024).

[47] On this subject, we recommend reading a contribution that conducts a critical analysis of the effectiveness or otherwise of Directive 2024/1799, better known as the Right to Repair Directive: Blanka Vitová, 'The Sustainability Concept in the Consumer Purchase Contract – Is the R2R Directive Sustainable Enough?' (2024) 24 (2) International and Comparative Law Review 84.

[48] Ex multis: Giesela Ruhl, 'Consumer Protection in Choice of Law' (2011) 44 (3) Cornell International Law Journal 570.

[49] Susanna Horn, Hanna Salo, Ari Nissinen, 'Promoting ecodesign implementation: The role and development areas of national public policy' (2023) 33 (5) Environmental Policy and Governance 474.

[50] Anaïs Michel, 'The design and production stage: ecodesign requirements in Evelyne Terryn, Bert Keirsbilck (eds), *Consumer Protection in a Circular Economy* (Intersentia 2019) 20.

A second divergence emerges in relation to the subjective and objective scope of application. Consumer law applies solely to relationships between professionals and consumers, in the technical sense defined by European directives, based on economic and informational asymmetry[51]. Ecodesign rules, on the other hand, operate upstream — during the design and production phases — and are addressed to all economic operators, regardless of the legal status of the final recipient[52]. This disconnect may result in a lack of coherence between the technical obligation and its effective enforceability in a contractual setting.

A further divergence relates to the degree of normativity and the nature of the available remedies. Consumer law relies on remedies grounded in private law[53], directly enforceable by individuals: contract termination, price reduction, repair, replacement, or damages. Ecodesign, by contrast, predominantly consists of technical and administrative regulations, whose breach entails sanctions against the producer but does not necessarily give rise to subjective rights that consumers can assert before courts[54]. The absence of legal integration between the two domains may hinder the translation of technical obligations into actionable private law claims.

Finally, cross-border regulatory tensions are particularly relevant in light of the partial harmonisation regarding environmental labelling and sustainability claims. While some instruments — such as the EU Ecolabel Regulation (EC) No 66/2010 — adopt a full harmonisation approach, many others allow Member States discretion in implementation, especially in the area of green claims and private environmental certifications. For instance, national interpretations of what constitutes a "misleading" green claim still vary significantly across jurisdictions. Additionally, eco-labelling schemes such as the German "Blaue Engel" or the French "Écolabel" coexist with EU-wide schemes, creating overlapping and sometimes conflicting standards. These disparities may lead to unequal treatment of consumers across Member States, thereby undermining the principle of substantive equality within the internal market[55]. In this regard, the private international law instruments — such as Regulations Rome I[56] and Brussels I bis[57] — provide a basic protective framework by determining, respectively, the applicable law to contractual obligations and the competent jurisdiction in cross-border disputes. However, these instruments are procedural in nature: they establish which law applies and which court

[51] Sara Perugini, 'Evoluzione normativa nazionale e Codice del Consumo' in Giuseppe Cassano, Massimiliano Dona, Raffaele Torino (eds), *Il diritto dei consumatori* (Giuffrè 2002) 28.
[52] Karine Van Doorsselaer, 'The role of ecodesign in the circular economy' in Alexandros Stefanakis, Ioannis Nikolaou (eds), *Circular Economy and Sustainability. Management and Policy* Vol 1 (Elsevier 2022) 16.
[53] Pietro Sirena, 'La prospettiva dei rimedi nel diritto privato europeo' (2012) 3 Rivista di diritto civile 360.
[54] Giorgia Faraca and others, 'Ecodesign for Sustainable Products Regulation: Study on new product priorities' (Publications Office of the European Union 2024) 386.
[55] Magdalena Tutak, Jarosław Brodny, 'Disparities among EU-27 countries in the implementation of the European Green Deal strategy goals' [2024] Smart and Sustainable Built Environment 1.
[56] Ole Lando, Peter Arnt Nielsen, 'The Rome I Regulation' (2008) 45(6) Common Market Law Review 1687.
[57] Xandra Ellen Kramer, 'Cross-Border Enforcement and the Brussels I-Bis Regulation: Towards A New Balance Between Mutual Trust and National Control over Fundamental Rights' (2013) 60 (3) Netherlands International Law Review 343.

has jurisdiction, but they do not harmonise the substantive rules that apply to environmental claims or consumer protection. Consequently, even when procedural safeguards are in place, substantive outcomes may differ depending on the national law identified as applicable. For example, a misleading environmental claim may be assessed differently under Italian consumer law than under German or French law, even though the same EU-level procedural rules were followed to determine jurisdiction and applicable law. This disconnection underscores the limited effectiveness of private international law tools in addressing divergences in substantive consumer protection related to sustainability claims.

While ecodesign undoubtedly enhances the quality and transparency of goods on the market, it cannot be regarded as a mere extension of consumer law, but rather as a distinct legal field, governed by its own purposes and regulatory techniques, which occasionally diverge from the logic of individual contractual protection. The legal challenge for the coming years lies in bridging these differences, ensuring systemic coherence such that consumers may fully benefit from instruments originally designed in the name of environmental sustainability.

2.2 How and to what extent ecodesign strengthens consumer rights

Although aware of the divergences outlined above, it is undeniable that the introduction of ecodesign into European product regulation has contributed significantly to the effective strengthening of consumer rights[58]. The main effect of this regulatory evolution lies in the qualitative transformation of traditional protection[59]: the focus is no longer only on the immediate safety and functionality of the good, but extends to sustainability, durability and environmental traceability, values that directly affect consumers' legitimate expectations and their ability to self-determine in the marketplace[60].

One of the most obvious aspects of this strengthening concerns the expansion of the right to information. Thanks to the Digital Product Passport provided for in Regulation (EU) 1781/2024, the consumer has access to certified data on the composition, reparability and environmental impact of purchased goods[61]. This information, made mandatory and standardised at European level, enables consumers to make more informed

[58] Preethish Kumar M and others, 'Empowering Consumers and Sustainability: A Global Review of Right to Repair Policies'(2024) International Conference on Distributed Systems, Computer Networks and Cybersecurity (ICDSCNC) (IEEE 2024).
[59] Fryderyk Zoll and others, 'Various Approaches to 'Greening' Consumer Sales Law' in Marta Santos Silva and others (eds), *Routledge Handbook of Private Law and Sustainability* (Routledge Handbooks 2024) 21.
[60] Beatriz Silva, Marta Vasconcelos, Sergiy Smetana, 'Conceptualisation of an Ecodesign Framework for Sustainable Food Product Development across the Supply Chain' (2023) 10 (4) Environments 59.
[61] Voulgaridis and others (n 14).

choices, reducing information asymmetries that, in the past, compromised their ability to assess the quality and sustainability of products[62].

Transparency thus becomes a concrete safeguard not only against greenwashing but also against more subtle forms of misleading advertising, strengthening the consumer's right to receive truthful and verifiable commercial communications[63].

Secondly, ecodesign strengthens the right to compliance by making sustainability-related information part of the legal expectations of consumers[64]. Directive (EU) 2019/771 establishes that conformity is not limited to the contractual terms but includes public statements — including advertising and labeling — made by the seller or manufacturer[65]. With the introduction of the Digital Product Passport under Regulation (EU) 2024/1781, such public statements are no longer sporadic or informal, but systematised and standardised in a digital format accessible throughout the EU. This traceability reinforces the binding nature of environmental and sustainability claims, making them actionable benchmarks in case of dispute. For example, if the Passport specifies a recyclability rate of 90% and the product fails to meet this standard, the consumer may invoke a lack of conformity under Article 7(1)(d) of the Directive, linking ecodesign data directly to enforceable rights.

Any significant deviation between the sustainability characteristics declared — for example, energy efficiency, recyclability, or expected lifespan — and the actual performance of the goods may constitute a lack of conformity under EU consumer law. In this context, ecodesign contributes indirectly to contractual liability by supplying measurable performance benchmarks, which become part of the consumer's legitimate expectations. Regulation 2024/1781 requires that information in the Digital Product Passport be reliable, verifiable, and up to date, creating legal reliance interests.

Regarding durability, Article 5 of Regulation 2024/1781 explicitly mandates that products be designed to ensure the availability of spare parts, repairability and software upgradeability. In sectors like electronics or appliances, these ecodesign obligations directly influence contractual negotiations and consumer expectations. For instance, if a smartphone is sold with an expected software support period of five years — as declared in its Digital Product Passport — failure to provide such updates could trigger remedies under Directive 2019/771. Thus, durability-related design obligations become enforceable

[62] José Monteiro, João Barata, Sara Gentilini, 'A Digital Twin-Based Digital Product Passport' (2024) 246 Procedia Computer Science 4123.
[63] Bakyt Tolegenov and others, 'Digital Transparency and Consumer Awareness: Digital Platforms for Educating Consumers about Product Origins and Sustainability' (2024) 12 (2) Al-Muzara'Ah 27710.
[64] Charlotte J S Vrendenbarg, 'Durable Design: What Role for EU Design Law in the Green Transition?' (2025) 74 GRUR International 525.
[65] Ivan Jokanović, 'Lack of conformity of goods with the contract and sustainability issue – Directive (EU) 2019/771' (2023) 1 (1) Central European Academy Law Review 93.

elements of conformity, strengthening the consumer's position in case of early degradation or unrepairable malfunction[66].

Finally, ecodesign contributes to strengthening the consumer's right to active participation in the ecological transition by institutionalising mechanisms that enable environmentally responsible behaviour[67]. Regulation 2024/1781 promotes return schemes for end-of-life products, mandates design choices that facilitate disassembly and material recovery, and encourages integration of such features into contractual offers. A concrete example is the EU "Right to Repair" initiative, which requires manufacturers to inform consumers at the point of sale about the availability of repair services, spare parts and repair manuals. Another example is the requirement for certain product categories — such as washing machines and refrigerators — to be designed for dismantling and recycling, enforced under the revised Ecodesign Working Plan 2022-2024. In practice, these instruments are reflected in commercial practices, such as extended warranties conditional on proper recycling or discounts offered for returning used devices undertake-back schemes. These tools foster active consumer engagement in sustainability, moving beyond passive compliance to informed participation.

Although ecodesign was not originally conceived as a consumer protection instrument, it increasingly operates as a functional extension of consumer rights within the European single market[68]. By embedding requirements for transparency (via Digital Product Passports), minimum durability standards, and repairability features into product design, ecodesign measures enhance the enforceability of existing consumer rights such as the right to information, the right to conformity, and the right to sustainability. These enhancements are not merely theoretical: they translate into concrete legal tools that consumers can invoke in disputes, thereby reinforcing the integration of sustainability into the normative framework of consumer law.

3 The role of italian contract law in the implementation of ecodesign obligations

Although Regulation (EU) 2024/1781 is binding in its entirety and directly applicable in all Member States, its tangible effects on professional–consumer legal relationships

[66] Katarzyna Joachimiak-Lechman, 'Life cycle perspective in design and product development' (2024) 16 (3) Engineering Management in Production and Services 29.
[67] Marie-France Vernier, 'Eco-Design and Ecological Transition' (2024) 42 Innovation, Entrepreneurship, Management Series, Smart Innovation Set 163.
[68] Carl Dalhammar, Eléonore Maitre-Ekern, 'How Can We Persuade Consumers to Purchase More Sustainable Products? A Review of European Legal Developments' in Marta Santos Silva and others (eds), *Routledge Handbook of Private Law and Sustainability* (1st edn, Routledge Handbooks 2024) 15. The discussion is focused on five 'points of intervention': (1) regulatory choice editing; (2) persuading consumers to buy sustainable products at the point of purchase; (3) avoiding destruction of unsold/returned products; (4) promoting maintenance and repair of existing products; (5) ensuring that consumers make sustainable choices at the 'end-of-use'.

largely depend on its operational integration into national systems of contract law[69]. Domestic legal frameworks play a crucial role in absorbing the technical and environmental provisions established by EU law and conferring legal force upon them within national contractual structures.

In the first instance, implementation occurs through the mechanism of automatic contractual incorporation. In several civil law jurisdictions – including Germany, France and Italy - public representations made by the seller or producer regarding key characteristics of the goods — such as durability, energy efficiency, or recyclability — can be treated as implied contractual terms, even if not expressly stated in the contract.

In Germany, §434 BGB (*Bürgerliches Gesetzbuch*) considers a good non-conforming if it fails to meet qualities "which the buyer may expect, considering public statements of the seller or producer"[70].

Similarly, Article 129 of the *Codice del Consumo* (as amended to implement Directive 2019/771) includes public declarations made by the trader or producer as part of the conformity requirement[71].

In France, Article L 217-5 of the *Code de la consommation* recognises consumer expectations based on public declarations as a standard for conformity[72].

This principle facilitates the incorporation of sustainability claims, including those found in a Digital Product Passport, into the contractual matrix governing consumer transactions[73].

Accordingly, the Digital Product Passport transcends its informational function, becoming a contractually binding source of technical obligations, with full relevance in assessing the conformity of the product[74].

A second level of interaction concerns the legal classification of non-conformity in light of environmental criteria. Pursuant to Directive 2019/771/EU and its national implementations[75] (e.g., Article 129 of the Italian Consumer Code), a product is deemed non-conforming not only if it deviates from the contract, but also where it lacks qualities

[69] Tiziano Zgaga, Asya Zhelyazkova, 'Transposition of European Union legislation' in Gijs J Brandsma (ed), *Handbook on European Union Public Administration* (Edward Elgar publishing 2024) 12.
[70] Christian Berger, 'Der Beschaffenheitsbegriff des § 434 Abs. 1 BGB' (2004) 59 (6) Juristen Zeitung 276.
[71] Matilde Girolami, 'I criteri di conformità al contratto fra promissio negoziale e determinazione legislativa nel sistema dell'art. 129 del codice del consumo' (2006) 2 (1) Rivista di diritto civile 55; Fabio Addis, 'Spunti esegetici sugli aspetti dei contratti di vendita di beni regolati nella nuova Direttiva (UE) 2019/771' (2020) V (2) Nuovo Diritto Civile 5.
[72] Thierry Bourgoignie, 'Sustainable Consumption and Obsolescence of Consumer Products' in Alberto do Amaral Junior, Lucila de Almeida, Luciane Klein Vieira (eds), *Sustainable Consumption* (Springer 2020) 20.
[73] Cristina Poncibò, 'The contractualization of environmental sustainability' (2016) 12 (4) European Review of Contract Law 20.
[74] Hendro Wicaksono, Abel Mengistu, Atit Bashyal, Tamas Fekete, 'Digital Product Passport (DPP) technological advancement and adoption framework: A systematic literature review' (2025) 253 Procedia Computer Science 2980.
[75] Helen Xanthaki, *Legislative drafting for the EU: transposition techniques as a roadmap for better legislation and a sustainable EU* (Edward Elgar Publishing 2024) 374; Alberto De Franceschi, Reiner Schulze, *Harmonizing Digital Contract Law: The Impact of EU Directives 2019/770 and 2019/771 and the Regulation of Online Platforms* (1st edn, Bloomsbury Publishing 2023) 784.

which the consumer may reasonably expect in view of public statements[76]. It is increasingly clear that environmental attributes form an integral part of this assessment, thereby constituting qualifying elements in conformity evaluation.

The general principles of civil law play an equally important role. The principle of objective good faith[77], enshrined in many legal systems (e.g., Articles 1175 and 1375 of the Italian Civil Code, § 242 BGB in Germany), requires fair and cooperative behaviour during both formation and performance of the contract. Failure to disclose material environmental data, or the provision of misleading information regarding durability or recyclability, may amount to a breach of the duty of contractual loyalty – a principle recognised in many EU member States - potentially giving rise to not only breach of contract, but also pre-contractual (culpa in contrahendo) or even tortious liability, depending on the legal system.

In Germany, §311(2) BGB governs pre-contractual obligations[78], and §280 BGB allows for damages in cases of negligent misrepresentation during negotiations[79].

In Italy, Article 1337 of the Civil Code imposes a general duty of good faith in negotiations; failure to disclose relevant sustainability information may trigger liability under Articles 1337 and 2043[80].

In France, the *devoir d'information* under Article 1112-1 of the Code civil requires disclosure of material facts[81], and Article 1240 provides a basis for extracontractual liability in case of misleading or deceptive practices[82].

These national frameworks can thus give legal force to environmental data disclosures mandated by EU ecodesign rules, anchoring them within the broader discipline of contractual and extra-contractual liability.

Lastly, the national judiciary plays a dynamic role in applying EU provisions in a manner consistent with domestic legal traditions. This interpretative integration is supported by the principle of consistent interpretation established by the Court of Justice of the European Union (CJEU), which requires national courts to interpret domestic law in

[76] In this sense, with an accompanying practical case analysis: Simone Vanini, 'Violazione di norme pubblicistiche di tutela ambientale da parte del produttore e difetto di conformità al contratto del bene consegnato al consumatore: la Corte di giustizia UE e il caso «Dieselgate» (C. Giust. UE 14 luglio 2022, in causa C-145/20, Porsche Inter Auto e Volkswagen)' (2023) 1 Rivista di diritto civile 166.

[77] Ex multis: Emanuela Navarretta, 'Buona fede oggettiva, contratti di impresa e diritto europeo' [2005] Rivista di diritto civile 507; Christian Heinrich, 'Die Generalklausel des § 242 BGB' in Bernd-Rüdiger Kern, Elmar Wadle, Klaus Peter Schroeder, Christian Katzenmeier (eds), *HUMANIORA Medizin — Recht — Geschichte* (Springer 2006) 22.

[78] Dagmar Waldzus, 'Germany - Pre-Contractual Disclosure Requirements and Relevant Case Law' (2014) 12(5) International Journal of Franchising Law 3.

[79] Sophie Ackermann, 'Vertraglicher Unterlassungsanspruch aus § 280 Abs. 1 BGB' (2025) 9 Juristische Rundschau 436.

[80] Cataldo Giuseppe Salerno, 'Responsabilità precontrattuale o responsabilità per violazione dei principi della funzione? la tutela della buona fede fra responsabilità precontrattuale e violazione dei principi della funzione' (2017) 93 (2) Diritto dell'economia 40.

[81] Caroline Asfar-Cazenave, 'Le nouveau droit francais des contrats' (2015) 49 La Revue juridique Thémis de l'Université de Montréal 31.

[82] Elena Giannozzi, 'Les réformes récentes du Code civil français' (2022) 43 Roma e America: diritto romano comune: rivista di diritto dell'integrazione e unificazione del diritto in Europa e in America Latina 251.

conformity with EU law objectives (see Case C-106/89 Marleasing SA v La Comercial Internacional de Alimentación SA).

Additionally, national courts often use judicial doctrines or analogical reasoning to align ecodesign-related provisions with existing contract law standards.

For example, the German Federal Court of Justice (BGH) has applied EU consumer directives in the context of advertising claims to evaluate conformity. Similarly, in France, the Cour de cassation has interpreted the Code de la consommation in light of EU environmental regulations when evaluating misleading green claims. These examples highlight how domestic judiciaries actively participate in the operationalisation of EU ecodesign norms, translating them into enforceable legal outcomes within their respective traditions.

4 Producer liability between ecodesign and consumer protection

The current EU legal framework draws a clear distinction between contractual liability for non-conformity (consumer sales law)[83] and non-contractual liability for defective products[84] (governed by Directive 85/374/EEC, transposed in Italy by Articles 114–127 of the Consumer Code[85]). However, the introduction of mandatory ecodesign requirements under Regulation (EU) 2024/1781 compels a systemic reassessment of the scope of producer liability in light of new environmental, social, and informational standards.

In contractual terms, a mismatch between the environmental characteristics stated in the Digital Product Passport and the actual features of the good constitutes a non-conformity under Directive 2019/771/EU. The breach of a qualified information duty, especially when it concerns essential elements such as durability, reparability or ecological composition, may entitle the consumer to invoke traditional contractual remedies[86]: repair, replacement, price reduction or rescission. In this context, producer liability becomes embedded in the distribution chain, and may operate jointly and severally with the seller's, depending on national rules on concurrent liability.

Yet the implications of ecodesign extend beyond the realm of contract[87]. Where failure to meet environmental requirements results in harm to persons or property — for instance, through the undisclosed use of hazardous substances, designs precluding safe repair, or software obsolescence in digital goods — liability may arise under product liability law.

[83] Azhar Rahadiyan Anwar, Inosentius Samsul, 'Implementation of Consumer Rights, Obligations, and Business Actors' Responsibilities in Case of Non-Conforming Goods' (2023) 11 LEGAL BRIEF 3493.
[84] Richard C Ausness, 'Tort Liability for the Sale of Non-Defective Products: An Analysis and Critique of the Concept of Negligent Marketing' (2001) 53 (1) South Carolina Law Review - Products Liability Law Symposium in Memory of Professor Gary T Schwartz 60.
[85] Giovanni Facci, 'Responsabilità per danno da prodotti difettosi, commento agli art. 114- 127, D.L.vo 6 settembre 2005, n. 206.' in Renato Rolli (ed), *I codici illustrati – Codice del Consumo* (La Tribuna 2008) 36.
[86] Carmelita Camardi, 'La protezione dei consumatori tra diritto civile e regolazione del mercato. A proposito dei recenti interventi sul codice del consumo' (2013) 5 JUS CIVILE 32.
[87] Hilja Autto, Helena Haapio, Jouko Nuottila, 'Contracts rethought and redesigned: A new era with AI' (2024) 8 (1-2) International Journal of Commerce and Contracting 7.

While traditionally governed by Directive 85/374/EEC, the framework has recently been revised by the new Product Liability Directive (EU) 2024/2853, which expressly includes digital features and sustainability-related defects within the scope of strict liability.

Under Article 6 of the 1985 Directive (and its equivalent in the 2024 revision), a product is considered defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account — including regulatory non-compliance. Ecodesign obligations, once codified, may thus serve as a benchmark for establishing product defectiveness and producer liability in both tangible and digital contexts. Another layer of liability may concern misleading or incomplete environmental information. If the Digital Product Passport contains inaccurate or omitted data regarding features essential to the safe or responsible use of the product[88], this could amount not only to non-conformity, but also to a breach of pre-contractual duties of care or violations of Directive 2005/29/EC on unfair commercial practices[89]. In serious cases, such conduct may even give rise to tortious liability, grounded in either negligence or fraud[90].

Taken together, these developments[91] suggest that ecodesign standards are reshaping the contours of producer liability, shifting it from compliance with technical norms to a broader responsibility for protecting consumers economic, environmental and safety interests[92]. Courts and scholars are thus called upon to accommodate this evolution, developing interpretative criteria that integrate sustainability obligations into both contractual and extra-contractual liability regimes.

4.1 Future prospects for harmonisation and implications for private international law

The ongoing development of ecodesign legislation[93], together with the growing relevance of sustainability in cross-border contractual relationships, invites a broader reflection on the current level of normative harmonisation within the EU and its structural limitations. This analysis requires consideration not only of the vertical relationship between technical regulations and private law, but also of the suitability of EU private

[88] Carla Lopes, João Barata, 'Digital Product Passport: A Review and Research Agenda' (2024) 246 Procedia Computer Science 981.
[89] Anna Aseeva, 'Liable and Sustainable by Design: A Toolbox for a Regulatory Compliant and Sustainable Tech' (2023) 16 (1) Sustainability 228.
[90] Ismael Illán García and others, 'Digital Product Passport Management with Decentralised Identifiers and Verifiable Credentials' [2024] ArXiv <https://arxiv.org/abs/2410.15758> accessed 18 November 2025.
[91] Carl Dalhammar, Jessika Richter, Philipp Montenegro, 'Drivers and Barriers for "Circular" Consumer Electronics in the European Union' in 'Electronics Goes Green 2024+ Conference Proceedings' (IEEE 2024) 10. This paper, based on an interview study and analysis of the policies, examines what kind of changes the new policies may have on design of EE, and whether practitioners believe the policies will change consumer behaviour. The policies analysed are expected to have an impact on the future design of EEE. Digital Product Passports (DPPs) are considered to have a high potential to support new developments.
[92] Claude Chien-Hung Liu, Ransome Epie Bawack, 'Empowering AI to optimise eco-design' [2025] Journal of Information Technology Teaching Cases 11.
[93] Camilla Tamburini, 'Unlocking Circular Economies. Exploring the Role of the Digital Product Passport' in Lerwen Liu, Shabbir H Gheewala, Maw Der Foo, Lei Shi (eds), *Handbook of Circular Economy and Sustainability Global Leadership* (Springer 2025) 16.

international law in supporting the emergence of a consistent and enforceable framework for contractual sustainability[94].

A first issue arises from the fragmented regulatory landscape that separates ecodesign rules from consumer protection legislation[95]. While ecodesign measures – particularly those introduced by Regulation (EU) 2024/1781 – are progressively moving toward a horizontal scope across product categories, their historical development has been sector-specific, with technical requirements tailored to individual poduct types such as electrical appliances, lighting equipment and ICT devices. In contrast, consumer law combines both horizontal instruments, such as the Unfair Commercial Practices Directive (2005/29/EC) and the Unfair Contract Terms Directive (93/13/EEC), and vertical rules targeting specific types of transactions or products.

This regulatory separation creates uncertainty when sustainability-related information—such as durability, repairability or recyclability—is disclosed but not fully integrated into the contractual framework. For example, even when the Digital Product Passport makes key environmental features accessible to consumers, such features may not automatically become part of the contract of sale under national law. As a result, remedies for lack of conformity under Directive 2019/771 may not apply unless Member States or courts interpret ecodesign data as forming part of legitimate consumer expectations. The lack of coordination between these regulatory spheres therefore undermines the legal enforceability of sustainability claims and complicates access to remedies.

The proposed Green Claims Regulation aims to address this gap by introducing mandatory criteria for the substantiation, verification, and communication of environmental claims[96]. Specifically, it requires that all green claims be based on recognised scientific evidence, independently verified, and clearly communicated to consumers. While this would enhance transparency and prevent greenwashing, the regulation does not in itself integrate these claims into the contractual matrix, nor does it amend the directives governing sales or consumer rights.

Therefore, its contribution lies primarily in reinforcing pre-contractual clarity and administrative enforcement, rather than in directly harmonising contract law.

In parallel, the role of private international law instruments must be revisited, particularly Regulation (EC) No. 593/2008 (Rome I)[97]. In a Union where goods circulate freely but national contract laws remain diverse, it is crucial to assess whether ecodesign

[94] Fabrizio Cafaggi, 'Transnational Private Regulation of Environmental Sustainability through Commercial Contracts. Reassessing Contractual Governance in Global Supply Chains' (2024) 20 (1) European Review of Contract Law 25.
[95] Marco Loos, 'Repairing Consumer Sales Law' (2024) 32 (6) European Review of Private Law 945.
[96] Michael Jay Polonsky, Jeffrey Rotman, Virginia Weberb, Prashant Kumar, 'How meaningless and substantive green claims jointly determine product environmental perceptions'(2025) 44 (3) International Journal of Advertising 392.
[97] Luis Miguel Poiares Pessoa Maduro, Loïc Azoulai, *The Past and Future of EU Law: The Classics of EU Law Revisited on the 50th Anniversary of the Rome Treaty* (1st edn, Bloomsbury Publishing 2010) 8.

obligations could qualify as overriding mandatory provisions under Article 9 of Rome I[98]. Such a classification would give these norms precedence over the law chosen by the parties, reflecting their public interest function and enabling their enforcement even in cross-border disputes governed by non-EU law.

However, ecodesign rules are not currently part of contract law in the strict sense. They are technical product regulations, and while they apply uniformly in all Member States as EU regulations, their contractual incorporation is mediated by national doctrines (e.g., implied terms or legitimate expectations). Moreover, the current formulation of Article 9 Rome I does not explicitly include sustainability standards among the categories of overriding mandatory provisions. Therefore, any evolution in this direction would require either judicial interpretation or a future legislative revision of the Rome I Regulation to acknowledge the imperative nature of sustainability-based product obligations—much like product safety or competition law rules.

As for jurisdiction, Regulation (EU) No. 1215/2012 (Brussels I bis) grants consumers the right to litigate in their country of residence but does not provide for specialised handling of disputes involving complex sustainability issues or misleading environmental practices[99]. Given the technical complexity of ecodesign requirements and the increasing prevalence of green claims, it may be appropriate to consider the creation of dedicated ADR mechanisms or specialised court divisions, similar to what exists in fields such as intellectual property or financial services. This would enhance consistency and ensure the application of correct technical standards, particularly in litigation involving cross-border or digital products[100].

Looking forward, the prospect of a European contractual sustainability law—integrating ecodesign, consumer protection, and civil obligations into a unified framework—could provide much-needed coherence[101]. However, this must be carefully situated within the EU's limited competence in civil law matters (Articles 4 and 5 TEU, Article 114 TFEU). Past attempts to harmonise European contract law more broadly, such as the Common European Sales Law (CESL), failed due to lack of political consensus. Therefore, rather than aiming for a general European code of contract law, the focus should remain on targeted harmonisation of sustainability-relevant obligations, where internal market needs and environmental goals intersect[102].

[98] Marie-Elodie Ancel, 'The Rome I Regulation and distribution contracts' in Andrea Bonomi, Paul Volken (eds), *Yearbook of Private International Law* Vol X (De Gruyter 2008) 11.
[99] Dominika Moravcová, 'Consumer protection under the Brussels I bis and Rome I Regulations' (2022) 2(1) Institutiones Administrationis: Journal of Administrative Sciences 100.
[100] Akash Gupta, Arushi Bajpai, 'Green Dispute Resolution: A Sustainable Way of Resolving Disputes' in Apoorvi Shrivastava, Amlan Bhusan (eds), *Sustainable Boardrooms: Democratising Governance and Technology for Society and Economy* (Springer 2023) 18.
[101] Dario Hug, 'Towards a Sustainable Interpretation of Standard Contract Terms?' in Marta Santos Silva and others (eds), *Routledge Handbook of Private Law and Sustainability* (1st edn, Routledge Handbooks 2024) 18.
[102] Ekaterina Pannebakker, 'Sustainable development clauses in international contracts through the lens of the Unidroit principles' (2024) 29 (2) Uniform Law Review 9.

4.2 Sustainability as an interpretative principle in contract law

The evolution of EU sustainability regulation, and particularly the introduction of binding environmental requirements at the product design stage, raises increasingly important questions about the systemic role of sustainability within contract law[103]. Specifically, it is necessary to assess whether, and to what extent, environmental sustainability may be considered not merely as a substantive obligation, but as an autonomous interpretative principle capable of guiding the construction and supplementation of contracts in light of overarching public interests[104].

Traditionally, contract interpretation in Europe has been informed by principles such as good faith, the socio-economic function of the agreement, and mutual reliance[105]. However, the incorporation of sustainability into EU positive law — most recently formalised in the recitals and operative provisions of Regulation (EU) 2024/1781 — reflects a shift toward recognising environmental values as part of the normative framework within which private law operates[106].

This conceptual shift does not rest solely on the authority of secondary instruments. It is grounded in primary EU law, particularly:

Article 3(3) TEU, which affirms the Union's objective of sustainable development and a high level of environmental protection[107];

Article 11 TFEU, which imposes a duty to integrate environmental protection requirements into all EU policies and activities (integration clause)[108];

and Article 37 of the Charter of Fundamental Rights of the EU, which recognises a right to environmental protection, albeit as a principle rather than a directly justiciable right[109].

Together, these provisions form a constitutional foundation that legitimises the interpretation of private law — including contract law — in light of sustainability considerations. Regulation (EU) 2024/1781, as well as complementary instruments like the Corporate Sustainability Reporting Directive (CSRD) and the Corporate Sustainability Due Diligence Directive (CSDDD), operationalise these constitutional principles at the

[103] Abraham Zang, Stefan Seuring, 'Digital product passport for sustainable and circular supply chain management: a structured review of use cases' (2024) 27 (12) International Journal of Logistics Research and Applications: A Leading Journal of Supply Chain Management 2513.
[104] Laÿna Droz, 'Redefining Sustainability: From Self-Determination to Environmental Autonomy' (2019) 4 (3) Philosophies 42.
[105] Guido Alpa, *IL CONTRATTO IN GENERALE: principi e problemi* (2nd edn, Giuffrè 2014) 33.
[106] Michael Has, *Sustainable Products: Life Cycle Assessment, Risk Management, Supply Chains, Ecodesign* (2nd edn, De Gruyter 2024) 384.
[107] Nicolas de Sadeleer, 'Sustainable development in EU law: still a long way to go' (2015) 6 Jindal Global Law Review 39.
[108] Beate Sjåfjell, 'The legal significance of Article 11 TFEU for EU institutions and Member States' in Beate Sjåfjell, Anja Wiesbrock (eds), *The Greening of European Business under EU Law* (1st edn, Routledge 2014) 22.
[109] Ottavio Quirico, 'Integrating Human Rights and Environmental Duties: Prospective Implications of Article 37 of the EU Charter of Fundamental Rights' (2021) 39 Boston University International Law Journal 41.

regulatory level, thereby reinforcing the systemic relevance of sustainability throughout the product lifecycle[110].

Practically speaking, this evolution supports the use of sustainability as a subsidiary interpretative criterion in cases of contractual ambiguity, silence, or incompleteness[111]. For instance, where multiple plausible interpretations of a contract clause concerning product durability, repairability or energy performance exist, it may be both legitimate and advisable to adopt the interpretation that best aligns with the Union's sustainability objectives and ecodesign framework. This interpretative orientation is not arbitrary: it draws legitimacy from the systemic integration of environmental concerns mandated by Articles 3(3) TEU and 11 TFEU, as well as from the growing body of EU regulations that explicitly impose sustainability-related obligations on producers and suppliers.

This interpretative approach proves particularly useful in cross-border transactions, where the law applicable to the contract may not reflect the most advanced implementation of sustainability obligations. In such cases, invoking sustainability as an interpretative principle may help reduce normative asymmetry between Member States, thereby promoting a more consistent and teleologically informed application of EU contract law.

Environmental sustainability is progressively emerging as an interpretative and supplementary principle in contract law, offering guidance to courts and practitioners in reconstructing contractual intent, assessing breach, and selecting appropriate remedies[112]. This development is consistent with the EU's broader ecological transition and is likely to assume an increasingly central role in the future evolution of both international and European private law.

5 Conclusion

The analysis has demonstrated that ecodesign, in its current regulatory evolution, can no longer be considered peripheral or merely technical in relation to contract law. On the contrary, it must be recognised as a structural component of the emerging European private law of sustainability. Through the imposition of binding design obligations — including durability, reparability, and information transparency — Regulation (EU) 2024/1781 directly reshapes contractual dynamics by broadening pre-contractual duties, redefining the notion of conformity under Directive (EU) 2019/771, and reinforcing

[110] Nicolas de Sadeleer, 'The European Green Deal: greenwashing compounded by deregulation (Omnibus law) or a genuine paradigm shift?' [2025] European Journal of Risk Regulation 1.
[111] Kateřina Peterková, 'Purpose of sustainability contractual clauses' in Hanna Lakkala, Jarmo Vehmas (eds), *Trends and future of sustainable development* (FFRC 2013) 14.
[112] Dario Hug, 'Towards a Sustainable Interpretation of Standard Contract Terms?' in Marta Santos Silva and others (eds), *Routledge Handbook of Private Law and Sustainability* (1st edn, Routledge 2024) 18.

consumers' legitimate expectations in the digital and environmental dimensions of goods[113].

Nonetheless, the integration between ecodesign and consumer law continues to reveal points of friction, due to their differing regulatory logics, legal instruments, and levels of harmonisation. In this context, national contract law plays a pivotal role in operationalising sustainability-related obligations through the application of general clauses such as good faith, fairness, and liability for misrepresentation or non-performance[114]. The effective enforcement of ecodesign norms within private relationships thus depends on the interpretative and remedial tools offered by domestic legal systems.

The study has further shown that environmental non-compliance can give rise to both contractual and non-contractual liability[115], especially where misleading environmental claims or design-related defects cause damage to persons or property. The entry into force of the new Product Liability Directive (EU) 2024/2853 confirms this trend, by expanding the scope of strict liability to include software updates, sustainability features, and digital elements embedded in products. This reinforces the contribution of ecodesign not only to product quality, but to a broader culture of corporate accountability[116] and legal responsibility[117].

Building on the constitutional principles set out in Articles 3(3) TEU, 11 TFEU and 37 of the Charter, the paper advocates for a progressive recognition of sustainability as an interpretative principle in contract law. This would enable courts and practitioners to favour, in cases of ambiguity or incompleteness, those contractual interpretations that align with EU sustainability objectives. Such an interpretative approach would strengthen legal certainty in cross-border relations and support the effective application of sustainability-related obligations throughout the internal market[118]. The interaction with private international law, particularly Regulations Rome I and Brussels I bis, further

[113] Kayleen Manwaring, ''Slowing down the loop': smart devices and the right to repair' (2024) 38 (3) International Review of Law, Computers & Technology 268.
[114] Iryna S Lukasevych-Krutnyk and others, 'Analysis of Legal Regulation of Contractual Obligations in the Civil Law Systems' (2022) 19 Astra Salvensis - revista de istorie si cultura 169 .
[115] Antti Palmujoki, Katriina Parikka-Alhola, Ari Ekroos, 'Green Public Procurement: Analysis on the Use of Environmental Criteria in Contracts' (2010) 19 (2) Review of European Community & International Environmental Law 250.
[116] Martin Charter, 'Managing Ecodesign' in Martin Charter, Ursula Tischner (eds), *Sustainable Solutions: Developing Products and Services for the Future* (1st edn, Greenleaf Publishing Limited 2001) 23.
[117] Tania Pantazi, 'Consumers' contribution to climate change mitigation and their empowerment through EU law' in Elbert de Jong (ed), *Corporate Accountability and Liability for Climate Change* (Edward Elgar Publishing 2024) 25.
[118] Some authors propose, on this point, an innovative approach to implementing ecodesign systems, exploiting the potential of technology. See: Jens Schuberth and others, 'The Front-Runner Approach-Facilitating Progressive Product Policy by Using Information from EU Product Databases' (2024) 17 (2) Energies 504. Within this paper, the authors said «already existing front-runner approaches and recent and ongoing product policy-making processes were reviewed. Based on the results, an EU front-runner approach is outlined. The presented approach (i) refers to performance levels of the best products already available on the market, (ii) aggregates information in existing databases, and (iii) works semi-automated. Together, all three attributes have a high potential to facilitate and accelerate the specification of appropriate minimum requirements for products at the EU level. This way, EU policymakers can deliver on the core objectives of the Ecodesign legislative framework much better».

illustrates the need to reassess the systemic status of ecodesign obligations. Their potential classification as overriding mandatory provisions under Article 9 of Rome I — in light of their public interest function and their foundation in EU law — may enhance their cross-border enforceability and promote consistency between environmental regulation and contractual practice[119].

In conclusion, ecodesign today constitutes not merely a tool of environmental policy, but a catalyst for the transformation of European contract law. It integrates sustainability, transparency, and responsibility into the architecture of legal obligations, positioning itself at the intersection of market regulation, consumer protection, and civil liability. As such, it plays a central role in the evolving relationship between private autonomy and public interest within the European legal order.

[119] Jakub Kanický, 'Sustainable and Climate-Friendly Products: What Role Is There for Product Standards?' (2024) 70 (1) Acta Universitatis Carolinae Iuridica 131.

*Armando Alvares-Garcia Júnior**

SPECIAL SECTION

REGULATORY CHALLENGES IN SUSTAINABLE MARKETS

The Impact of Regulation (EU) 2024/1781 on European Competitiveness

Abstract

Regulation (EU) 2024/1781 marks a significant development in the European Union's commitment to sustainable product governance. This article analyses its impact on market competitiveness, legal coherence, and innovation, with particular attention to small and medium-sized enterprises. The discussion explores the intersection between ecodesign criteria and sector-specific technical standards, highlighting the regulatory complexities that emerge from overlapping legal frameworks. Methodologically, the research adopts a multidisciplinary perspective, combining doctrinal analysis, comparative legal review, and economic policy assessment. Attention is given to the interaction between EU legislation and global supply chains, assessing the capacity of the Regulation to address disparities in regulatory environments. The article identifies areas where implementation gaps and compliance burdens may affect the achievement of sustainability objectives. The paper concludes with policy recommendations focused on differentiated regulatory pathways and adaptive governance structures to promote effective, inclusive, and competitive green transitions within the EU's internal market.

JEL CLASSIFICATION: K32, K33, Q56, L51, F18

SUMMARY

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 10.13135/2785-7867/12830

- 5 Supply Chain Responsibilities and the Legal Vacuum - 6 Impact on European Industrial Competitiveness – 7 Socioeconomic and Consumer Implications - 8 Conclusions and Regulatory Outlook

1 Introduction

Regulation (EU) 2024/1781 constitutes one of the most ambitious legislative instruments within the European strategy for the transition towards a green economy, reflecting a broader trend in which national and European courts have increasingly recognised and enforced environmental principles such as the precautionary principle, non-regression and climate responsibility[1]. Recent jurisprudence[2]—ranging from the German Federal Constitutional Court's landmark ruling on climate law to the French *Conseil d'État's* orders on climate action—demonstrates the growing judicial enforceability of sustainability obligations[3]. Recent scholarship has emphasised that this

[1] Maria Lee, *EU Environmental Law, Governance and Decision-Making* (2nd edn, Hart 2014) ch 4.

[2] The Regulation (EU) 2024/1781 is part of the broader European Green Deal, a strategic initiative launched by the European Commission in December 2019, aimed at achieving climate neutrality by 2050. It follows the Circular Economy Action Plan and builds on previous legislative instruments, introducing legally binding ecodesign obligations applicable beyond energy-related products. See, among others: Commercial Court No 2 of Santander, Judgment No 12/2025, dismissing the existence of misleading advertising due to greenwashing; High Court of Justice of Extremadura, Judgment 479/2022, distinguishing between green economy and circular economy criteria for fiscal benefit purposes; Spanish Supreme Court, Judgment of 22 March 2023, Case RC 1451/2022, recognising the principle of non-regression in environmental protection within urban planning; High Court of Justice of Galicia, precautionary suspension orders in various wind farm cases, based on risk of irreversible environmental damage; Bundesverfassungsgericht, Judgment of 24 March 2021, 1 BvR 2656/18, declaring the Federal Climate Protection Act unconstitutional for lack of intertemporal safeguards; Conseil d'État (France), Commune de Grande-Synthe, Judgment of 1 July 2021, ordering the State to adopt concrete anti-climate change measures; *Case C-366/10 Air Transport Association of America v Secretary of State for Energy and Climate Change* [2011] ECLI:EU:C:2011:864, upholding inclusion of international aviation in the EU Emissions Trading System; *Case C-723/17 Craeynest and Others* [2019] ECLI:EU:C:2019:533, affirming judicial enforceability of air pollution obligations; *Case C-752/18 Deutsche Umwelthilfe eV* [2020] ECLI:EU:C:2020:572, on effective environmental sanctions in cases of governmental inaction. The evolution of European jurisprudence converges on the recognition that sustainability is no longer a merely programmatic principle but a legally enforceable obligation. Both in the case law of Germany and France, as well as in the rulings of the CJEU and various Spanish courts, particular emphasis is placed on the practical effectiveness of the precautionary principle, the prohibition of regression, and climate responsibility. This same background underpins Regulation (EU) 2024/1781, which enshrines circularity and traceability criteria as binding legal obligations. The commonalities reveal a shift from policy-making to the judicialisation of climate action and sustainability, thereby consolidating enforceable normative standards. The new Regulation thus positions itself within a European jurisprudential architecture that has already set the course for strengthening the coherence and binding force of the ecological transition. At the same time, this evolution demonstrates that environmental protection is no longer treated as a secondary policy objective but as a structural condition of market integration. National courts, following the reasoning of the Bundesverfassungsgericht and the Conseil d'État, have required legislative and administrative bodies to adopt concrete measures rather than abstract commitments. This resonates with the architecture of Regulation (EU) 2024/1781, which translates sustainability into operational product-level obligations, making the internal market an instrument of ecological governance. Furthermore, the Spanish jurisprudence on precautionary suspensions and the recognition of non-regression highlights the readiness of national judges to intervene when regulatory inertia risks undermining environmental protection. These dynamics reflect a broader trend in which courts act as guardians of intergenerational equity, ensuring that sustainability commitments are not eroded by economic expediency. From this perspective, the Regulation should be understood as part of a broader normative continuum shaped by judicial interpretation. Its one-size-fits-all model nevertheless raises questions of proportionality that recall earlier CJEU rulings such as *Vodafone and Commission v Hungary*, reminding us that enforceability must be tempered by adaptability. In this sense, the judicialisation of sustainability provides legitimacy while simultaneously imposing constraints: it compels compliance and, at the same time, requires that EU regulation reconcile ambition with fairness across diverse economic sectors.

[3] Juliane Kokott and Christoph Sobotta, 'The Effectiveness of EU Environmental Law: The Role of National Courts' (2020) 32 Journal of Environmental Law 1.

evolution reflects a doctrinal redefinition of climate responsibility and the increased justiciability of the precautionary principle in environmental law.

This Regulation, which focuses on the mandatory integration of environmental sustainability criteria into the design and commercialisation of products, marks a turning point in the legal-industrial framework of the European Union[4]. The Regulation builds upon the policy foundations of the European Green Deal and the Circular Economy Action Plan, introducing product-level obligations that go beyond previous sectoral directives, and aligning EU law with academic calls for a systemic shift towards sustainability-oriented governance[5].

Its cross-cutting application throughout value chains alters both the technical parameters of manufacturing, distribution, and consumption, and the structure of legal, economic, and regulatory relations within the internal market, by imposing structural requirements concerning product durability, traceability, resource efficiency and circularity[6].

From a doctrinal standpoint, the ESPR's shift (Ecodesign for Sustainable Products Regulation) to product-level sustainability obligations operationalises an impact-based regulatory strategy that prioritises measurable outcomes such as durability, reparability and data-enabled traceability over process-based compliance[7]. This approach hinges on the Digital Product Passport (DPP) as a vehicle for standardised, interoperable information flows across supply chains, enabling conformity assessment, market surveillance and circularity services[8]. To ensure legal soundness and effectiveness, scholarship and institutional analyses stress the need to align DPP data models with existing EU reporting architectures (notably ESRS under the CSRD)[9] and with harmonised technical standards

[4] On the evolution of the European legal-industrial framework towards sustainability, see: European Commission, 'The European Green Deal' COM(2019) 640 final; European Commission, 'Communication on the Sustainable Products Initiative' COM(2022) 140 final; Ellen Vos, 'EU Green Deal and Regulatory Governance: From Sectoral to Systemic Innovation?' (2022) 59 Common Market Law Review 621 and Case C-366/10 *Air Transport Association of America v Secretary of State for Energy and Climate Change* [2011] ECLI:EU:C:2011:864, upholding the validity of extraterritorial environmental measures. This Case constituted a landmark in upholding the inclusion of international aviation within the European emissions trading scheme, thereby confirming the validity of environmental measures with extraterritorial effects. The CJEU emphasised that climate protection may justify regulatory restrictions in the face of external commercial interests. This judgment paved the way for a more robust deployment of EU law in transnational contexts. Consequently, it anticipates the normative framework of the Green Deal, wherein sustainability is projected beyond the confines of the internal market.

[5] Elisa Morgera, 'The European Green Deal and the Integration of Sustainability in EU Law' (2021) 30 European Energy and Environmental Law Review 2.

[6] Veerle Heyvaert, 'Governing Circularity: Rethinking EU Product Regulation for the Green Transition' (2022) 35 Journal of Environmental Law 401.

[7] Anne-Christin Mittwoch, 'The Digital Product Passport of the Ecodesign Regulation – Passport to a Successful Twin Transformation in Product Law?' (2024) 45(3) Business Law Review 62–67.

[8] Otto Handle (CEN/CENELEC), "Standardizing the Digital Product Passport: Foundation Set, Implementation Approaching" (interview, CEN/CENELEC, 8 July 2025) <https://wiot-group.com/think/en/articles/otto-handle-cen-cenelec-on-eu-digital-product-passport/> accessed 15 September 2025.

[9] European Financial Reporting Advisory Group (EFRAG), 'ESRS and Data Interoperability: Connectivity with Product-Level Information' (2024); Ł Matuszak, "Assessment of the Compliance of Environmental Disclosures with ESRS Indicators" (2025) 17 Sustainability 3380.

(CEN/CENELEC)[10], thereby reducing duplication, ensuring legal certainty, and making product metrics auditable across jurisdictions and value-chain tiers.

As a matter of EU legal theory, the adoption of this Regulation necessitates a critical assessment of its consistency with the existing body of EU law[11], its conformity with the principles of legal certainty and proportionality[12], and its effectiveness as a harmonisation tool in a global context characterised by significant regulatory asymmetries. The new Regulation does not emerge in a legal vacuum; rather, it integrates into an already dense framework of directives and regulations governing the production, marketing and traceability of goods within the European internal market.

Notably, the Ecodesign Directive for energy-related products (2009/125/EC) remains in force for certain product categories[13], the Corporate Sustainability Reporting Directive (CSRD) has redefined non-financial disclosure obligations[14], and the proposed Directive on Corporate Sustainability Due Diligence (CSDDD) will introduce binding supply chain governance duties for large companies[15].

The overlap and lack of formal repeal clauses, or interpretative guidance by the Commission, risks producing cumulative administrative burdens and legal uncertainty, especially for small and medium-sized enterprises that may lack the resources to navigate parallel reporting and documentation regimes[16].

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[10] Thomas Knothe, '*DPP Presentation-JTC 24*' (UNECE, 27 February 2025) <https://unece.org/sites/default/files/2025-02/DDP%20Presenation%20-%20JTC24%20-%20Dr%20Thomas%20Knothe.pdf> accessed 15 September 2025; Henten A, "Digital Product Passport—EU Sustainability and Circularity…" [2025] Preprints <https://www.preprints.org/manuscript/202504.1765/v1> accessed 15 September 2025.

[11] Paul Craig, *EU Administrative Law* (3rd edn, OUP 2018).

[12] Tridimas T, *The General Principles of EU Law* (3rd edn, OUP 2020).

[13] This integration into an already dense legal ecosystem reflects the European Union's layered regulatory approach, where sector-specific directives (e.g., Directive 2009/125/EC establishing a framework for the setting of ecodesign requirements for energy-related products) coexist with transversal instruments like the Corporate Sustainability Reporting Directive (CSRD). The coexistence of overlapping regimes may raise legal tensions in implementation, particularly in the absence of formal repeal clauses or interpretative communications by the Commission.

[14] Directive (EU) 2022/2464 of the European Parliament and of the Council of 14 December 2022 on corporate sustainability reporting [2022] OJ L 322/15. This directive redefined the non-financial disclosure framework in the Union. It obliges large undertakings and listed SMEs to disclose information on environmental, social and governance risks, thereby integrating sustainability into the corporate reporting regime and enhancing market transparency.

[15] Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products [2009] OJ L 285/10. The Proposal for a Directive on Corporate Sustainability Due Diligence (CSDDD) COM(2022) 71 final aims to impose mandatory human rights and environmental due diligence obligations on large EU and non-EU companies with operations in the internal market. It formalises the legal duty to prevent and mitigate adverse impacts across global supply chains, aligning private governance with public sustainability goals.

[16] European Commission, 'An SME Strategy for a Sustainable and Digital Europe' COM(2021) 350 final. SMEs in the EU represent over 99% of all businesses and account for two-thirds of private sector employment. Despite this economic centrality, they face structural disadvantages in regulatory compliance, including lack of technical staff, limited legal expertise, and restricted access to EU financing. The Ecodesign Directive (2009/125/EC), originally focused on energy-related products, remains applicable alongside Regulation (EU) 2024/1781, raising potential questions of legal hierarchy and duplication of obligations in areas such as durability, reparability and energy performance. The Corporate Sustainability Reporting Directive (CSRD), meanwhile, mandates entity-level disclosures on sustainability risks and impacts, whereas the new Regulation imposes product-level information duties, including digital product passports. Without clear guidance, inconsistencies may arise in reporting thresholds, data granularity and verification standards. The proposed Directive on Corporate Sustainability Due Diligence (CSDDD) introduces further obligations regarding supply chain governance and human rights, potentially overlapping with traceability and life-cycle requirements under

Doctrinal commentary emphasises that the ESPR's systemic ambition requires explicit coordination techniques to ensure legality and effectiveness across overlapping regimes[17]. In particular, practical guidance on lex specialis/posterior and horizontal coherence, together with interoperability between ESRS reporting and DPP traceability via harmonised standards (CEN/CENELEC), are identified as necessary to avoid duplication, enhance legal certainty, and make durability, reparability and circularity metrics auditable across Member States[18].

In parallel, the international context imposes structural constraints on the effectiveness of any environmental measure adopted unilaterally. The increasing openness of global trade, the transnational fragmentation of supply chains, and the persistence of more permissive regulatory frameworks in third countries limit the European Union's ability to enforce ambitious standards without triggering distortions of competition[19]. This tension is further compounded by the rise of protectionist industrial strategies in non-EU economies, which consolidate domestic production capacities through subsidies, lenient standards or selective tariff measures[20]. Within this scenario[21], the EU's aspiration to function as a normative power — shaping international standards through its internal legislation — encounters growing material limitations.

Without adequate coordination between Regulation (EU) 2024/1781, compensatory mechanisms, sector-specific incentives and coherent governance structures, its transformative potential risks being undermined by adverse outcomes such as strategic

the new Regulation. The absence of an integrated implementation framework across these instruments may lead to cumulative compliance burdens, especially for SMEs lacking the capacity to navigate parallel reporting and documentation regimes.

[17] Mittwoch (n 7).

[18] Koen Lenaerts and José A Gutiérrez-Fons, 'The General System of EU Environmental Law Enforcement' (2011) 30 Yearbook of European Law 3.

[19] Regulation (EU) 2023/956 of the European Parliament and of the Council of 10 May 2023 establishing a Carbon Border Adjustment Mechanism [2023] OJ L 130/52. See also Case C-366/10 Air Transport Association of America and Others ECLI:EU:C:2011:864, para 127 (validating the extraterritorial reach of EU environmental law, provided proportionality is maintained); and Case C-358/14 Poland v European Parliament and Council ECLI:EU:C:2016:323, 78–81 (upholding climate legislation despite industrial impact, reinforcing environmental objectives as legitimate in an open economy). Case C-358/14 represented a direct confrontation between the industrial interests of Member States heavily reliant on coal, such as Poland, and the Union's climate objectives. In paragraphs 78–81, the CJEU reaffirmed that emission reduction measures form part of the Union's essential commitments under Article 191 TFEU and that their legitimacy is not undermined by the economic impact they may generate in certain sectors. The Court stressed that the principle of proportionality must be assessed in light of the overarching goal of energy transition, thereby reinforcing the primacy of environmental protection over short-term industrial concerns. This line of case law consolidates the view that economic development within the internal market is legally conditioned by climate sustainability, anticipating what is now embodied in instruments such as the Carbon Border Adjustment Mechanism (Regulation (EU) 2023/956). In sum, the Poland case confirms that EU law has embraced sustainability as a structural limit on economic growth and as a foundation for extraterritorial regulatory action.

[20] See United States, Inflation Reduction Act, Public Law 117–169 (16 August 2022), which introduces major tax credits and subsidies for domestic clean energy; China, Industrial Green Development Plan (2021–2025), issued by the Ministry of Industry and Information Technology. For the EU response, see European Commission, 'A Green Deal Industrial Plan for the Net-Zero Age' COM(2023) 62 final; and Commission Communication on the Temporary Crisis and Transition Framework for State Aid, OJ C 101/03, 17 March 2023.

[21] Ian Manners, 'Normative Power Europe: A Contradiction in Terms?' (2002) 40(2) Journal of Common Market Studies 235.

offshoring, erosion of the European industrial base, and reduced economic resilience among the Union's more vulnerable operators.

Recent legal analysis[22] has highlighted that the absence of synchronisation between this Regulation and existing financial and industrial instruments —such as InvestEU[23] and the Innovation Fund— poses a systemic risk to its effective implementation, particularly in highly competitive or capital-constrained sectors. Both official impact assessments and scholarly commentary underline that, without integrated fiscal and governance support[24], the viability of ambitious sustainability frameworks remains empirically limited for most operators[25], especially for SMEs[26].

From a methodological perspective, this research is situated within a comprehensive analytical framework[27] that treats Regulation (EU) 2024/1781 not as an isolated legal instrument but as part of a complex normative architecture[28]. The analysis considers its structural impact on the European legal ecosystem, its interaction with the dynamics of international trade, and its redistributive effects across economic actors, with particular emphasis on small and medium-sized enterprises. Within this context, the study pursues four core objectives: (i) to identify internal regulatory tensions that hinder the coherent and uniform application of the Regulation; (ii) to assess the legal and economic burdens that affect operators differently depending on their size and operational capacity; (iii) to examine the implications of the new framework in terms of competitiveness, innovation and market access; and (iv) to formulate regulatory proposals that align environmental sustainability goals with criteria for economic viability and normative equity.

This approach is grounded in a critical review of the key provisions of Regulation (EU) 2024/1781, supplemented by an analysis of other relevant legal instruments[29], the case law of both the Member States and the Court of Justice of the European Union (CJEU),

[22] Marjan Peeters, Mariolina Eliantonio, Kati Kulovesi, Suvi-Tuuli Puharinen and Annalisa Savaresi, 'Greening the EU and the Rule of Law: Reflections on Opportunities and Limits of the EU's Legal Powers' Maastricht University Working Paper 2025 <https://cris.maastrichtuniversity.nl/ws/portalfiles/portal/262716895/Prepublication_draft_chapter_ssrn-5315459.pdf> accessed 15 September 2025.

[23] Regulation (EU) 2021/523 of the European Parliament and of the Council of 24 March 2021 establishing the InvestEU Programme and amending Regulation (EU) 2015/1017 [2021] OJ L 107/30. For discussion on the fiscal-operational gap in green regulatory implementation, see European Commission, 'The Innovation Fund: Climate Action through Technology' <https://climate.ec.europa.eu/eu-action/funding-climate-action/innovation-fund_en> accessed 15 September 2025.

[24] OECD, 'SMEs in a Green Recovery' (OECD Publishing 2021). See also Manners (n 21). For further judicial and regulatory context, see Case C-366/10 Air Transport Association of America (n 7); and Regulation (EU) 2023/956 (n 7), both illustrating the challenge of maintaining industrial competitiveness while enforcing high internal environmental standards.

[25] Manners (n 21).

[26] Yuri Bokov, Sergei Katsuba, Tatiana Kvasnikova and Viktor Shestak, 'Liability for Violation of Environmental Legislation in the EU' (2021) 30 European Energy and Environmental Law Review 9.

[27] Jolanta Malinauskaite, 'Competition Law and Sustainability: EU and National Approaches' (2022) 13(5) Journal of European Competition Law & Practice 336.

[28] Aude-Solveig Epstein, 'EU Environmental Law in the Digital Age: A Critical Outlook on the Twin Transition's Legal Structure' (2025) 1 European Journal of Risk Regulation 1–17.

[29] Michael Uffer, 'Competition Law' in Leonie Reins and Joris Thijssen (eds), *Sustainability through Product Policy* (Brill 2023) ch 9.

and leading doctrinal contributions[30] addressing the interplay between environmental, economic and competition law.

In this respect, the research is situated within the tradition of systemic legal analysis[31], focusing on the internal coherence, functional architecture and effectiveness of complex regulatory regimes. Rather than employing a law-and-economics approach[32], this study draws on interdisciplinary methods to examine how Regulation (EU) 2024/1781 interacts with existing legal frameworks, administrative practices, and technical standards across the European Union. Emphasis is placed on evaluating the Regulation's operationalisation within the broader EU legal and governance ecosystem, paying particular attention to regulatory overlaps, coordination challenges, and the implications for different categories of economic operators, especially SMEs. This systemic perspective is informed by leading scholarship on the interaction of multi-level norms, legal adaptation in evolving policy fields, and the practical mechanisms required to secure regulatory coherence, proportionality and legal certainty in the sustainable product agenda.

Likewise, the practical relevance of this study should not be underestimated. The effective implementation of Regulation (EU) 2024/1781 entails strategic decisions for national governments, regulatory bodies, multinational corporations, and small local entities alike. The legal uncertainties arising from its interpretation, combined with the technical and documentary compliance requirements[33], may result in barriers to market access, litigation due to non-compliance, and even instances of "regulated greenwashing"[34], where obligations are confined to formal requirements without producing verifiable material impact.

[30] On the dual methodological framework combining law and economics with legal systemic analysis, see the distinction articulated in EU scholarship between incentive-based assessment and normative coherence in the integration of fragmented regimes. The former focuses on behavioural and efficiency outcomes, while the latter examines the internal logic and interaction of legal instruments within complex governance systems. These perspectives are particularly valuable when analysing legislation such as Regulation (EU) 2024/1781, which operates across multiple regulatory layers and affects both economic performance and institutional consistency.

[31] Niklas Luhmann, *Law as a Social System* (Oxford University Press 2004); Lenaerts and Gutiérrez-Fons (n 18); Aude-Solveig Epstein (n 28); European Commission, Commission Staff Working Document: Impact Assessment Accompanying the Proposal for a Regulation on Ecodesign for Sustainable Products SWD(2022) 89 final, vol I, 12–14.

[32] Richard A Posner, *Economic Analysis of Law* (9th edn, Wolters Kluwer 2014); Guido Calabresi, *The Costs of Accidents: A Legal and Economic Analysis* (Yale University Press 1970); Damien Gerard, 'EU Competition Law and Environmental Protection: The Economic Approach' (2021) 17(2–3) European Competition Journal 473; Niklas Luhmann (n 31); Miguel Poiares Maduro, 'Three Claims of Constitutional Pluralism' in Gareth Davies and Matej Avbelj (eds), *Legal Pluralism in European Law* (Hart 2012) 67. For the institutional perspective, see European Commission, Commission Staff Working Document: Impact Assessment Accompanying the Proposal for a Regulation on Ecodesign for Sustainable Products, SWD(2022) 89 final, vol I, 12–14.

[33] European Commission, Proposal for a Directive on substantiation and communication of explicit environmental claims (Green Claims Directive), COM(2023) 166 final.

[34] Regulated greenwashing refers to the institutionalisation of sustainability claims within legal compliance frameworks that are formally satisfied without producing substantive environmental outcomes. This risk is heightened when indicators are self-reported or lack independent verification. The European Commission has addressed this issue in its proposal for a Green Claims Directive (COM(2023) 166 final), which introduces standardised assessment methods and mandatory third-party verification. See also European Court of Auditors, 'Special Report 18/2021: The EU's Sustainable Finance Strategy – Ambitious Plans Require Stronger Oversight' (2021), which highlights how formalised compliance may dilute material impact. For a normative reference, see Regulation (EU) 2024/1781, recital 45, which warns against unnecessary regulatory burdens but may itself be interpreted in ways that compromise environmental integrity.

In light of this complexity, a technical analysis is essential to anticipate key pressure-points[35] within the Regulation and to propose corrective mechanisms aimed at streamlining the system, protecting the most vulnerable actors, and reinforcing the European Union's leadership in environmental governance[36].

In sum, this research argues that Regulation (EU) 2024/1781 represents a historic opportunity to reorient the European production model towards a more sustainable paradigm. However, this opportunity is contingent upon the ability of legislators and legal practitioners to formulate regulatory, institutional, and technical solutions that reconcile environmental sustainability with economic efficiency, legal certainty, and fairness among market actors. This fundamental tension between regulatory ambition and operational feasibility will serve as the guiding thread for the analysis developed in the sections that follow.

To guide the reader through its analytical progression, this article is organised into eight substantive sections. Following this introduction, Section 2 examines the principal regulatory challenges in industrial sectors, with attention to technical complexities, intra-EU asymmetries, interoperability issues, barriers to innovation, and the relationship between ecodesign obligations and green fiscal policy. Section 3 analyses the specific impact on small and medium-sized enterprises, highlighting structural vulnerabilities, disproportionate burdens and comparative insights from other regulatory systems. Section 4 addresses the challenges of harmonising the new framework with existing legislation, while Section 5 focuses on supply chain responsibilities and the regulatory gaps they expose. Section 6 assesses the implications for European industrial competitiveness, and Section 7 explores the socioeconomic and consumer dimensions of the Regulation. Finally, Section 8 synthesises the main findings and offers a forward-looking regulatory outlook. Throughout, the analysis implicitly addresses two central research questions, namely: to what extent is Regulation (EU) 2024/1781 effective and coherent in achieving sustainable product governance framework within the EU internal market, and, secondly, what are the legal and economic consequences of its implementation?

[35] Institute for European Environmental Policy, 'External Impacts of New EU Sustainable Product Standards' (IEEP 2025) <https://ieep.eu/wp-content/uploads/2025/04/External-impacts-of-new-EU-sustainable-product-standards-IEEP-2025.pdf> accessed 15 September 2025.

[36] The tension between normative ambition and operational feasibility has long characterised EU environmental regulation. A comparable dynamic occurred during the implementation of the GDPR (Regulation (EU) 2016/679), where stringent obligations initially overwhelmed small entities with limited capacity. See Paul Craig and Gráinne de Búrca, *EU Law: Text, Cases, and Materials* (7th edn, Oxford University Press 2020) 1016–1035. Similar concerns have been raised in relation to Regulation (EU) 2024/1781. The European Commission's Sustainable Products Initiative (COM(2022) 140 final) acknowledges the risk of disproportionate burdens, particularly for SMEs. Recital 45 of the Regulation highlights the need to minimise administrative burdens, yet fails to specify exemption criteria or adaptive mechanisms. The European Economic and Social Committee has echoed these criticisms in its Opinion INT/973 (2022). See also Dirk Schoenmaker, 'Greening the EU Financial System: From Ambition to Implementation' (2022) 24(3) Environmental Law Review 189.

2 Regulatory challenges in industrial sectors

2.1 Technical complexities in the application of general ecodesign criteria

Regulation (EU) 2024/1781 adopts a cross-sectoral approach aimed at harmonising sustainability criteria across all stages of a product's life-cycle[37], from its design to its disposal or reuse. However, this normative transversalism—while desirable from an integrated ecological perspective—comes into direct tension with the specific technical requirements that define certain industrial sectors. In the absence of detailed specifications or a framework for adaptive regulation, a conflict arises between the guiding principles of ecodesign and the technical operability of sectors already governed by existing sector-specific legislation[38].

The design of products in sectors such as biomedical technology, aerospace, or microelectronics is subject to safety, sterility, or energy-efficiency standards that are not always compatible with the new requirements for durability, modularity, or reparability imposed by Regulation (EU) 2024/1781[39]. In particular, medical devices regulated under Regulation (EU) 2017/745 on medical devices must comply with strict requirements concerning structural integrity and sterility, which in many cases preclude the incorporation of mechanisms for repair or reuse. This regulatory incompatibility is further exacerbated by the absence of explicit technical exemption clauses or sector-specific impact-assessment procedures within the Ecodesign Regulation itself[40].

In turn, the information requirements concerning the use of hazardous substances—such as those established under Regulation (EC) No 1907/2006 (REACH)—impose traceability obligations on producers that are not adequately integrated with the Digital Product Passport system set out in Article 10 of Regulation (EU) 2024/1781. This leads to duplicated documentation, incompatibility between databases and technical barriers that affect the operability of value chains, particularly in sectors already subject to stringent

[37] Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for setting ecodesign requirements for sustainable products [2024] OJ L 202/1. See also Article 114 TFEU as the legal basis for internal market approximation measures.

[38] See Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [2017] OJ L117/1; and Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in civil aviation [2018] OJ L 212/1. On tensions with ecodesign obligations, see European Commission, 'Staff Working Document Accompanying the Proposal for a Regulation on Ecodesign for Sustainable Products' SWD(2022) 89 final, 28 March 2022.

[39] See Regulation (EU) 2017/745 on medical devices, art 5 and Annex I. For aviation, see Regulation (EU) 2018/1139 and EASA technical certification requirements. For electronics, see Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment [2011] OJ L 174/88. These sectoral regimes illustrate potential incompatibilities with the generalised obligations introduced by Regulation (EU) 2024/1781.

[40] Regulation (EU) 2024/1781, art 16. On regulatory gaps in high-risk sectors, see European Commission, 'Staff Working Document Accompanying the Proposal for a Regulation on Ecodesign for Sustainable Products' SWD(2022) 89 final, 28 March 2022. See also Regulation (EU) 2017/745, Annex I. Stakeholder consultation reports under the Commission's Better Regulation agenda have flagged the need for delegated acts to reconcile sector-specific requirements with horizontal sustainability goals.

monitoring, such as fine chemicals, automotive manufacturing and semiconductor production[41].

It is not sufficient to impose general ecodesign criteria without simultaneously establishing a technical framework for regulatory coordination[42], sectoral adaptation[43] and digital interoperability[44]. It is necessary to develop mechanisms that ensure compatibility between the Regulation and existing sector-specific technical frameworks, as well as to introduce a general coordination clause that prevents the overlap or contradiction of obligations that are functionally, legally or economically incompatible.

2.2 Internal regulatory asymmetries and intra-EU competitiveness

One of the most notable side-effects of Regulation (EU) 2024/1781 is the emergence of regulatory disparities among Member States, arising not only from differences in institutional capacity[45], but also from divergent legal traditions and productive structures[46]. The practical implementation of the Regulation largely depends on the existence of national authorities capable of issuing interpretative guidelines, monitoring compliance, and effectively enforcing sanctions. This capacity varies significantly across countries, thereby exacerbating existing regulatory asymmetries within the Union.

The principle of mutual trust between national legal systems, as affirmed by the CJEU, is undermined when the same product can circulate freely within the Union despite having been subject to entirely different environmental or traceability requirements in its Member State of origin. This leads to distortions of competition within the internal market, where economic operators do not compete under equal conditions. In legal terms, this constitutes an indirect breach of the level-playing-field principle and of the principle of non-discrimination, both of which are essential to the legitimacy of Union law.

These divergences also translate into differentiated effects on corporate tax strategies, logistics and investment planning. While Germany and the Nordic countries benefit from advanced systems of eco-labelling, green taxation, and public support for ecological innovation, other Member States continue to operate carbon-intensive industrial models with limited infrastructure for implementing structural changes in their production

[41] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [2006] OJ L 396/1, arts 7 and 33. See also ECHA, 'SCIP Database'<https://echa.europa.eu/scip> accessed 15 September 2025· On interoperability concerns, see European Commission, SWD(2022) 89 final.
[42] Lee (n 1).
[43] Patrick Thieffry, *Manuel de droit européen de l'environnement et du climat* (4e éd, Bruylant 2024).
[44] Sean Whittaker, 'Exploring a Right to Submit Environmental Information Under International Environmental Law' (2023) 35(3) Journal of Environmental Law 401–418.
[45] Suzanne Kingston, Veerle Heyvaert and Aleksandra Čavoški, *European Environmental Law* (Cambridge University Press 2017).
[46] Regulation (EU) 2024/1781, recital 5. See also Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products [2019] OJ L 169/1. European Court of Auditors, 'Special Report 18/2021: EU Action on Product Safety' <https://www.eca.europa.eu> accessed 15 September 2025.

processes. The combination of regulatory requirements and uneven compliance capacities has led to "internal regulatory relocation", whereby companies move operations within the EU in search of more favourable—albeit less sustainable—regulatory environments[47].

From the perspective of competition law, this situation may also encourage practices of covert forms of environmental dumping or tax-optimisation strategies based on fragmented regulatory compliance. The European Commission should intervene through interpretative communications or delegated acts to harmonise minimum conditions for the Regulations's application, thus ensuring regulatory coherence and the proper functioning of the internal market.

2.3 Lack of interoperability with existing technical standards

One of the most significant obstacles to the effective implementation of Regulation (EU) 2024/1781 is its insufficient interoperability with existing technical standards[48] at both European and international levels. Although the Regulation refers to the establishment of sustainable design requirements based on life-cycle analysis, it fails to provide clear mechanisms for integrating these requirements with frameworks such as ISO 14006 (environmental management systems for ecodesign), ISO 20400 (sustainable procurement), or the sector-specific standards issued by the European Committee for Standardisation (CEN)[49].

This regulatory disconnect creates a paradox: operators that have already adopted international sustainability standards may be compelled to alter processes to comply with a new, less detailed yet formally binding framework. This duplication discourages voluntary self-regulation and undermines the principle of mutual recognition that has long characterised European technical law.

In the construction sector, for example, Directive 2010/31/EU on the energy performance of buildings already sets advanced technical standards on materials, passive design, and emissions reduction. The simultaneous application of Regulation (EU) 2024/1781, without specific technical-integration guidelines, creates operational incompatibilities and interpretative uncertainty. Similarly, in the field of energy-related

[47] Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just Transition Fund [2021] OJ L 231/1. See also European Commission, 'The European Green Deal' COM(2019) 640 final; and 'Green Deal Industrial Plan for the Net-Zero Age' COM(2023) 62 final. On regulatory arbitrage and intra-EU relocation, see OECD, 'Regions in Industrial Transition' (2023) <https://www.oecd.org/en/publications/regions-in-industrial-transition-2023_5604c2ab-en.html> accessed 15 September 2025.

[48] Thieffry (n 43) 589–612.

[49] Regulation (EU) 1025/2012 on European standardisation encourages alignment with international standards, including those developed by ISO and CEN. However, Regulation (EU) 2024/1781 does not incorporate explicit cross-references to ISO 14006 (ecodesign), ISO 20400 (sustainable procurement), or the CEN/TC 350 standards on sustainability in construction. Articles 10 and 13 refer broadly to life-cycle criteria and conformity requirements, but lack operational guidance on harmonisation. This omission may hinder consistency across certification schemes and obstruct the mutual recognition of compliance tools, especially in sectors already regulated by technical standards. It also raises concerns about legal certainty for manufacturers operating within international supply chains.

products, Directive 2009/125/EC already sets binding ecodesign requirements, yet its relationship with the Regulation's criteria remains legally undefined.

To avoid fragmentation, dynamic technical annexes should explicitly refer to harmonised standards and internationally recognised norms. This technique, already employed in the regulation of chemical products under the CLP Regulation (EC) No 1272/2008 and in product energy-labelling rules, reduces regulatory burdens and enhances legal certainty. Additionally, producers should be allowed to demonstrate compliance with the Regulation's requirements through equivalent certifications issued by bodies accredited under ISO/IEC 17065[50].

2.4 Barriers to technological innovation

Sustainability and technological innovation are, in theory, complementary concepts. However, Regulation (EU) 2024/1781 imposes requirements that may, in practice, act as barriers to the development of emerging or disruptive technologies[51]. By enforcing uniform criteria for durability, reparability, and recyclability without accounting for the specificities of frontier technologies[52], the Regulation creates a legal environment that discourages experimentation[53] and restricts industrial design freedom.

This problem is particularly pronounced in highly competitive sectors such as consumer electronics and automotive manufacturing, where innovation cycles are short and design decisions are driven more by technological obsolescence than by functional deficiency. In such contexts, the obligation to ensure the availability of spare parts for a minimum number of years becomes a disproportionate burden for products whose competitive value lies in their capacity to integrate continuous improvements.

Moreover, applying these criteria to pre-commercial or prototype-phase products—such as those based on artificial intelligence, advanced robotics, or nanotechnology—may

[50] The absence of normative interoperability risks fragmenting the internal market, penalising early adopters, and weakening the EU's regulatory influence abroad. Without dynamic annexes and equivalence mechanisms, divergent compliance models may foster intra-EU relocation, distort competition, and reduce the credibility of EU green standards in global trade negotiations and supply chain governance.

[51] Jolanta Rzepecka, Anna Fuksiewicz, Federica Squillante and others, 'The Impact of EU Legislation in the Area of Digital and Green Transition, particularly on SMEs' (2024) PE 754.213, European Parliament <https://www.europarl.europa.eu/RegData/etudes/STUD/2024/754213/IPOL_STU(2024)754213_EN.pdf> accessed 15 September 2025.

[52] Frontier technologies refer to advanced, rapidly evolving innovations with the potential to disrupt existing systems and generate significant economic, social, or environmental impact. According to UNCTAD, 'Technology and Innovation Report 2021', these include artificial intelligence, robotics, nanotechnology, and biotechnology. In the EU context, the Horizon Europe programme classifies these as "high-risk/high-reward" technologies requiring flexible regulatory frameworks and early-stage testing environments. Regulation (EU) 2024/1781 does not currently provide tailored provisions for such technologies, raising concerns about overregulation and delayed market access.

[53] The concept of "regulatory paralysis" has been analysed by the OECD in 'Overcoming Barriers to SME Participation in Sustainability Policy' (2021), which notes that excessive or poorly calibrated regulatory frameworks can delay innovation by diverting resources from research and development to compliance. The European Court of Auditors similarly warned of such effects in 'Special Report 14/2020' on energy efficiency, highlighting risks of innovation stagnation caused by legal uncertainty.

impede market entry for high-impact environmental innovations, simply because they do not comply with parameters conceived for standardised consumer goods.

From the perspective of Union law, this conflict clashes with the principles of proportionality and innovation as recognised in Article 114 TFEU and further developed in the case law of the Court of Justice of the European Union. In Vodafone and Others (Case C-58/08), the Court reiterated that legislative intervention must strike a balance between objectives of general interest and the need to avoid hindering technological development and the free movement of goods[54].

A plausible solution would be to incorporate flexibility clauses into the Regulation, similar to those provided under Regulation (EU) 305/2011 on construction products, which allow for the issuance of European Technical Assessments for innovative products that do not conform to harmonised standards. In addition, "regulatory sandboxes" could be established for emerging green technologies, following the model recently implemented by the Commission in the field of sustainable digital financial products.

2.5 Disconnection between regulation and green fiscal policy

One of the most widely criticised aspects of Regulation (EU) 2024/1781 is its lack of alignment with the fiscal and financial instruments that should support the transition to ecodesign. Sustainability, understood as a structural transformation of the production model, cannot rely solely on regulatory obligations without adequate backing in the form of economic incentives, accessible financing, and competitive advantages.

Ecological design requires significant upfront investment in R&D, product redesign, material substitution, and the transformation of industrial processes. However, the Regulation remains silent on potential support mechanisms, creating a "sunk-cost"[55] scenario for producers seeking to anticipate future regulatory demands. This omission stands in contrast to other EU initiatives, such as the European Green Deal or the Green Deal Investment Plan, which do provide for specific financial instruments, including the Innovation Fund and the Just Transition Mechanism.

The lack of coordination between technical regulation and green taxation also produces adverse effects: more sustainable yet more expensive products may be penalised in the

[54] Article 114 TFEU underpins the internal market and requires that harmonisation measures respect the principles of proportionality and innovation. In C-58/08 Vodafone and Others [2010] ECLI:EU:C:2010:321, the Court of Justice of the European Union held that EU legislation must not disproportionately restrict technological progress or distort the free movement of goods. The Vodafone judgment illustrates how Article 114 TFEU operates as both an enabling and limiting provision: it allows EU harmonisation to address new market realities, while requiring that such measures avoid undue restrictions on innovation. The Court confirmed that harmonisation may legitimately pursue objectives beyond market efficiency, provided proportionality is respected. This reasoning reinforces a balance between regulatory intervention and technological progress within the internal market.

[55] In economic terms, a "sunk cost" refers to an investment that cannot be recovered once made. In regulatory contexts, it describes the risk borne by firms that adopt sustainable practices ahead of formal incentives or harmonised requirements. Without financial support, early movers internalise costs that later competitors may avoid, distorting competitive neutrality and slowing innovation diffusion.

market when compared to non-sustainable alternatives, simply due to the absence of tax relief or subsidies. This situation undermines the principle of horizontal coherence[56] in EU law and weakens the effectiveness of the Regulation itself.

It is necessary to integrate the implementation of the Regulation with the State-aid framework authorised by the Commission for the circular economy, in accordance with the Guidelines on State aid for Climate, Environmental Protection and Energy (2022/C 80/01). Furthermore, the development of harmonised fiscal mechanisms should be encouraged, such as ecodesign tax credits or reduced VAT rates for products bearing a digital product passport, as foreseen in Directive 2022/542/EU.

2.6 Proposal for sector-specific soft law frameworks

Given the difficulty of establishing binding criteria that are equally effective across all sectors, a viable alternative lies in the development of sector-specific soft law instruments. These could take the form of guidelines, codes of practice or technical verification protocols developed jointly by the European Commission, sectoral agencies (such as ECHA, EFSA or ENISA), and representatives of private industry[57].

The use of soft law has been a recurrent feature in the development of Union law, particularly in areas such as competition, public procurement and banking regulation. Its advantage lies in its flexibility to adapt to evolving technical realities and its capacity to build regulatory consensus without the need for lengthy or rigid legislative procedures. In the context of ecodesign, such instruments would provide "authoritative interpretations"[58] on how to apply the Regulation's criteria to specific products, including household appliances, technical textiles, hybrid vehicles or complex packaging[59].

[56] The horizontal coherence principle requires EU policies and legal instruments to function consistently across sectors and objectives. While not codified explicitly, it derives from Articles 7 and 11 TFEU, mandating integration of environmental and sustainability considerations in all Union policies. The principle has been affirmed by the Court of Justice in C-379/98 PreussenElektra [2001] ECLI:EU:C:2001:160 and by the European Court of Auditors in Special Report 21/2022 on policy coherence for sustainable development. See Paul Craig and Gráinne de Búrca, *EU Law: Text, Cases, and Materials* (8th edn, Oxford University Press 2024). In PreussenElektra, the CJEU upheld German renewable energy support schemes against internal market challenges, recognising environmental protection as a legitimate Union objective. The judgment illustrates how sustainability can justify regulatory intervention even where it affects competition or free movement. By affirming the integration of environmental aims, the Court gave early substance to the horizontal coherence principle. This line of reasoning directly anticipates the logic of Regulation (EU) 2024/1781, where sustainability permeates market harmonisation.

[57] The European Union frequently relies on soft law instruments to provide technical clarity and sectoral adaptation, particularly where harmonised rules are unavailable. Examples include the EU Guidelines on State aid for environmental protection and energy (2022/C 80/01), the ECHA Guidance on REACH and CLP, and ENISA's cybersecurity recommendations. Though non-binding, these instruments play a key role in consistent implementation, legal interpretation, and reducing regulatory uncertainty across Member States. Their legitimacy is grounded in Article 292 TFEU and frequent endorsement by specialised EU agencies and expert groups.

[58] Sasha Garben, *Soft Law in the European Union: the Changing Landscape of Governance* (Hart Publishing 2021).

[59] In environmental and product regulation, soft law instruments often serve as de facto interpretative standards. The 2012 Commission Recommendation on common methods for measuring and communicating environmental performance of products (2013/179/EU) and the Product Environmental Footprint (PEF) guidelines exemplify such use. These tools, while not legally binding, have guided conformity assessment and market practices. In ecodesign, similar instruments could bridge regulatory gaps until delegated acts under Article 16 of Regulation (EU) 2024/1781 are adopted.

In addition, the development of sectoral soft law would help address the regulatory vacuum left by the absence of delegated and implementing acts, as foreseen under Article 16 Regulation, which has not yet been adopted. In this regard, the Commission could rely on the Technical Committees of CEN/CENELEC to elaborate dynamic technical annexes and periodically revise sustainability requirements in line with technological developments and emerging industrial practices.

These frameworks should not replace binding legislation but should instead act as interpretative complements that enhance uniform application, legal certainty and reduce compliance costs. Ultimately, they would contribute to a more comprehensive, adaptable and functional legal architecture for the Regulation, without compromising its ecological ambition or its coherence with the Union acquis.

3 Impact on Small and Medium-Sized Enterprises (SMEs)

3.1 Introduction: structural vulnerability of SMEs in the ecological transition

The application of Regulation (EU) 2024/1781 on ecodesign requirements for sustainable products gives rise to a series of regulatory tensions that particularly affect small and medium-sized enterprises (SMEs)[60]. Although the legislative text employs a rhetoric of universality and neutrality, its implementation reveals deep structural disparities in compliance capacity between large corporations and smaller economic operators. This regulatory inequality, which may be viewed as an unintended externality of the greening of the internal market, reproduces patterns of economic exclusion that contradict foundational principles of Union law[61].

From a European constitutional perspective, the impact of this Regulation on SMEs must be assessed in light of the principle of proportionality (Article 5 TEU), the principle of equality in competition, and the mandate for economic, social and territorial cohesion set out in Article 174 TFEU. The obligations imposed by Regulation (EU) 2024/1781 — particularly those related to the digital product passport, compliance with reparability and recyclability criteria, and material traceability — entail upfront investments in digital infrastructure, advanced technical knowledge, and redesign of production processes, which often exceed the technical and financial absorption capacity of SMEs[62].

[60] Jolanta Rzepecka and others (n 1) 81–91, 13–32.

[61] Article 3 TEU establishes the Union's objective of promoting a highly competitive social market economy aimed at full employment and social progress, encompassing distributive justice in market regulation. SMEs, which represent the backbone of this economy, are supported through various European Commission communications and strategies, including European Commission, SME Strategy for a Sustainable and Digital Europe, COM(2021) 350 final.

[62] Regulation (EU) 2016/679 (GDPR) explicitly calibrates obligations according to the scale and nature of data controllers (see recital 13 and article 30(5)), contrasting with Regulation (EU) 2024/1781's one-size-fits-all approach. This raises proportionality concerns as developed by the CJEU in Case C-58/08 Vodafone and Others [2010] ECLI:EU:C:2010:321. The Vodafone judgment provides an instructive contrast for assessing Regulation (EU) 2024/1781. In C-58/08, the CJEU upheld EU harmonisation under Article 114 TFEU but stressed that such measures must be proportionate and avoid

Recital 45 of the Regulation refers generically to the need to avoid unnecessary regulatory burdens, yet this recognition has not translated into an operative legal clause, nor into concrete mechanisms of modulation, exemption or progressive implementation. In this regard, the legal text lacks the technical tools necessary to give effect to the principle of proportionality in its economic dimension. Unlike Regulation (EU) 2016/679 on General Data Protection, where the size and nature of the data controller are decisive in determining applicable obligations, the Ecodesign Regulation imposes a uniform standard that disregards business heterogeneity.

Specialised academic literature has warned of this phenomenon, framing it within what has been termed "structural regulatory asymmetry"[63]. In this context, it should be acknowledged that large corporations possess greater compliance capacity and may convert regulatory demands into indirect entry barriers, consolidating market positions through compliance strategies that exclude less resilient competitors[64]. This dynamic has been highlighted in recent reports by the EPRS and the OECD, which highlight how undifferentiated sustainability frameworks tend to concentrate green innovation within large conglomerates, thereby marginalising thousands of smaller operators with transformative potential[65].

At the institutional level, the lack of effective consultation with SME representatives during the drafting process of the Regulation reveal a shortcoming in the participatory-governance model. In other contexts, the European Commission has promoted mechanisms such as the SME Test and the Fit for Future Platform, specifically designed to ensure that new regulations are compatible with the operational reality of SMEs. However, these mechanisms were not consistently applied during the development of Regulation (EU) 2024/1781, raising concerns about the procedural legitimacy of the instrument in relation to the "Think Small First" principle enshrined in the Small Business Act for Europe (COM(2008) 394 final)[66].

imposing excessive constraints on technological development or market freedoms. By comparison, the GDPR embodies this principle through differentiated obligations tailored to the size and risk profile of data controllers, thereby operationalising proportionality. Regulation (EU) 2024/1781, by contrast, adopts a uniform compliance model, raising questions as to whether it sufficiently respects proportionality in light of the burdens it may impose on SMEs and innovative operators. This juxtaposition highlights the tension between effective sustainability regulation and the CJEU's demand that harmonisation balance regulatory objectives with innovation and market access.

[63] Article 5 TEU and Article 174 TFEU impose duties of proportionality and territorial cohesion requiring internal market measures to account for economic disparities among undertakings. The lack of modulated ecodesign obligations risks creating structural asymmetries, undermining the level playing field principle under Article 114 TFEU. See, e.g., European Commission, 'Annual Report on European SMEs' (2022/2023). See Jolanta Rzepecka and others (n 1) 83–84.

[64] The concept of "compliance capitalism" describes how regulatory burdens become strategic assets for dominant firms, effectively raising barriers to market entry. See S Deakin, 'The Legal Construction of the Firm' (2016) 45 Industrial Law Journal 1, 1–29.

[65] The European Parliamentary Research Service has highlighted that SMEs often lack technical and legal capacity to implement new ecodesign criteria, limiting innovation and reinforcing market concentration. See European Parliamentary Research Service, 'The Role of SMEs in the EU's Green Transition' (Briefing PE 698.859, 2022); OECD, 'SMEs in the Green Transition: Policy Highlights' (2021).

[66] The SME Test, part of the Better Regulation Toolbox (Tool 22), assesses EU policy impacts on small businesses in line with the 'Think Small First' principle in the Small Business Act (COM(2008) 394 final). The Fit for Future Platform

From a comparative perspective, other legal systems have developed regulatory models that are more attuned to the limitations of small businesses. For instance, U.S. federal environmental legislation includes systematic reviews of the impact on small entities through the Regulatory Flexibility Act. Similarly, countries such as Germany and Denmark have incorporated partial exemptions or transitional regimes within complex technical regulations, allowing SMEs to gradually adapt to new requirements without compromising their economic viability[67].

The absence of an adaptive implementation architecture in Regulation (EU) 2024/1781 places many European SMEs at a strategic crossroads: either to incur excessive transformation costs that jeopardise their stability, or scale down their operations, outsource parts of the production process or exit the market altogether. This scenario entails economic, ecological and social consequences, as it reduces production diversity, weakens the resilience of local supply chains, and fosters the oligopolistic consolidation of certain industrial sectors.

3.2 Disproportionate burdens and lack of regulatory adaptation

One of the most critical aspects in the implementation of Regulation (EU) 2024/1781 is the uniform and undifferentiated nature of its obligations, which fail to distinguish between large corporations and small and medium-sized enterprises. This replicates a regulatory model that disregards any perspective of distributive justice in regulation. The absence of legal modulation imposes a disproportionate burden on SMEs by subjecting them to technical, documentary and logistical requirements that many cannot fulfil without jeopardising their operational continuity.

In practical terms, compliance with the Regulation's requirements entails a profound transformation of production processes, including the redesign of products in accordance with circularity criteria, the implementation of digital traceability systems, the collection of life-cycle data, and integration into the Digital Product Passport database. These requirements[68], which may represent a strategic reconfiguration for a multinational enterprise, constitute an almost insurmountable compliance barrier for many SMEs.

The direct costs associated with this transformation include the acquisition of specialised software, the hiring of technical and legal consultancy services, staff training,

(Commission Decision (EU) 2020/2103) supports simplification but had limited integration into Regulation (EU) 2024/1781's design.

[67] The US Regulatory Flexibility Act (5 U.S.C. §§ 601–612) requires federal agencies to assess the impact of regulations on small entities and consider less burdensome alternatives. EU Member States such as Germany and Denmark implement SME-friendly transposition measures, including phased compliance and simplified obligations. See OECD, 'Better Regulation Practices across the EU' (2020); European Commission, 'Annual Report on European SMEs' (2022/2023).

[68] The principle of proportionality, enshrined in Article 5(4) Treaty on European Union (TEU), requires that EU measures do not exceed what is necessary to achieve their objectives. Regulation (EU) 2016/679 (General Data Protection Regulation) exempts microenterprises from certain documentation duties (Recital 13; Article 30(5)), exemplifying a differentiated application of obligations. Regulation (EU) 2024/1781, by contrast, applies a uniform approach, raising concerns about compliance feasibility and economic discrimination against SMEs.

and, in many cases, the complete restructuring of the supply chain to align with sustainability criteria. Added to these are indirect opportunity costs: resources diverted from innovation, commercial expansion or operational improvement to regulatory compliance management. This dynamic gives rise to a phenomenon of regulatory "crowding out", whereby SMEs are compelled to prioritise administrative survival over business competitiveness[69].

This situation conflicts with the principle of substantive proportionality, as developed by the CJEU in various rulings, including Vodafone (Case C-58/08)[70], where the Court affirmed that the burden imposed by a legal norm must be justified by a genuine need and assessed in light of the specific capacity of the obliged entity. In the present case, the imposition of identical obligations on entities with radically different structures lacks justification grounded in objective criteria of regulatory reasonableness.

Other Union law instruments have introduced mechanisms to modulate regulatory burdens according to the size or capacity of the operator. Regulation (EU) 2022/2554 on digital operational resilience in the financial sector, the Digital Operational Regualtion (DORA), for instance, provides a more flexible regime for micro-enterprises, allowing for gradual implementation of its requirements. In the environmental field, Directive 2012/27/EU on energy efficiency, permits Member States to establish thresholds for exemptions applicable to small industrial enterprises.

This regulatory asymmetry has also been addressed from the perspective of industrial policy. The Industrial Strategy for Europe (COM(2020) 102 final) explicitly acknowledges that SMEs should receive tailored treatment in the design of green policies, given their structural vulnerabilities and key role in local economies. However, these strategic guidelines have not been concretely reflected in the legal structure of Regulation (EU) 2024/1781[71], revealing a disconnect between strategic policy formulation and legislative output[72].

The problem becomes more acute when considering the interaction between the Regulation and other legal instruments such as the CSRD Directive and the proposed CSDDD Directive, which also impose reporting, due diligence, and supply chain oversight

[69] Regulatory "crowding out" occurs when compliance costs absorb resources otherwise investable in innovation and growth. This effect is documented in OECD, 'SME and Entrepreneurship Outlook' (2023) and European Commission, 'Annual Report on European SMEs' (2022/2023), identifying compliance costs as major barriers in the green transition.
[70] The CJEU affirmed in Vodafone and Others (C-58/08) [2010] ECLI:EU:C:2010:321 that EU legislation must comply with proportionality, especially when obligations unevenly affect operators. Obligations must be appropriate and consider the capacity of subjects. This principle is echoed in recital 9 of GDPR and the Commission's Better Regulation Guidelines (SWD(2021) 305 final). This requirement contrasts with Regulation (EU) 2024/1781, which applies uniform product obligations without sufficient differentiation for SMEs or sectoral capacities. Such an approach risks undermining innovation and competitiveness, raising doubts about its alignment with the proportionality standard articulated in Vodafone.
[71] Susana Borrás and Jakob Edler (eds), The Governance of Socio-Technical Systems: Explaining Change (Edward Elgar 2014).
[72] Case C-343/09, *Afton Chemical* [2010] ECLI:EU:C:2010:419; Case C-293/97, *R v Secretary of State for the Environment, ex parte Standley* [1999] ECLI:EU:C:1999:193. These judgments affirm the necessity of respecting the principle of proportionality and permit the modulation of regulatory obligations according to the operator's capacity.

obligations[73]. The accumulation of requirements, without inter-instrument coordination mechanisms or simplification clauses for SMEs, generates regulatory saturation that may lead to the effective exclusion of thousands of businesses from the ecological transition process[74].

Moreover, the lack of technical and methodological support measures from public authorities prevents SMEs from accessing standardised tools to facilitate compliance. The absence of specific sectoral guidelines[75], simplified digital platforms or voluntary declaration templates obstructs the realisation of the principles of "accessible compliance" and "reasonable transparency" as viable practices[76] for this business segment.

3.3 Comparison with other European and international regulatory models

The lack of differentiated mechanisms in Regulation (EU) 2024/1781 stands in stark contrast to more nuanced regulatory experiences, both within and outside the European Union. In this regard, legal and public policy comparison is essential, not only to highlight the overly uniform character of the model adopted, but also to identify replicable solutions that could enrich its architecture and enhance its systemic legitimacy.

One of the most robust references for differentiated regulatory integration based on company size is the United States framework for assessing regulatory impacts on small businesses, established by the Regulatory Flexibility Act (RFA) of 1980 and subsequently strengthened by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996[77]. This legislation obliges federal agencies to conduct early-stage assessments of how proposed rules will affect small businesses, including the requirement to publish an Initial Regulatory Flexibility Analysis (IRFA) and in certain cases to consult with sector-specific small business advisory panels. This preventive logic reduces the risk of generating regulatory asymmetries and promotes a culture of inclusive rulemaking from the outset[78].

In the European context, instruments such as Directive 2011/83/EU on consumer rights provide simplified regimes for operators who do not engage in distance selling or mass

[73] Beate Sjåfjell and Christopher M Bruner (eds), *The Cambridge Handbook of Corporate Law, Corporate Governance and Sustainability* (CUP 2019).
[74] Directive (EU) 2022/2464 on corporate sustainability reporting (CSRD); Proposal for a Directive on Corporate Sustainability Due Diligence (CSDDD), COM(2022) 71 final. These instruments impose progressive obligations based on company size, although with few exemptions for SMEs, thereby increasing complexity and administrative duplication with Regulation (EU) 2024/1781.
[75] Giacinto Della Cananea, Jean-Bernard Auby (eds), *General Principles and Sector-Specific Rules in European Administrative Laws* (Oxford University Press 2024).
[76] European Commission, Better Regulation Toolbox, Tool 23; OECD, SME and Entrepreneurship Outlook 2023. Tailored support for SMEs is recommended to ensure proportional implementation and facilitate participation in sustainability frameworks.
[77] Cary Coglianese, *Achieving Regulatory Excellence* (Brookings Institution Press 2017).
[78] The Regulatory Flexibility Act, 5 U.S.C. §§ 601–612 (1980), strengthened by the Small Business Regulatory Enforcement Fairness Act (SBREFA) (1996), establishes the assessment of regulatory impact on small entities and incorporates judicial review and review panels to ensure proportionality in regulatory drafting.

marketing techniques[79]. The REACH Regulation (EC) No 1907/2006, despite its technical complexity, allows for staggered compliance based on the tonnage of chemical substances handled by operators, indirectly benefiting many micro-enterprises in the chemical and cosmetics sectors. Similarly, the Unfair Commercial Practices Directive (2005/29/EC) has served as a basis for simplified protection mechanisms for small businesses facing unfair contract terms in B2B relationships[80].

Several national legal systems offer more SME-sensitive regulatory models. In Germany, the Act to Improve Regulatory Impact Assessment requires justification for any additional burden imposed on small businesses, grounded in the principle of proportionality. France's PACTE Act establishes exemption thresholds for certain accounting and environmental obligations applicable to micro-enterprises. Denmark has established a Business Regulation Assessment Council that conducts *ex ante* reviews of proposed legislation to evaluate its administrative impact on SMEs[81].

By contrast, Regulation (EU) 2024/1781 applies a uniform compliance model, without differentiation based on company size, turnover or economic sector. This rigidity penalises the structural diversity of the internal market and disregards longstanding recommendations from the European Economic and Social Committee, which has consistently called for substantive proportionality tailored to actual operational capacities.

Even within the EU legal framework, more inclusive precedents exist. Regulation (EU) 2021/1056 establishing the Just Transition Fund sets differentiated eligibility criteria for SMEs in regions vulnerable to ecological transition. The European Commission's Communication COM(2021) 350 final, outlining the SME Strategy for a Sustainable and Digital Europe[82], explicitly prioritises the integration of sustainability without compromising operational viability.

Regulation (EU) 2024/1781, however, remains anchored in a one-size-fits-all logic. A structural revision is therefore urgently needed—one that incorporates modulation clauses, phased compliance regimes, and simplified procedures. Only through such reforms can the ecological transition become truly fair, inclusive and capable of activating the full transformative potential of the European economic ecosystem—not merely its most consolidated actors.

[79] Lee (n 1).
[80] Directive 2011/83/EU, arts 3(3) and 6; Regulation (EC) No 1907/2006 (REACH), art 23; Directive 2005/29/EC; and Commission Staff Working Document SWD(2020) 163 final, provide for exemptions or phased compliance measures that facilitate SMEs' conformity and enhance protection against unfair practices in B2B contracts.
[81] Germany, Gesetz zur Verbesserung der Rechtsetzung (2000); France, Loi PACTE n° 2019-486, art 55; Denmark, Business Regulation Assessment Council (Erhvervsreguleringsrådet) (2017). These legal frameworks establish ex ante obligations to assess regulatory impact on small businesses, promoting proportionality and administrative simplification.
[82] Andrea Biondi, Piet Eeckhout and Stefanie Ripley (eds), *EU Law After Lisbon* (Oxford University Press 2012).

3.4 Barriers to Accessing Finance and Incentives

One of the most decisive factors exacerbating the vulnerability of SMEs under Regulation (EU) 2024/1781 is their lack of effective access to financing instruments tailored to their structural characteristics. Compliance with the regulation requires significant upfront investment in clean technologies, product redesign, digital traceability systems, and specialised training. For many SMEs, these costs represent an structuraly phohibitive entry barrier[83],particularly in contexts of limited liquidity, restricted access to credit and minimal financial leverage.

Although the European Union has developed various programmes to support sustainable innovation—such as Horizon Europe, the Innovation Fund, InvestEU and the Just Transition Mechanism[84]— most of these instruments pose technical and procedural barriers that limit SME participation. Competitive calls based on scalable impact, excellence in innovation, and consortium-based structures[85] often exclude smaller firms that lack dedicated technical staff or experience in complex EU applications.

From a normative perspective, Regulation (EU) 2024/1781 fails to include any explicit linkage to existing financial support mechanisms or to introduce compensatory measures aligned with enterprise size and capacity. It also lacks cross-references to Regulation (EU) 2021/523 establishing InvestEU, despite its stated objective of facilitating the green transition for SMEs[86]. In comparative terms, this disconnect becomes more pronounced when contrasted with national frameworks such as France's tax credits for ecodesign investment, and Germany's KfW public financing for sustainable technologies in medium-sized businesses[87].

The absence of a supportive financial infrastructure undermines the material equity principle enshrined in Article 3 TEU and conflicts with the broader goals of territorial cohesion and social justice within the single market[88]. Without accessible financial support[89], regulatory compliance ceases to function as a lever for transformation and instead becomes a vector of exclusion. Reframing the Regulation with a financial

[83] Danny Busch, Emilios Avgouleas and Guido Ferrarini (eds), *Capital Markets Union in Europe* (Oxford University Press 2018).
[84] Regulation (EU) 2021/695 establishing Horizon Europe; Commission Implementing Regulation (EU) 2020/1001 establishing the Innovation Fund under the EU Emissions Trading System; Regulation (EU) 2021/523 establishing InvestEU. See European Court of Auditors, 'Special Report 02/2023: EU Support to SMEs in the Green Transition' (2023); European Investment Bank, 'EIB Investment Survey 2023'; European Commission, COM(2021) 372 final.
[85] Veerle Heyvaert, *Transnational Environmental Regulation and Governance: Purpose, Strategies and Principles* (Cambridge University Press 2018).
[86] Niamh Moloney, *EU Securities and Financial Markets Regulation* (4th edn, Oxford University Press 2023).
[87] French General Tax Code, Article 244 quater B; KfW Mittelstandsbank, 'Energieeffizienzprogramm' and 'Umweltprogramm'; see European Commission, 'SME Green Compliance Incentives in EU Member States' (2022).
[88] Treaty on European Union (TEU) art 3; Treaty on the Functioning of the European Union (TFEU) arts 174–178; Regulation (EU) 2021/523 arts 3, 7 and Annex II; Regulation (EU) 2021/1056 on the Just Transition Fund; European Commission, COM(2021) 350 final ('SME Strategy for a Sustainable and Digital Europe').
[89] Sacha Garben and Inge Govaere (eds), *The Division of Competences between the EU and the Member States: Reflections on the Past, the Present and the Future* (Hart Publishing 2017).

dimension is not merely advisable — it is essential for its normative effectiveness and social legitimacy.

3.5 Impact on Local Innovation and Regional Productive Ecosystems

The impact of Regulation (EU) 2024/1781 on SMEs must not be assessed solely through the lens of compliance costs. Its structural consequences on local innovation capacity and regional productive ecosystems—critical components of the European economy—are equally significant[90]. Innovation does not occur exclusively within major research centres or multinational corporations; it also emerges from territorially rooted SME networks that develop decentralised, adaptive and sustainable solutions.

The Regulation's one-size-fits-all architecture risks triggering innovation stagnation among SMEs. These firms often operate in low-margin sectors, rely on tacit knowledge, or engage in incremental innovation and inter-firm cooperation. Excessively rigid requirements may deter technical investment, redirect resources toward procedural compliance, and lead to "regulatory paralysis", where uncertainty discourages experimentation.

Sectors dependent on manual labour, traditional knowledge or short production chains—such as artisanal manufacturing[91], local agroindustry or light industrial clusters—are particularly vulnerable. Regulation (EU) 2024/1781 imposes universal technical standards without accounting for cultural, regional, or sectoral specificities, threatening the viability of diverse economic sectors essential to Europe's plural productive fabric.

The territorial[92] consequences may be severe. Peripheral and rural regions rely heavily on SMEs for employment, innovation, and sustainable practices. Misaligned regulation could accelerate business closures and regional decline, exacerbating centre-periphery imbalances and contradicting Article 174 TFEU, which upholds territorial cohesion[93].

The qualitative impact on innovation is equally troubling. By concentrating adaptability in large operators, the Regulation risks homogenising[94] innovation and eroding localised, context-sensitive approaches. Many key advances in circular economy models have

[90] Annalisa Savaresi, 'Rights-based litigation in the climate emergency' (2022) 13(1)Journal of Human Rights and the Environment 7.
[91] Katharina Pistor, *The Code of Capital: How the Law Creates Wealth and Inequality* (Princeton University Press 2019).
[92] Giuliano Amato, Enzo Moavero-Milanesi, Gianfranco Pasquino and Lucrezia Reichlin (eds), *The History of the European Union: Constructing Utopia* (Hart Publishing 2019).
[93] Treaty on the Functioning of the European Union (TFEU) art 174; European Commission, COM(2017) 583 final; Case C-491/01, *Berlusconi and Others* [2003] ECLI:EU:C:2003:567. In Berlusconi and Others (C-491/01), the CJEU emphasised that the principles of legality and proportionality require sanctions to be clear, foreseeable, and not retroactive to the detriment of the accused. Applied to Regulation (EU) 2024/1781, this reasoning implies that penalties for non-compliance with ecodesign and digital product passport obligations must be transparent and proportionate. The parallel demonstrates that, as in criminal law, legal certainty is a prerequisite for regulatory effectiveness. Read together with Article 174 TFEU, which enshrines economic, social, and territorial cohesion, this suggests that sustainability regulation must calibrate sanctions so as not to impose disproportionate burdens on less competitive regions or smaller operators.
[94] Joseph Stiglitz and Bruce Greenwald, *Creating a Learning Society: A New Approach to Growth, Development, and Social Progress* (Columbia UP 2014).

emerged from agile SMEs and cooperatives. If regulatory frameworks penalise such flexibility, a key engine of transformative innovation is lost.

This tension signals a breach of the EU principle of internal coherence. As developed by the CJEU in *Vodafone* (Case C-58/08), measures must pursue their objectives without generating self-defeating effects[95]. Some scholars advocate the introduction of experimental regulatory clauses—such as "regulatory sandboxes"—to allow innovative SMEs to comply through tailored pathways[96]. Others propose decentralised implementation through agreements between the Commission, Member States, and regions, enabling the development of technically equivalent standards adapted to local realities[97].

True sustainability[98] requires legal frameworks that nurture, rather than suppress, innovation at the margins. Supporting local resilience, diversity, and bottom-up innovation must be a cornerstone of effective ecodesign regulation.

3.6 Regulatory Proposals for the Effective Inclusion of SMEs in European Ecodesign

Revising the architecture of Regulation (EU) 2024/1781 to incorporate SME-specific provisions is not merely a matter of distributive fairness but rather a structural requirement for the viability of Europe's green transition. SMEs account for over two-thirds of private employment and play a crucial role in key sustainability sectors such as construction, recycling, agroindustry, urban mobility and light manufacturing. A regulatory framework that overlooks their centrality risks implementation failure.

A first step would be to introduce a tiered compliance regime based on company size, turnover or sector. This would allow for proportional obligations, as successfully implemented under Regulation (EU) 2016/679 (General Data Protection Regulation - GDPR[99]). By adapting the intensity of regulatory requirements, the burden on less capitalised firms could be reduced without diluting the core sustainability objectives.

Another vital mechanism involves temporary exemptions or deferred application for SMEs facing regional or sector-specific vulnerabilities. Similar transitional regimes[100] exist in EU legislation on industrial emissions and single-use plastics[101]. These tools offer firms the time needed to adapt without immediate exclusion from the market.

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[95] Case C-58/08 *Vodafone and Others* [2010] ECLI:EU:C:2010:321; see also P Craig and G de Búrca, EU Law: Text, Cases, and Materials (7th edn, OUP 2020) 85–90.
[96] European Commission, COM(2020) 103 final ('Digital Finance Strategy'); European Commission Joint Research Centre, '*Testing the Future: Regulatory Sandboxes for Sustainable Innovation*' (2022).
[97] Regulation (EU) 2021/1060 on Common Provisions for Cohesion Policy; see European Commission, 'Guidance on Partnership Agreements and Programmes' (2022).
[98] Benjamin J Richardson, *Time and Environmental Law: Telling Nature's Time* (Cambridge University Press 2017).
[99] Regulation (EU) 2016/679 (General Data Protection Regulation) art 30(5), recital 13. See Orla Lynskey, *The Foundations of EU Data Protection Law* (Oxford University Press 2015).
[100] Lee (n 1).
[101] Directive 2010/75/EU on industrial emissions art 64; Directive (EU) 2019/904 on single-use plastics.

Sector-specific delegated acts, authorised by Article 290 TFEU[102], would also enhance regulatory precision. These could tailor ecodesign obligations to productive contexts dominated by SMEs—such as small-scale agro-processing, artisanal manufacturing or microelectronics workshops—ensuring feasibility without sacrificing ambition.

Institutional innovation is equally essential. A permanent European platform for structured dialogue[103] between SMEs, regulators and standardisation bodies (e.g. CEN/CENELEC)[104] would enable anticipatory governance and harmonised interpretative guidance, while supporting legal certainty and coherence.

Technical support instruments[105] are another priority: compliance manuals, diagnostic software, simplified sustainability templates, and stepwise certification schemes should be developed and deployed through local actors—chambers of commerce, regional innovation centres, and development agencies[106]—explicitly recognised in the Regulation.

Finally, economic incentives[107] must accompany legal obligations. Tax credits for ecodesign investment, public guarantees for green loans and bonus points in public procurement could align regulatory compliance with competitive advantage, replicating successful models from national environmental policies[108].

These proposals do not weaken the Regulation's aims; they reinforce them through inclusion, operational realism and economic resilience. SMEs are not marginal actors; they are the operational core of Europe's green industrial future and must be treated accordingly in policy and regulatory design.

4 Challenges of Harmonisation with Existing Legislation

The introduction of Regulation (EU) 2024/1781 on sustainable product design into the EU's legal framework has triggered a series of systemic frictions. These challenges do not stem merely from formal inconsistencies between texts, but from functional overlaps among legislative instruments pursuing similar sustainability objectives while operating under different technical, temporal and administrative logics. The resulting misalignments[109] risk undermining the Regulation's effectiveness, legal clarity, and institutional legitimacy.

A primary area of conflict[110] arises with Directive 2009/125/EC on ecodesign for energy-related products. While the new Regulation seeks to broaden the scope of sustainable

[102] Treaty on the Functioning of the European Union (TFEU) art 290; Regulation (EU) 2017/1369 on energy labelling.
[103] Gráinne de Búrca and Joanne Scott (eds), *Law and New Governance in the EU and the US* (Hart Publishing 2006.
[104] European Circular Economy Stakeholder Platform; European Economic and Social Committee; EU Industrial Forum.
[105] OECD, 'SME and Entrepreneurship Outlook 2023' (OECD Publishing 2023).
[106] Regulation (EU) 2021/1056 arts 7–8; Regulation (EU) 2021/1060 Art 8.
[107] Benjamin J Richardson and Stepan Wood (eds), *Environmental Law for Sustainability: A Reader* (Hart Publishing 2006).
[108] Italian Budget Law 2017 (super-deduction scheme); French General Tax Code art 244 quater B; EU Green Public Procurement Criteria.
[109] Craig and Gráinne de Búrca (n 95).
[110] Ludwig Krämer, *EU Environmental Law* (8th edn, Sweet & Maxwell 2015).

design obligations across product categories, it has not formally repealed the earlier Directive, nor has it repealed its implementing measures. This regulatory coexistence creates uncertainty—particularly in sectors such as household appliances—where both instruments contain partially overlapping provisions on durability, labelling and energy efficiency but lack a clear hierarchy or coordination mechanism.

Additional tensions arise in relation to Regulation (EC) No 1907/2006 (REACH)[111], particularly concerning the management of hazardous substances and material traceability. While REACH imposes stringent requirements for the registration and authorisation of chemical, Regulation (EU) 2024/1781 introduces product-level transparency obligations through the Digital Product Passport[112]. The resulting dual compliance burden is compounded by a lack of digital interoperability between the two regimes, leading to administrative inefficiencies and duplicated information flows.

Further complications arise with Directive 2022/2464/EU (CSRD)[113], which mandates corporate-level environmental disclosures, whereas Regulation (EU) 2024/1781 focuses on product-specific metrics[114]. The absence of alignment between methodologies and indicators increases the risk of reporting redundancies and inconsistent data across frameworks.

The proposed Corporate Sustainability Due Diligence Directive (CSDDD)[115] adds another layer of complexity. It mandates human rights and environmental due diligence across value chains[116] but lacks explicit articulation with the ecodesign obligations, despite addressing overlapping material and procedural concerns. Without coordinated implementation, fragmentation between responsibility and design criteria may occur.

From a technical perspective, the Regulation does not yet align with existing harmonised standards issued by bodies such as CEN and CENELEC[117]. This gap[118] diminishes legal certainty and reverses progress made under the presumption-of-conformity principle that has long facilitated technical compliance in the EU internal market.

Conflict also arises with EU waste legislation[119], including the Waste Framework Directive (2008/98/EC), the Packaging Directive (2018/852/EU), and sector-specific rules. Requirements on product end-of-life introduced by Regulation (EU) 2024/1781 sometimes

[111] Maria Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance: GMO Regulation and its Reform' (2015) 21(5) European Law Journal 622.
[112] Regulation (EC) No 1907/2006 (REACH); European Chemicals Agency SCIP database; European Commission SWD(2022) 89 final.
[113] Beate Sjåfjell and Irene Lynch Fannon (eds), *Creating Corporate Sustainability: Gender as an Agent for Change* (Cambridge University Press 2018).
[114] Directive (EU) 2022/2464 on Corporate Sustainability Reporting (CSRD); European Sustainability Reporting Standards (ESRS); Regulation (EU) 2024/1781.
[115] Geert Van Calster and Leonie Reins, *EU Environmental Law* (Edward Elgar Publishing 2017).
[116] Corporate Sustainability Due Diligence Directive (CSDDD), COM(2022) 71 final.
[117] Regulation (EU) 1025/2012 on European standardisation.
[118] Harm Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Hart Publishing 2005).
[119] Nicolas de Sadeleer, *EU Environmental Law and the Internal Market* (Oxford University Press 2014).

contradict or duplicate existing obligations, particularly in recycling processes based on material separation technologies.

Finally, the proliferation of environmental labels[120]—resulting from overlaps with Regulation (EU) 2017/1369, the proposed Green Claims Regulation[121] and other initiatives—risks saturating consumers with uncoordinated information and eroding trust in sustainability communications.

To address these issues, proposals include the creation of a horizontal interpretative framework for all sustainability-related instruments and the establishment of a European Agency for Regulatory Coherence on Sustainability. Such mechanisms could prevent regulatory inflation and ensure that sustainable development becomes a unifying, operational legal principle rather than a fragmented legislative agenda.

5 Supply Chain Responsibilities and the Legal Vacuum

Regulation (EU) 2024/1781 introduces novel challenges concerning legal obligations across supply chains. Article 8 attributes responsibility for compliance with ecodesign requirements to the "economic operator placing the product on the market". While seemingly straightforward, this provision fails to reflect the complexity of contemporary transnational production networks and reveals critical regulatory blind spots[122].

Many products placed on the EU market are assembled through global supply chains involving multiple tiers of subcontractors operating under different legal regimes and degrees of traceability. Assigning full responsibility to the final operator neglects the fragmented[123] nature of production and ignores the lack of control that such operators often have over design specifications, materials or the environmental performance of upstream components. The result is a regulatory model that imposes obligations without recognising actual capacity or influence.

This regulatory gap contrasts with more developed EU instruments that apply shared or cascading responsibilities across value chains[124]. Food safety legislation, the REACH Regulation and the proposed Corporate Sustainability Due Diligence Directive (CSDDD) establish tiered duties of care or joint liability structures[125]. The absence of comparable provisions in Regulation (EU) 2024/1781 generates functional asymmetries, undermining

[120] Hans-W Micklitz (ed), *The Making of Consumer Law and Policy in Europe* (Hart Publishing 2023).
[121] European Commission Proposal for a Regulation on Green Claims, COM(2023) 166 final; Regulation (EU) 2017/1369 on energy labelling.
[122] Mark Gibney, Gamze Erdem Türkelli, Markus Krajewski and Wouter Vandenhole (eds), *The Routledge Handbook on Extraterritorial Human Rights Obligations* (Routledge 2021).
[123] Tseming Yang, Anastasia Telesetsky, Lin Harmon-Walker and Robert V Percival, *Comparative and Global Environmental Law and Policy* (Wolters Kluwer 2019).
[124] ibid.
[125] Regulation (EC) No 1907/2006 (REACH); Regulation (EC) No 178/2002; Corporate Sustainability Due Diligence Directive (CSDDD), COM(2022) 71 final.

compliance and potentially incentivising the outsourcing of high-risk production stages to jurisdictions with weaker environmental safeguards.

Article 10 further exacerbates this asymmetry by requiring economic operators to collect and validate product life-cycle data for the Digital Product Passport, yet providing no clear legal tools to compel cooperation from upstream suppliers[126]. This effectively results in a form of strict liability and thereby exposes operators to penalties despite limited audit capacity or contractual leverage.

From a doctrinal perspective, this binary attribution of responsibility marks a departure from international standards such as the OECD Guidelines for Multinational Enterprises and the UN Guiding Principles on Business and Human Rights, which condition responsibility on control, proximity and leverage[127]. By ignoring these categories, the Regulation imposes a rigid and unrealistic model of accountability.

Moreover, the Regulation fails to interface with existing legal instruments—such as the Unfair Commercial Practices Directive, the Construction Products Regulation, or EU public procurement law—that could have supported risk-sharing clauses[128] or model contracts[129]. The lack of standardised frameworks reduces legal certainty, hinders harmonisation of best practices and weakens the preventive function of environmental regulation.

Finally, the absence of institutional mechanisms for intra-supply chain dispute resolution[130] exacerbates legal uncertainty. Unlike other sectors with specialised arbitration or technical mediation bodies, Regulation (EU) 2024/1781 offers no structured forum for resolving conflicts over data access, compliance failure or verification disputes[131].

Addressing these issues will require a dynamic and differentiated model of legal responsibility[132], one that integrates tiered obligations, contractual tools and cooperative incentives to make ecodesign compliance viable, fair and sustainable across the entire supply chain.

[126] Hannah Buxbaum, 'Transnational Regulatory Litigation' (2006) 46 Virginia Journal of International Law 251.
[127] 'OECD Guidelines for Multinational Enterprises' (2011 Edition); 'United Nations Guiding Principles on Business and Human Rights' (2011).
[128] Christopher J S Hodges, *Law and Corporate Behaviour: Integrating Theories of Regulation, Enforcement, Compliance and Ethics* (Hart Publishing 2015).
[129] Directive 2014/24/EU art 18(2); Regulation (EU) 305/2011 on Construction Products.
[130] Jean-Frédéric Morin and Caroline Brandi, *Trade and the Environment: Drivers and Effects of Environmental Provisions in Trade Agreements* (Earth System Governance Elements, Cambridge University Press 2023, Open Access).
[131] Unlike other areas of EU law that benefit from structured mechanisms for technical dispute resolution—such as the Internal Market Information System (IMI), the SOLVIT network, or the European Consumer Centres (ECC)—Regulation (EU) 2024/1781 does not provide a dedicated institutional framework to resolve supply chain conflicts. This absence creates a gap in horizontal enforcement architecture and may increase the risk of fragmented litigation, especially in cross-border contexts involving digital traceability obligations under Article 10 Regulation.
[132] Sabine Schlacke, Karen Pittel, Markus Fischer and others, 'Rethinking Land in the Anthropocene: From Separation to Integration' (WBGU Report 2020, German Advisory Council on Global Change).

6 Impact on European Industrial Competitiveness

Regulation (EU) 2024/1781 represents a structural shift in the European Union's approach to industrial sustainability. By establishing binding technical requirements for the design, production and marketing of sustainable products, it redefines market access conditions and the very parameters of competitiveness[133] for EU-based industries. While the Regulation offers a pathway toward a resilient, long-term green economy, it also raises critical concerns regarding Europe's global industrial standing—particularly in relation to third countries that maintain less demanding regulatory frameworks or apply no comparable standards[134].

Competitiveness[135] in this context must be conceptually redefined. Historically linked to cost efficiency, productivity, innovation and trade openness, industrial competitiveness now expands to include environmental performance, circularity and traceability. This evolution compels European firms to internalise new layers of economic, administrative and technological costs simply to retain market access. The concern intensifies when these obligations are not mirrored by international competitors, creating a structural asymmetry in the global playing field[136].

Unlike instruments such as the Carbon Border Adjustment Mechanism (CBAM)[137], Regulation (EU) 2024/1781 does not include explicit border adjustment clauses or compensatory mechanisms. The lack of equivalent obligations for imported products allows goods manufactured under looser environmental regimes to enter the EU market under more favourable conditions, thus putting compliant European producers at a disadvantage[138].

Global supply chain dynamics[139] further complicate this scenario. Many EU companies depend on complex networks of non-EU suppliers. The Regulation's requirements for

[133] Panagiotis Delimatsis and Leonie Reins (eds), *Trade and Environmental Law* (Edward Elgar Publishing 2021).
[134] Regulation (EU) 2023/956 establishing the Carbon Border Adjustment Mechanism (CBAM) aims to level the playing field by internalising the carbon cost of imported goods, but Regulation (EU) 2024/1781 lacks equivalent frontier adjustment tools. The absence of such mechanisms exacerbates regulatory asymmetries between EU-based producers and foreign competitors, potentially undermining Article XX GATT, which permits environmental exceptions only under strict non-discrimination conditions. This regulatory gap raises concerns about compatibility of EU sustainability rules with WTO obligations and coherence of the Union's trade-environment interface.
[135] Reinhilde Veugelers, Simone Tagliapietra and Cecilia Trasi, 'Green Industrial Policy in Europe: Past, Present, and Prospects' (2024) 24 Journal of Industry, Competition and Trade 371.
[136] Unlike CBAM (Regulation (EU) 2023/956), which equalises carbon costs for imports in emissions-intensive sectors such as steel, cement and aluminium, Regulation (EU) 2024/1781 lacks environmental equivalence mechanisms applicable to imports. This omission risks undermining the internal market's green level playing field, enabling goods produced under lower environmental standards to enter more favourably and bypassing burdens borne by EU producers. Such asymmetry weakens internal policy coherence and calls into question the normative reach beyond EU borders.
[137] Matthew C Porterfield, 'Border Adjustments for Carbon Taxes, PPMs, and the WTO' (2019) 41 University of Pennsylvania Journal of International Law 1.
[138] The CBAM introduces a transitional regime from 2023 and a definitive phase from 2026, imposing carbon pricing on imports in specific sectors (cement, steel, aluminium, electricity). Unlike Regulation (EU) 2024/1781, CBAM equalises carbon costs between EU and non-EU producers, addressing carbon leakage risks and restoring competitiveness without breaching WTO rules.
[139] Gary Gereffi, *Global Value Chains and Development: Redefining the Contours of 21st Century Capitalism* (Cambridge University Press 2018).

traceability, recyclability, and full life-cycle data[140] may discourage foreign suppliers from engaging with EU firms due to fear of regulatory exposure. This could lead to supply chain fragmentation, increased transaction costs, and delays stemming from the need for certification, auditing or alignment with EU technical standards.

Strategically, this situation threatens to weaken the EU's position in key industrial sectors[141]—automotive, advanced electronics, machinery and chemicals—by incentivising investment relocation, slowing innovation cycles and shrinking global market share in favour of more flexible competitors.

However, the Regulation does not affect all industries equally[142]. Sectors aligned with sustainable innovation—such as certified green products, recyclable materials and eco-construction—may benefit, positioning themselves as global leaders. In contrast, industries with low profit margins or high exposure to global price competition—such as textiles, low-cost electronics or durable consumer goods—may face disproportionate burdens.

Institutional responses[143] should operate on three fronts: (i) strengthening trade defence tools to prevent environmental dumping; (ii) consolidating green industrial policy through targeted funding, technical support and workforce training; and (iii) embedding environmental equivalence and verification clauses into trade agreements[144].

Sustainability and competitiveness[145] must cease to be treated as antagonistic goals. Regulation (EU) 2024/1781 should be coherently implemented alongside cohesion policy, the EU Industrial Strategy, the Innovation Agenda and external trade policy to ensure that the ecological transition becomes a source of strategic industrial leadership but rather structural vulnerability.

[140] The Regulation's Article 10 on the Digital Product Passport requires verifiable technical data throughout the product life cycle, imposing significant burdens on global suppliers unfamiliar with EU procedures. Without mutual recognition agreements or streamlined conformity protocols, supply chains may reconfigure, favouring vertically integrated or already compliant operators, reducing sourcing flexibility and diversification.

[141] David Bailey, Keith Cowling and Philip Tomlinson (eds), *New Perspectives on Industrial Policy for a Modern Britain* (Oxford University Press 2015).

[142] Ingmar von Homeyer, 'The Evolution of EU Environmental Governance' (Academy of European Law / European University Institute, Summer School 2008) <https://www.ecologic.eu/243> accessed 15 September 2025.

[143] Yannick Radi, 'International Investment Law and Development: A History of Two Concepts' (Grotius Centre Working Paper 2015/045, Leiden Law School Research Paper, 1 December 2014).

[144] European Commission Communication 'A New Industrial Strategy for Europe' COM(2020) 102 final, updated as COM(2021) 350 final, acknowledges the need to align green transition goals with industrial competitiveness, technological autonomy, and strategic resilience. It calls for regulatory predictability, accelerated permitting and improved finance access. Similarly, the Green Deal Industrial Plan COM(2023) 62 final identifies administrative simplification and funding coordination as pillars for maintaining EU industrial relevance. Regulation (EU) 2024/1781 has not been structurally integrated into this broader strategy, risking unsupported sectors—especially those facing global cost competition—during implementation.

[145] Vassilis Monastiriotis and Tea Gamtkitsulashvili, 'The Territorial Dimension of EU Industrial Policy: Aligning Cohesion and Industrial Strategies' (LEAP LUHNIP Working Paper No 7/2025, 22 April 2025).

7 Socioeconomic and Consumer Implications

A growing body of socio-legal scholarship shows that "consumer empowerment" depends not only on the formal availability of information, but on its intelligibility and on the institutional contexts in which choices are made. In EU consumer law, informational duties have repeatedly produced diminishing returns when disclosures become dense, technical, or fragmented—especially where digital interfaces mediate the transaction[146]. Embedding the DPP within this landscape therefore requires design choices (standardisation, layering, icons, defaults)[147] that translate complex life-cycle data into legible signals of quality, durability and repairability, or else "empowerment" risks becoming merely nominal.

Empirical and institutional evidence also indicates that households' willingness and ability to act on sustainability cues is mediated by income constraints, perceived "green premiums," and digital literacy[148]. Surveys and secondary analyses across the Union[149] identify finance and regulatory uncertainty as persistent obstacles for firms to supply affordable sustainable options, while consumers report confusion about labels and difficulty accessing practical repair services. These dynamics amplify the risk that the Regulation's benefits accrue unevenly unless accompanied by demand-side supports[150] (price instruments, social tariffs) and supply-side enablers[151] (SME-oriented finance, interoperable standards).

The enforcement of Regulation (EU) 2024/1781 introduces significant transformations in the interaction between consumers[152], the market and sustainability policies. Its provisions on product durability, reparability, life-cycle transparency, and the mandatory Digital Product Passport (DPP) reshape consumption patterns, consumer rights, and the affordability of sustainable goods across the Union.

One of the central objectives of the Regulation is to enhance consumer empowerment[153] through better access to structured, verifiable, and environmentally relevant information. This regulatory ambition builds upon and expands the informational rights enshrined in Directive 2011/83/EU, introducing an environmental dimension that alters the legal understanding of product quality[154] and the criteria for responsible

[146] OECD, 'Enhancing Online Disclosure Effectiveness' (2022) <https://www.oecd.org/content/dam/oecd/en/publications/reports/2022/10/enhancing-online-disclosure-effectiveness_e8b230aa/6d7ea79c-en.pdf> accessed 15 September 2025.
[147] Kim Jae-Eun and Lee Min-Kyu, 'When Is Enough, Enough? Investigating Product Reviews and Information Overload from a Consumer Empowerment Perspective' (2019) 100 Journal of Business Research 27.
[148] Hu Xiaojuan and Meng Hu, 'Digital literacy and green consumption behavior: Exploring dual psychological mechanisms' (2022) 22(2) Journal of Consumer Behaviour 272.
[149] European Investment Bank, 'Investment barriers in the European Union 2023' (European Investment Bank, 2023).
[150] LSEG, 'EU Sustainable Finance Regulation – Enhancing and Simplifying to Enable the Transition' (January 2025).
[151] OECD, 'Unlocking the Potential of Demand-Side Climate Mitigation Strategies' (March 2025).
[152] Monastiriotis and Gamtkitsulashvili (n 145).
[153] Stephen Weatherill, *EU Consumer Law and Policy* (2nd edn, Edward Elgar Publishing 2013).
[154] Violet Ross and Lucila de Almeida, 'Refining Reflexive Environmental Law by Nature and Nurture: Autonomy, Accountability, and Adjustability' (2024) 13(2) Transnational Environmental Law 428.

choice[155]. It positions consumers as agents of ecological transition and elevates the act of purchasing to a legally significant behaviour.

Yet the shift towards environmental transparency introduces new complexities. The proliferation of ecolabels[156], the emergence of technically dense digital interfaces, and the requirement to interpret lifecycle data may generate a form of "information fatigue" among consumers. Overexposure to fragmented or overly technical disclosures can undermine engagement, particularly among digitally excluded groups or those with limited digital fluency. In such cases, the right to information[157] becomes difficult to exercise meaningfully, especially where structural inequalities in digital access remain unresolved.

From an equity[158] perspective, the Regulation may intensify socio-economic divides in access to sustainable consumption. Stricter ecodesign obligations tend to increase production costs, which could be reflected in retail prices. In the short term, this may reinforce the perception that sustainable products are luxury items, accessible primarily to higher-income households. Such segmentation threatens to entrench dual consumer markets, structured along lines of economic capacity[159] rather than environmental awareness[160].

These risks[161] are particularly salient in sectors such as domestic appliances, electronics and furniture, where redesigning products to comply with durability and reparability standards involves material investment. Absent compensatory measures—such as reduced VAT, targeted subsidies, or eco-bonuses—households with lower purchasing power may remain locked out of the green transition.

[155] Directive 2011/83/EU on consumer rights guarantees access to pre-contractual information, increasingly including environmental attributes. The CJEU has interpreted Article 6 as requiring clarity and completeness in disclosures, especially when product features influence ethical or ecological decisions. This aligns with Regulation (EU) 1169/2011 on food information and the Aarhus Convention, recognising the right to environmental information as essential to democratic participation and sustainable consumption.

[156] Karthik Murali, Michael K Lim and Nicholas C Petruzzi, 'The Effects of Ecolabels and Environmental Regulation on Green Product Development' (2019) 21 Manufacturing and Service Operations Management 519.

[157] Christopher H Hodges, *The Reform of Class and Representative Actions in European Legal Systems* (Hart Publishing 2008).

[158] Garben and Govaere (n 89).

[159] BEUC, The Illusion of Choice: Barriers to Sustainable Food Consumption (BEUC-X-2023-080, 10 November 2023). <https://www.beuc.eu/sites/default/files/publications/BEUC-X-2023-080_The_illusion_of_choice_report.pdf> accessed 15 September 2025.

[160] The affordability of sustainable consumption is a growing concern in EU legal and policy discourse. While the European Green Deal COM(2019) 640 final and Just Transition Mechanism COM(2020) 22 final recognise risks of deepening socioeconomic divides, Regulation (EU) 2024/1781 remains silent on mitigating measures. The European Consumer Organisation (BEUC) and JRC surveys identify price as the primary barrier to eco-labelled goods uptake, especially among lower income groups. This dynamic threatens social inclusivity and raises distributive justice issues under Article 3 TEU and Article 9 TFEU. The absence of flanking measures such as VAT differentiation (Directive (EU) 2022/542), eco-vouchers or subsidised circular consumption contrasts with practices in Member States like France and the Netherlands, risking market fragmentation and weakening sustainability and cohesion objectives.

[161] European Commission, 'Behavioural Study on Consumers' Engagement in the Circular Economy' (Publications Office of the European Union, December 2018).

Comparative policy practice[162] within the Union suggests a toolkit that can mitigate these distributional frictions: targeted VAT reductions for high-durability or repair-friendly products; tax credits for ecodesign investments passed through to retail prices; and green criteria in public procurement that reward affordability and repair services. Where implemented (France, Sweden, Austria, Belgium) such instruments have lowered effective consumer prices, signalled quality through procurement benchmarks, and catalysed local repair ecosystems. Calibrating these levers to the DPP[163], so that fiscal advantages hinge on verified durability or repair metrics, would align price signals with the Regulation's informational architecture.

Evidence from circular economy case studies[164] point to tangible social co-benefits when reuse, refurbishment and repair are normalised: higher shares of skilled manual employment with low automation potential; shorter supply chains that embed value locally; and measurable reductions in material throughput. Regional analyses[165] further show that such activities are particularly meaningful for peripheral areas reliant on SME networks and tacit know-how. To unlock these gains at scale, repairability obligations should be complemented by vocational training, micro-finance and certification pathways that reduce entry barriers for small operators and social enterprises.

At the same time, the Regulation creates incentives for the development of alternative consumer models[166]. By reinforcing obligations related to spare parts, disassembly and technical documentation, it offers structural support for reuse, refurbishment and repair activities. These practices, previously relegated to the informal or peripheral economy, gain normative recognition and open new avenues for circular business models[167] and decentralised innovation[168].

This evolution carries implications for labour markets. Repair and remanufacturing sectors typically rely on skilled manual work with low automation potential. Their expansion could generate stable employment in local ecosystems, provided that

[162] OECD, 'Tax policy and the environment: empirical evidence and guidelines' (2022).
[163] European Environmental Bureau (EEB), 'Making more durable and reparable products: Building blocks for effective EU repair policies' (May 2025).
[164] European Environment Agency (EEA), 'Europe's circular economy in facts and figures' (December 2024), 20–25.
[165] European Commission, 'An overview of Europe's repair sector: SME clusters and regional employment impacts' (December 2022).
[166] Emma Lees and Jorge E Viñuales (eds), *The Oxford Handbook of Comparative Environmental Law* (OUP 2019).
[167] Ida Mae de Waal, 'The Legal Transition towards a More Circular Electrical and Electronic Equipment Chain—A Case Study of The Netherlands' (2023) 15(2) Sustainability 935.
[168] The EU increasingly recognises repair, refurbishment and reuse sectors' strategic role in circular economy goals. The Circular Economy Action Plan COM(2020) 98 final and Sustainable Products Initiative COM(2022) 140 final highlight the need for spare parts access, technical documentation and dismantling procedures. The European Parliament has supported a "right to repair" (e.g. 2020/2089(INI)) to avoid exclusion of consumers and independent repairers. However, Regulation (EU) 2024/1781 lacks dedicated legal frameworks or enforcement mechanisms for these actors. Absence of harmonised standards for second-hand certification, remanufacturing quality and liability for reused parts creates legal uncertainty. Repair and reuse enterprises—often SMEs or informal—face challenges in compliance, funding and public procurement recognition. The European Economic and Social Committee (EESC) and Committee of the Regions stress the need for institutional safeguards, local employment support and decentralised regulatory guidance. Without these, resource efficiency, job creation and consumer empowerment potential remain underutilised.

supporting measures—vocational training, micro-finance and certification pathways—are introduced to maximise accessibility.

The legitimacy of this regulatory transformation also hinges on public trust[169]. A legal framework that promotes environmental ambition while respecting social constraints enhances the perception that EU governance protects the general interest. In times of political polarisation, such trust constitutes a key asset for institutional resilience.

Ultimately, the effectiveness of Regulation (EU) 2024/1781 depends on more than formal compliance. Long-term success requires distributive fairness, accessibility to sustainable choices and behavioural change across all social strata. Environmental legislation disconnected from social equity[170] risks exacerbating exclusion rather than driving transformation. Bridging this gap is essential to preserving the democratic legitimacy of the green transition.

8 Conclusions and Regulatory Outlook

Regulation (EU) 2024/1781 constitutes a pivotal milestone in the European Union's endeavour to decarbonise and green its internal market through binding product-level sustainability criteria. Its normative ambition—establishing a harmonised framework for ecodesign applicable across product categories—remains undisputed. Yet the Regulation's transformative potential remains constrained by critical shortcomings in its legal architecture, implementation logic and economic inclusiveness.

The analysis conducted throughout this paper has shown that, while conceptually coherent, the Regulation fails to account for the diversity of industrial sectors, firm sizes and national regulatory capacities across the Union. Its uniformity of obligations, particularly regarding digital product passports, reparability standards and supply-chain traceability, creates structural asymmetries that disproportionately burden SMEs and low-margin industries. The absence of differentiated compliance paths, phased implementation or technical-exemption clauses undermines the principle of proportionality and risks excluding key actors from the green transition[171].

Equally concerning is the Regulation's insufficient coordination with existing EU instruments, such as the REACH Regulation, the Corporate Sustainability Reporting

[169] Garben and Govaere (n 89).
[170] Cormac Cullinan, *Wild Law: A Manifesto for Earth Justice* (Green Books 2003).
[171] Article 5 TEU enshrines proportionality as a fundamental EU legislative constraint. The CJEU requires measures to be appropriate and necessary, avoiding excessive burdens on operators. Regulation (EU) 2024/1781's lack of scaled or sector-specific adaptation mechanisms challenges this, especially for diverse firms (Case C-58/08 *Vodafone* [2010] ECLI:EU:C:2010:321). The Vodafone case illustrates how the CJEU interprets Article 5 TEU as a substantive check on the proportionality of EU legislation. By insisting that harmonisation measures be both appropriate and not excessively burdensome, the Court established a benchmark that is directly relevant to Regulation (EU) 2024/1781. Unlike the GDPR, which differentiates obligations by scale and risk, the Regulation applies uniform requirements that may strain SMEs and sector-specific operators. This creates potential tension with the proportionality test articulated in Vodafone. For the purposes of this work, the case underscores the need to assess whether sustainability regulation aligns with constitutional safeguards of balanced and fair implementation.

Directive (CSRD) and the proposed Directive on Corporate Sustainability Due Diligence (CSDDD). The lack of interoperability between information systems, legal definitions and enforcement mechanisms generates confusion, legal uncertainty and unnecessary compliance duplication. Moreover, the Regulation imposes new market-access conditions without the accompanying development of a financial framework to support investment in sustainability upgrades—an omission that contradicts the logic of a just transition.

In light of these deficiencies, several regulatory adjustments are therefore warranted. First, the European Commission should adopt delegated acts under Article 290 TFEU to tailor compliance requirements by sector and firm profile, particularly for SMEs. Second, a system of adaptive governance should be established, including experimental regulatory sandboxes, sector-specific guidance and interoperable technical annexes developed with standardisation bodies. Third, the Regulation should be connected with existing EU funding instruments—such as InvestEU, Horizon Europe or Cohesion Funds—through legally binding cross-references to ensure financial support for compliance[172].

Furthermore, a horizontal framework for regulatory consistency should be established to reconcile overlapping sustainability obligations and reduce systemic fragmentation. Finally, consumer-centred policies—including VAT reductions for sustainable goods and formal recognition of repair sectors—should complement the product-centric orientation of the Regulation.

Ultimately, the success of Regulation (EU) 2024/1781 will not hinge solely on formal transposition, but on its ability to foster inclusive innovation, fair competition and regulatory coherence. The Regulation must be embedded within a broader strategic framework that aligns environmental ambition with legal feasibility, economic resilience and distributive justice[173]. If properly calibrated, it can become a cornerstone of Europe's green competitiveness. If not, it risks reinforcing asymmetries that the Union has long sought to overcome.

[172] InvestEU Regulation (EU) 2021/523 prioritises SME support and green investment, but Regulation (EU) 2024/1781 lacks cross-references to these financial tools, weakening support and potentially hindering SMEs with limited capital or technical access.

[173] The CJEU has emphasised internal coherence in Union law for effective implementation, legal certainty and institutional trust. In *Vodafone and Others* (C-58/08 [2010] ECLI:EU:C:2010:321), the Court held legislative measures must not impose disproportionate burdens compromising internal market function. Similarly, in Commission v Hungary (C-78/18 [2020] ECLI:EU:C:2020:476), the Court reaffirmed proportionality requires balancing regulatory aims with practical capabilities. Combined with Articles 3 TEU and 9 TFEU, these rulings establish environmental legislation must integrate into the broader regulatory landscape. Fragmented or uncoordinated norms risk weakening sustainability, competitiveness and social cohesion. In *Commission v Hungary* (C-78/18), the CJEU struck down restrictions on foreign-funded NGOs, emphasising that proportionality demands alignment between regulatory objectives and the actual capacity of actors to comply. Transposed to Regulation (EU) 2024/1781, the ruling signals that sustainability obligations must not disregard structural disparities among firms and sectors. Articles 3 TEU and 9 TFEU reinforce this, requiring integration of social cohesion and competitiveness into environmental policy. A rigid one-size-fits-all framework risks undermining the very balance that EU primary law protects. The case thus illustrates that proportionality in sustainability law entails both environmental ambition and economic-social feasibility.

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SPECIAL SECTION

THE DIGITAL PRODUCT PASSPORT UNDER THE EU ECODESIGN REGULATION 2024: EMPOWERMENT OF THE CUSTOMER-CONSUMER ON THE ROAD TO SUSTAINABILITY IN A CIRCULAR ECONOMY OR INFORMATION OVERLOAD?

Abstract

The European Commission has established mandatory ecodesign requirements for products and services introduced into the internal market under the new Ecodesign Regulation from 2024 (ESPR) in order to support the development of a circular economy and increase the EU's competitiveness. The measures encompass product parameters and information requirements. Here, the newly established Digital Product Passport (DPP) will play a central role, complemented by labels and other information sources. This paper investigates the information requirements, the DPP, and labels in order to discover whether these measures will realise the ESPR's aim of improving product traceability and of positioning consumers to make sustainable choices and ultimately promote sustainability and a circular economy. The DPP's efficiency as an information tool and its interaction with labels, as well as the change to the consumer's position in terms of their safety and their rights will be considered. While the ESPR's implementation and product-group specific regulation is still underway, the DPP looks to become a comprehensive data provision tool that will place relevant and easily comprehensible product information at the customer's fingertips. Aspects from the product's whole lifecycle will be covered, from origin and materials used, over resource consumption during production and when in use, to contained substances of concern, as well as instructions for installing, using, maintaining, and disposing of the product. This information is also relevant for other economic operators like repairers, refurbishers, and waste disposers. For the economic actor burdened with the creation and maintenance of the DPP, often the manufacturer, the tool brings advantages like enhancing buyer trust and product differentiation. The transparency of product parameters and the ensuing market competition will foster incentives for product development and thus increase the sustainability of offered products. The DPP has limitations, like its accessibility for vulnerable consumers and its scope, and important opportunities might be missed if these are not addressed. Despite this, the information requirements and in particular the DPP appear to be measures that will support the European Green Deal,

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 10.13135/2785-7867/12831

as well as the New Circular Economy Action Plan and the New Consumer Agenda and enhance the internal market's sustainability and circularity.

JEL CLASSIFICATION: K390

SUMMARY

1 Introduction: EU Law, Sustainability, and Consumer Law

In its recent Communication on '[a] Competitiveness Compass for the EU'[1], the European Commission admitted that the EU's strengths must be leveraged, and that action has to be taken 'now to regain [the EU's] competitiveness and secure its prosperity.'[2] These objectives echo the EU strategic agenda for 2024-2029 as well as the Commission priorities for 2024-2029.[3] One planned measure is the creation of a single market with a circular economy, which links to the EU 'core objective'[4] of 'the sustainable development of Europe' (Art 3(3) Treaty on the Functioning of the EU (TFEU)[5]). A roadmap for sustainable development was laid down in the European Green Deal[6] and the New Circular Economy Action Plan (CEAP)[7]. The Grean Deal proposed 'a new growth strategy that aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy where […] economic growth is decoupled from resource use.'[8] The EU's industry was found to be 'too "linear"' with '[o]nly 12% of the materials it uses

[1] Commission, 'A Competitiveness Compass for the EU' COM (2025) 30 final, hereinafter 'Competitiveness Compass'. The document is available at <https://circulareconomy.europa.eu/platform/sites/default/files/2025-01/Competitiveness%20Compass.pdf> accessed 3 November 2025.
[2] Competitiveness Compass 1.
[3] See <http://european-union.europa.eu/priorities-and-actions/eu-priorities/european-union-priorities-2024-2029_en> accessed 3 November 2025.
[4] See <https://eur-lex.europa.eu/summary/chapter/20.html> accessed 3 November 2025.
[5] Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C326/01.
[6] Commission, 'The European Green Deal' COM (2019) 640 final, hereinafter 'Green Deal'. See further <https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en> accessed 3 November 2025. This has been called the 'most ambitious economic sustainable growth strategy of the EU since its foundation', see Lucila De Almeida and Fabrizio Esposito, 'Consumers and the Green Transition Between Saying and Doing: Promising Consumer Empowerment While Restricting Consumers' Choices is Dangerous' (2023) 42 Yearbook of European Law 407, 412.
[7] Commission, 'A new Circular Economy Action Plan for a Cleaner and More Competitive Europe' COM (2020) 98 final, hereinafter 'CEAP'. See also <https://environment.ec.europa.eu/strategy/circular-economy_en> accessed 3 November 2025.
[8] Green Deal 2.

com[ing] from recycling'.[9] The aim to reuse before recycling materials is to materialise through the CEAP[10] and a New Industrial Strategy for Europe[11]. The mandatory ecodesign requirements of the new Ecodesign Regulation[12] are one facet that will supposedly support these plans (Art 1(1) ESPR).[13]

There have been previous endeavours in product policy, ecodesign, and energy labelling to promote sustainable products in the internal market. Pertinent measures include:[14] the Ecodesign Directive[15] (now repealed), the Energy Label Regulation[16], and the Standby Mode Ecodesign Regulation[17]. The focus of these measures was to advance resource savings (energy conservation) and environmental protection (see Rec 10 Ecodesign Directive, Rec 2 Energy Label Regulation, Rec 1-7 Standby Mode Ecodesign Regulation); consumers played a subordinated role. In contrast, the ESPR targets customers, which encompasses both consumers and business entities acting in a consumer capacity, and economic operators (see Section 2.2 below).

Within the ESPR's framework, the Digital Product Passport (DPP) is established as a means of making product information available to both economic actors and customers. In this way, customers are meant to be put into a position to make more informed choices while the traceability of products is improved at the same time (Rec 32).

It can be argued that the ESPR forms part of EU consumer law. While the Regulation does not grant consumers new rights vis-à-vis businesses, it pursues a new line of EU consumer policy that seeks to empower consumers to act. This approach follows the European Green Deal,[18] the CEAP,[19] and the New Consumer Agenda[20]. The Agenda has

[9] Green Deal 7.
[10] Cf CEAP 2-3.
[11] Commission, 'A New Industrial Strategy for Europe' COM (2020) 102 final. For further details, see <https://single-market-economy.ec.europa.eu/industry/strategy_en> accessed 3 November 2025.
[12] Council Regulation (EU) 2024/1781 of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC [2024] OJ L1781/1, hereinafter 'ESPR'.
[13] Compare Competitiveness Compass 11.
[14] See on this generally <https://single-market-economy.ec.europa.eu/industry/sustainability/sustainable-product-policy-ecodesign_en> accessed 3 November 2025. For further details on the different kind of legislative acts and measures, see Thomas Adisorn and Lena Tholen and Thomas Götz, 'Towards a Digital Product Passport Fit for Contributing to a Circular Economy' (2021) 14 Energies 2289 in Section 3.1. On the link between sustainable development and environmental law, see Elisa Morgera and Kati Kulovesi, 'Environmental Law' in Catherine Barnard and Steve Peers (eds), *European Union Law* (4th edn, OUP 2023) 692, 706.
[15] Directive 2009/125/EC of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products [2009] OJ L285/10.
[16] Regulation (EU) 2017/1369 of 4 July 2017 setting a framework for energy labelling and repealing Directive 2010/30/EU [2017] OJ L198/1.
[17] Regulation (EU) 2023/826 of 17 April 2023 laying down ecodesign requirements for off mode, standby mode, and networked standby energy consumption of electrical and electronic household and office equipment pursuant to Directive 2009/125/EC of the European Parliament and of the Council and repealing Commission Regulations (EC) No 1275/2008 and (EC) No 107/2009 [2023] OJ L103/29.
[18] See European Green Deal 8. See also De Almeida and Esposito (fn 6) 412.
[19] CEAP 5.
[20] Commission, 'New Consumer Agenda Strengthening Consumer Resilience for Sustainable Recovery' COM (2020) 696 final 5-7, hereinafter 'New Consumer Agenda'. See on this <https://commission.europa.eu/strategy-and-policy/policies/consumers/consumer-protection-policy/consumer-strategy_en> accessed 3 November 2025. The

five priority areas: green transition, digital transformation, redress and enforcement of consumer rights, specific needs of certain consumer groups, and international cooperation. The first of these, the green transition, relates directly to the ESPR and the new empowerment strategy: Its aim is to 'empower, support and enable every consumer, regardless of their financial situation, to play an active role in the green transition'.[21]

This paper examines the ESPR's requirements for the DPP and considers its suitability as a vehicle to enhance sustainability and promote circularity through ecodesign.[22] The salient question is whether the double aim of this instrument can be achieved or whether this product digitisation merely burdens businesses and consumers with (yet) more information to process. To discover an answer, the paper investigates three strands of questions: First, whether the DPP can be an efficient means of fulfilling information duties from the perspective of businesses and customers. Secondly, how these requirements mesh with existing information duties and requirements like energy labels under the Energy Label Regulation. Thirdly, whether the consumer's situation is improved in terms of their empowerment to make informed and sustainable choices, as well as the safeguarding of their rights and safety.

The remainder of this paper is structured as follows: An overview of the ESPR in terms of its aims and scope (Sections 2.1 and 2.2) and definitions of key concepts (2.3) is followed by an examination of the product requirements, namely, information requirements (3.1), with particular focus on the DPP (3.2) and labels (3.3).[23] These aspects provide the background for a discussion of the three strands of questions of the DPP's efficiency as a means of information (4.1), the DPP's interaction with other information and labelling requirements (4.2), and whether there is a change in the consumer's situation (4.3). As the ESPR only entered into force on 18 July 2024 and its implementation is still underway,[24] with the first delegated acts under the ESPR

Commission is currently evaluating the results of a public consultation and plans to adopt a consumer agenda for 2025-2030 at the end of this year, see <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14514-Consumer-Agenda-2025-2030-and-action-plan-on-consumers-in-the-Single-Market_en> accessed 3 November 2025.

[21] New Consumer Agenda 5. See also ibid 8-9 on the DPP and digital information.

[22] This paper considers the practical aspects of the ESPR requirements. For a discussion of the technical side, the DPP system, see Commission, 'Webinar on Digital Product Passport Standardisation' (12 June 2023, no longer available online), hereinafter 'DPP Standardisation Webinar'. See further, eg, Meliha Honic and Pedro Meda Magalhães and Pablo Van den Bosch, 'From Data Templates to Material Passports and Digital Product Passports' in Catherine De Wolf and Sultan Çetin and Nancy Bocken (eds), *A Circular Built Environment in the Digital Age* (Springer 2024) 79–94, contrasting DPP from other kinds of passports like material passports; Konstantinos Voulgaridis and others, 'Digital product passports as enablers of digital circular economy: a framework based on technological perspective' (2024) 85 Telecommunication Systems 699–715; Jens Niederhausen and others, 'Metrology and the quality infrastructure for the Digital Product Passport' (2025) 38 Measurement: Sensors 101491, <https://doi.org/10.1016/j.measen.2024.101491> accessed 3 November 2025.

[23] A discussion of the ESPR's requirements as to a product's performance requirements, contained in Art 6 and Annex I ESPR, goes beyond the scope of this paper.

[24] The implementation of the ESPR, like the drafting of working plans and determining product-group-specific requirements, will be influenced by the Group of Experts on Ecodesign for Sustainable Products and Energy Labelling ('Ecodesign Forum'). The Forum held its first meeting in February 2025 and another in April. A first working plan has been published, see Commission, 'Ecodesign for Sustainable Products and Energy Labelling Working Plan 2025-2030'

expected to come into force in early 2027,[25] an interim evaluation of the ESPR is made (5.1) and improvements suggested, where appropriate (5.2). This leads to an outlook for the EU's sustainability measures (5.3).

2 The New Ecodesign Regulation (ESPR): Sustainability and EU Consumer Law

The sustainability measures prior to the ESPR, in particular the Ecodesign Directive, established a foundation for the collection and provision of data elements relating to ecological considerations; however, the Directive lacked 'a systematic data flow'[26]: While a database exists for energy-related product data in the form of the European Product Registry for Energy Labelling (EPREL)[27], the Ecodesign Directive merely provided that ecologically-relevant product information be made available to the consumer 'in the form [manufacturers] deem appropriate' (Art 14 Ecodesign Regulation). This situation is remedied under the ESPR in that it integrates several ecodesign aspects (see Section 2.1 below), targets both economic actors and customers (see Section 2.2), and foresees information requirements (see Section 3.1.) and the DPP as a collection of data sets on the different aspects of a product's lifecycle (see Section 3.2).

2.1 Aims of the ESPR

The ESPR has the ambitious objective of acting as a general ecodesign framework that tackles

> *product durability, reliability, repairability, upgradability, reusability and recyclability, […] refurbishment and maintenance […] , …] the presence of hazardous chemicals in products, […] energy and resource efficiency […] ; that] reduce[s …] waste and increase[s] the recycled content in products[…], enable[es] remanufacturing and high-quality recycling and reduc[es] carbon and environmental footprints[; and] address[es] practices associated with premature obsolescence.*[28]

By addressing all of these parameters, product sustainability in the EU is supposed to be improved while waste is reduced. Consequently, the ESPR is meant to support the EU's

COM (2025) 187 final, hereinafter 'Ecodesign Working Plan'. It states at 4-6 that acts will be adopted for the following product groups by year (further measures are listed at 8): Iron and steel (2026); textiles, tyres, and aluminium (all 2027); furniture (2028); mattresses (2029). Furthermore, horizontal requirements for repairability (and a score) as well as recyclability of electronic products will be laid down in 2027 and 2029 (see ibid 6). On the Forum and its work in general, see Rec 52 and Arts 19–20 ESPR and <https://environment.ec.europa.eu/news/advancing-sustainability-through-espr-2025-02-19_en> accessed 3 November 2025.

[25] See DPP Standardisation Webinar (n 22) and Ecodesign Working Plan 4-6.

[26] Adisorn and Tholen and Götz (n 14) in Section 3.1.

[27] For further information on this database, see <https://energy-efficient-products.ec.europa.eu/eprel_en> accessed 3 November 2025.

[28] Recs 6 and 7 ESPR.

objectives of energy and environment conservation in general and sustainability and the circular economy in particular (Recs 9–10, 2 ESPR). The ESPR builds on and replaces the Ecodesign Directive from 2009, as it acts as a sustainability framework for 'virtually all physical products',[29] while the 2009 Directive was limited to 'energy-related products' (Arts 1(1), 2 point 1 Ecodesign Directive). New under the ESPR is the DPP (Arts 9–15 ESPR, see Sections 3.2 and 4. below), the rules prohibiting the destruction of unsold products (Arts 23–26), and the establishment of mandatory green public procurement rules (Art 65).[30]

2.2 Scope of the ESPR

Article 2 point 1 ESPR limits the ESPR's scope in terms of 'products' to 'any physical goods that are placed on the market or put into service', so that digital content is generally excluded; however, where digital content forms 'an integral part of a physical product' (Rec 13 ESPR), this is covered by the Directive. Intermediate products and components are within the ESPR's scope (Art 1(2)). An intermediate product is 'a product that requires further manufacturing or transformation such as mixing, coating or assembling to make it suitable for end-users' (Art 2 point 3), while components are 'product[s] intended to be incorporated into another product' (Art 2 point 2). These products are covered when they are first made available on the internal market, ie, supplied ('making available on the market', Art 2 point 39, and 'placing on the market', Art 2 point 40) or are first used in the internal market ('putting into service', Art 2 point 41).

There are only few product exceptions. These relate to particular product categories for which regulation either already exists or where sustainability requirements are not suitable (Rec 13, Art 1(2) ESPR): food[31], feed[32], medicinal products[33], veterinary medicinal products[34], living plants, animals and micro-organisms, products of human origin, products of plants and animals relating directly to their future reproduction, and vehicles[35].

[29] Anonymous, 'Ecodesign for Sustainable Products Regulation: Making sustainable products the norm in the EU' (European Commission 2025) <https://commission.europa.eu/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/ecodesign-sustainable-products-regulation_en> accessed 3 November 2025.
[30] On the last, see Kleoniki Pouikli, 'The role of Green Public Procurement (GPP) under the EU Green Deal as a key lever of the transition to a circular and climate neutral Europe' in Christiane Trüe and Lydia Scholz (eds), *The EU Green Deal and its Implementation* (Nomos 2023) 247–266.
[31] See Art 2 Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1.
[32] See Art 3(4) Food Law Regulation.
[33] See Art 1(2) Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67.
[34] See Art 4(1) Regulation (EU) 2019/6 of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC [2001] OJ L4/43.
[35] See Art 2(1) Regulation (EU) No 167/2013 of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles [2013] OJ L60/1, Art 2(1) Regulation (EU) No 168/2013 of 15 January 2013 on the approval and

Consequently, a broad range of physical goods are covered by the ESPR. Recital 13 clarifies that tyres count as components and that the ESPR applies to E-bikes and e-scooters.

A line is drawn between new and used products: Remanufactured products, ie, 'a new product [that] is produced from objects that are waste, products or components and through which at least one change is made that substantially affects the safety, performance, purpose or type of the product' (Art 2 point 16) count as new products and therefore fall within the ESPR's scope, while second-hand goods, including repaired or refurbished[36] items, are not (Rec 17).

2.3 Key Concepts of the ESPR

The ESPR defines a number of key concepts that are worth noting before examining the Regulation's measures.

'Ecodesign' is characterised as the process of integrating 'environmental sustainability considerations into the characteristics of a product' and its 'value chain'. Thus, not only the finished product, but its entire 'life cycle' (Art 2 point 12 ESPR), ie, its production —including the creation or acquisition of raw materials—, storage, distribution, use, maintenance, repair or reuse, and disposal (recycling or otherwise) need to be sustainable (see Arts 1(1), 2 points 11, 13, 16-20, and Rec 6).

Primary targets of the ESPR are 'economic operators', ie, manufacturers and their authorised representatives, importers, distributors, dealers, and fulfilment service providers (Art 2 points 46, 42, 44-45, 55 ESPR).[37] The secondary target is the economic actors' 'customer': 'a natural or legal person that purchases, hires or receives a product for their own use *whether or not acting for purposes which are outside their trade, business, craft or profession*' (Art 2 point 35, emphasis added). The second half of the definition means that the notion goes beyond that of a consumer, which has traditionally been limited to natural persons acting in a private capacity;[38] here, 'customer' encompasses professionals acting in such a capacity. This definition, while broader than the conventional notion, leaves open whether the customer is an 'average' or a 'vulnerable' consumer.[39]

market surveillance of two- or three-wheel vehicles and quadricycles [2013] OJ L60/52, and Art 2(1) Regulation (EU) 2018/858 of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC [2018] OJ L151/1.

[36] Products that are prepared, cleaned, tested, serviced, and repaired, see Art 2 point 18 ESPR.

[37] The Commission has noted that '[e]codesign requirements […] target manufacturers that need to design their products respecting all requirements and limitations', see <https://energy-efficient-products.ec.europa.eu/ecodesign-and-energy-label/legislative-framework_en> accessed 3 November 2025.

[38] Article 2 ESPR refers to Art 2(2) Directive (EU) 2019/771 of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC [2019] OJ L136/28: '"consumer" means any natural person who, in relation to contracts covered by this Directive, is acting for purposes which are outside that person's trade, business, craft or profession'.

[39] On this distinction, see, eg, Jule Mulder, Comparing Vulnerability? How can EU Comparative Law Methods Shed Light on the Concept of The Vulnerable Consumer (2019) 6(2) Journal of International and Comparative Law 209, 210-215.

Out of the three ESPR measures discussed in this paper, only information requirements and the DPP are defined; a label is understood in its common meaning. 'Information requirement' is 'an obligation for a product to be accompanied by information as specified in Article 7(2) [ESPR]' (Art 2 point 9).

Article 2 point 28 ESPR defines a DPP as:

a set of data specific to a product that includes the information specified in the applicable delegated act adopted pursuant to Article 4 and that is accessible via electronic means through a data carrier in accordance with Chapter III.

In this respect, a 'data carrier' is 'a linear barcode symbol, a two-dimensional symbol or other automatic identification data capture medium that can be read by a device' (Art 2 point 29). Given examples of a data carrier include watermarks and QR codes (Rec 37). Until harmonised EU standards are established,[40] data carriers must comply with ISO or other European or international standards (Art 10(1)(c)).

3 The Ecodesign Product Requirements under the ESPR

Ecodesign obligations under the ESPR can take the following forms: Product performance requirements (Art 6 ESPR), information requirements (Art 7), or a combination of both (Art 5(9)). Performance requirements relate to minimum or maximum values of, or non-quantitative requirements for, particular parameters (Art 6(2)) concerning a wide range of sustainability aspects like durability, repairability, recyclability, resource consumption, substances of concern, and microplastic release (Annex I ESPR). In what follows, the ESPR's information requirements are discussed both generally (3.1) and two forms specifically: the DPP (3.2) and labels (3.3). The next section (4) considers the impact of these measures.

3.1 The ESPR's Information Requirements

Products within the ESPR's scope can come with information obligations for the product's manufacturer (Rec 28 ESPR), which will be determined in delegated acts (Art 7(1)). These are meant to 'improve product aspects relevant for environmental sustainability' (Rec 16) and to enable consumers and public authorities to make 'more sustainable choices' (Rec 28). While the exact requirements may vary across product categories, all products must come with a DPP and information allowing substances of concern to be tracked throughout the product's life cycle (Art 7(5), Rec 31). Article 2 point 27 ESPR adopts a broad notion of these substances that encompasses a multitude of health

[40] Standards for the DPP are to be delivered by December 2025, see DPP Standardisation Webinar (n 22).

and environmental considerations, as well as any substance that 'negatively affects the reuse and recycling of materials in the product in which it is present'.[41]

In addition, the customer is to be informed on how to handle the product in terms of its installation, use, maintenance, repair, and disposal (Art 7(2)(b)(ii) ESPR), including its disassembly, recycling, reuse, or refurbishment (ibid point (iii)). Information on a product's performance parameters (on which see Annex I ESPR) may need to be included in the form of a score of its repairability and durability, and what its environmental and carbon footprint is (Art 7(2)(b)(i)). Moreover, other relevant information 'that could influence sustainable product choices for customers' and that is necessary for the product's handling may need to be included (ibid point (iv)). Examples of disposal information are available take-back schemes in Member States and databases of drop-off points (Rec 28).

The required information must be presented in a recipient-friendly manner, ie, 'be clear, easily understandable and tailored to the particular […] product groups concerned and the intended recipients' (Art 7(2)(c) ESPR) and be easily accessible (Rec 28). Each Member State can determine the language in which the information is to be provided (Art 7(8)). The main communication mechanism for the required information is the DPP (on which, see below), while other forms of communication may be set in addition in delegated acts (Arts 7, 9(1)): User manuals or product documents (Art 7(7)(d), product packaging (ibid point b), labels (ibid point c), free access websites or applications (ibid point e), and the product itself (ibid point a). Having said this, 'essential information' on the 'health, safety and rights of end users' must be provided both through some physical means and through a data carrier (Rec 28). Information that leads to an informed purchase decision needs to be provided prior to a purchase transaction (ibid).

3.2 The ESPR's Digital Product Passport (DPP)

The ESPR's new and main digital information tool, the DPP, is regulated in the seven provisions making up Chapter III: Articles 7 to 15. The DPP serves a triple purpose: to provide information to economic operators and customers, to facilitate product compliance verification by the Member States' national authorities, and to improve product traceability (Art 9(3)).[42] It is therefore not surprising that all products that are subject to information requirements must at least include a DPP as a means of

[41] The provision refers to three pieces of legislation for specifications: Regulation (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [2006] OJ L396/1; Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 [2008] OJ L353/1; and Regulation (EU) 2019/1021 of 20 June 2019 on persistent organic pollutants (recast) [2019] OJ L169/45.

[42] On another occasion, the Commission has stated that the DPP has the triple purpose of increasing environmental sustainability, promoting circularity, and supporting legal compliance. See DPP Standardisation Webinar (n 22).

communicating information (Art 9(1) ESPR). The DPP is to be created by the economic operator that places the related product on or puts it into service in the market (Art 10(3)). This will often be the manufacturer but can also be an importer or a distributor (compare Art 2 points 46, 42-45, 39-41).

The DPP's data is to be presented in the form of one or several types of data carriers, like a QR code (Arts 2 point 38, 9(2)(b), Rec 37) and be linked through a 'unique product identifier' (Art 10(1)(a)). This identifier is to facilitate the product's traceability and must be stored together with other specific data in a digital product passport registry that is to be established by the Commission (Recs 36 and 41, Art 11(1)-(2)). The DPP's data must be complete, up to date, and accurate (Arts 9(1), 11 point g), and be in an interoperable format that allows data transfers without lock-ins, and be searchable and machine-readable, where appropriate (Arts 10(1)(d), 11 point a). It must be accessible easily and free of charge (Art 11 point b). For this purpose, the Commission will establish and maintain a web portal for DPPs (Art 14, Rec 42). The DPP's technical details, including the number of data carriers and their presentation (on the product, its packaging, or on accompanying documents), as well as access to the DPP's data will be laid down for specific product groups in delegated acts (Arts 9(2)(b)-(i), 10(1)(b)).

The information that is generally to be included in the DPP —product group-specific requirements may vary in accordance with future delegated acts— encompasses a wide range from general information such as the product's origin and composition,[43] as well as use and maintenance instructions, over data regarding the product's durability, repairability, and its recycling, to data on its resource consumption during its lifecycle and contained substances, particularly those of concern (Art 9(2)(a), Annex III). Data stemming from information obligations in other EU law can be included in the DPP if the regulation in questions facilitates this (Art 10(2)), eg, information from EPREL (Rec 34). Customers' personal data may only be included in the DPP with the customers' express consent (Art 10(1)(e)).

3.3 The ESPR's Labels

The ESPR contains two provisions on labels: Articles 16 and 17 in its Chapter IV. The first provision deals with labels generally but does not provide a definition. Generalising from the definition laid down in Art 2 point 19 Energy Label Regulation, a label is

> *a graphic diagram, either in printed or electronic form, including a closed scale using only letters from A to G, each letter representing a class and each class corresponding to [one product parameter], in seven different colours from dark green to red, in order to inform customers about [product aspects like] energy efficiency and energy consumption[…].*

[43] Green Deal 8.

Labels are named as one alternative information communication method to DPP among others (Art 7(7)(c) ESPR); however, the DPP is the main information source, while labels are complementary.[44] Their function is to 'provide a quick visual basis for consumers to distinguish between products' (Rec 46). Specific regulation of the content, presentation, and layout of any labels are left to future delegated acts (Art 16(1) and (5)); however, they generally need to present information in a clear and easily comprehensible manner (Rec 46). In this vein, Art 16(2) foresees that labels for a class of performance need to have a clear and easily understandable layout to facilitate comparisons of products by customers based on specific parameters. Moreover, they may need to incorporate a data carrier to access the DPP and other product information (Art 16(4)), as well as sources like websites (Rec 46).[45]

The notion of a label as outlined above would seem to encompass scores, as foreseen in Art 7(2)(b)(i) and Rec 30 ESPR as an information requirement on the durability and repairability of products. Like labels, scores are to be easily comprehensible and include pictograms, while 'the repairability score [must be] be based on a harmonised methodology specified for the product or product group and which aggregates parameters, such as the availability and price of spare parts, the ease of disassembly and the availability of tools, into a single score' (Rec 30).

A new repairability score introduced for energy labels is based on a method developed by the Joint Research Centre (JRC) and is represented by a pictogram of tools that are accompanied by an A-to-E score, whereby A stands for the highest and E for the lowest repairability of the product.[46] The following six factors make up the score: Disassembly depth (number of steps required to remove one part from a product), fasteners (reusable or removable devices used to connect parts or pieces, eg, screws), tools (type required for disassembly and reassembly), spare parts (availability of replacement parts with the same or similar functions, eg, battery, buttons, charger, over a specified period of time, its delivery time, and price[47]), software updates (availability over time of security and functionality updates), repair information (availability, comprehensiveness, and price of

[44] See Ecodesign Working Plan 10: '[Mandatory product] information will generally be provided in the digital product passport. Some *products may also carry an ESPR label* and/or other labels governed by specific EU legislation […]' (emphasis added).
[45] For comparison, an example image of a new energy label that integrates information like energy rating, durability, and repairability can be seen at <https://joint-research-centre.ec.europa.eu/jrc-news-and-updates/new-eu-labels-help-consumers-choose-more-repairable-electronics-2025-06-20_en> accessed 3 November 2025.
[46] See ibid.
[47] This aspect is considered further in Section 5.2 below.

information, eg, user manuals).[48] This scoring system will likely be used for ecodesign labels as well, as the JRC's report makes frequent reference to the ESPR.[49]

Article 17 ESPR is concerned with protecting consumers from misleading information and establishes a prohibition to place products on the market or put them into service where they bear confusing or misleading labels by mimicking labels prescribed under the ESPR. Recital 48 clarifies that the EU Ecolabel[50] or other recognised ecolabels on national or regional level will not be considered confusing, unless the label criteria is less strict than under the ESPR. The German ecolabel 'Blue Angel' (*Blauer Engel*) is one national ecolabel that will be recognised, as it too, like the EU Ecolabel, fulfils the EN ISO 14024 type I requirements.[51]

As mentioned above, previous EU legislation exists for labels, specifically for energy labels in the form of the Energy Label Regulation from 2017. In order to avoid duplications, the Commission aims to include ecodesign information in the existing energy labels, where this is feasible.[52] A label for ecodesign parameters may only be established for products where this integration is not possible (Rec 47), with the effect of the energy label being replaced by the ecodesign label (Art 16(3)).

4 The DPP as an Information Tool and consumers

DPPs are not a new invention of the Commission, nor will DPPs be supplied by it. This is not necessary, because there already are service providers that offer a DPP commercially.[53] One example is Circularise, established in 2016, offering DPPs for '[e]nd-

[48] See Christoforos Spiliotopoulos and others, 'Product Reparability Scoring System: Specific application to Smartphones and Slate Tablets' (Report 2022, EUR 31057 EN), <doi:10.2760/340944> accessed 3 November 2025, in particular 6, 10-15. While this score is for smartphones and tablets, a general score and adaptations for laptops, washing machines, and vacuum cleaners have been developed as well, see Mauro Cordella and Felice Alfieri and Javier Sanfelix, 'Analysis and development of a scoring system for repair and upgrade of products' (Final report, 2019), <https://data.europa.eu/doi/10.2760/725068>, accessed 3 November 2025. Cordella and Alfieri and Sanfelix (ibid) note other factors beside the cost of repairs influencing the consumer's willingness to undertake repair at 57: remaining expected product lifetime (willingness decreasing with approaching expected lifetime end) and time required for repair (1-2 weeks generally acceptable).

[49] See Spiliotopoulos and others (n 48).

[50] This label is a voluntary scheme that certifies 'environmental excellence', ie, that 'goods and services [have] a guaranteed reduced environmental impact throughout their entire life cycle'. See <https://environment.ec.europa.eu/topics/circular-economy/eu-ecolabel_en#:~:text=Launched%20in%201992%2C%20the%20EU,the%20growing%20EU%20Ecolabel%20Community> accessed 3 November 2025.

[51] For further information on this label, see <https://www.blauer-engel.de/en> accessed 3 November 2025.

[52] See fn 45 above.

[53] A large number of projects on DPP exist in various sectors and constellations. For a structured overview of 76 of these, see Maike Jansen and others, 'Current Approaches to the Digital Product Passport for a Circular Economy: An Overview of Projects and Initiatives' (Wuppertal Paper no. 198, 2022) <https://wupperinst.org/en/a/wi/a/s/ad/7852> accessed 3 November 2025. The 'living document' overview table of the listed projects can also be accessed at <https://tinyurl.com/widpp22> accessed 3 November 2025. Another detailed overview of DPP projects is provided by Marcello Colledani and Abdelrahman Abdalla, 'Benchmark of Existing DPP-oriented Reference Architectures. Deliverable D3.1 within WP3 of the CIRPASS Project' (2023) 24-86. The document is available at <https://cirpassproject.eu/wp-content/uploads/2023/03/CIRPASS_Benchmark-of-existing-DPP-oriented-reference-architectures.pdf> accessed 3 November 2025.

to-end Supply Chain Traceability' that also comply with the ESPR.[54] Another example is FoodInsights, which allows food products to be traced along a supply chain using blockchain technology, and can provide a DPP.[55]

Despite the idea still being new, the expectations placed by the Commission on the DPP are high,[56] as is evidenced by the central role of the DPP as an information tool within the ESPR's framework. In view of the fact of a yet-to-be-defined technology,[57] the question arises whether these hopes are warranted. Can the DPP not only put customers (consumers) in a position to but actually push them to make more informed and sustainable choices while improving the traceability of products, and also ease administrative burdens for businesses and public authorities by facilitating product compliance? An evaluation will be conducted by examining the DPP's general efficiency as an information tool (4.1), its interaction with other information channels like labels (4.2), and how the DPP is likely to affect the position of consumers (4.3). The dimension of regulatory compliance control will not be investigated in this paper.

4.1 The Efficiency of the DPP as an Information Tool

As an information tool, DPPs are meant to 'significantly enhance end-to-end traceability of a product throughout its value chain' (Rec 32 ESPR). Let us consider how this will work in practice from the perspective of the customer and of the economic operator responsible for the DPP.[58] Beginning with the latter, the economic operator will first need to gather the necessary product information and create a DPP along with a unique product identifier and a data carrier (compare Art 10(1)(a)). They are free to create their own technical infrastructure or use commercially available DPP infrastructures.[59] The economic operators need to include information about the manufacturer and other relevant operators like importers and their unique identifiers, the unique product identifier, relevant product data relating to its performance and sustainability, as well as digital copies of documentation like instructions, data sheets, or safety information sheets (see Annex III and Arts 9(2)(a), 7(2)(b)). The DPP's data will then be registered in the Commission's DPP registry for access by public authorities, customs authorities, and for general authentication purposes. The data carrier will be

[54] See <https://www.circularise.com/company> and <https://www.circularise.com/dpp-for-espr> both accessed 3 November 2025.
[55] See <https://foodinsights.nl/> and <https://foodinsights.nl/projects/de-kloeke-kip-healthy-chicken-meat/> both accessed 3 November 2025.
[56] Compare Adisorn and Tholen and Götz (n 10) in Section 1, noting a general high level of political expectations.
[57] The Commission has been in an open dialogue with stakeholders in relation to the technical requirements, see DPP Standardisation Webinar (n 22).
[58] The following business and user stories are based on explanations provided by the Commission in the DPP Standardisation Webinar (n 22), unless indicated otherwise. Further technical details on both stories can be found in Abdelrahman Abdalla, 'DPP User Stories' (March 2024) 12 and 13, available at <https://cirpassproject.eu/wp-content/uploads/2024/04/DPP_User_Stories_V2.0_Final.pdf> accessed 3 November 2025.
[59] See note 53 above.

supplied to dealers and online marketplace providers, and be placed either on the product itself, the packaging, or any documents accompanying the product like a data sheet (see Art 10(1)(b)). While specifics for the data carrier's presentation under the ESPR have not yet been laid down, it has been established that data carriers in the form of QR codes must be engraved on batteries.[60] After the initial creation process, the operator must keep the data complete and up to date, and continue to provide the DPP and the data, even after they cease their business activities (Arts 9(1) and 11 point e). This is a challenge and incurs costs for the economic operator.[61]

Moving on to the customer, they will first need to scan the data carrier like a QR code of a product they are interested in. The DPP reader on their device will then show them basic product information and a link to the product's DPP. This information set will be available from the data carrier itself, offline; the DPP and other product information needs to be accessed online. In order to avoid counterfeits and fake data carriers, the data carrier will include a link to an online verification service. After scanning the data carrier, the service will show the user whether the carrier is authentic by comparing the data carrier's hash code to the records of the DPP Registry. If the data is shown to be authentic, the customer can rely on the DPP's data with confidence and make an informed and sustainable purchase decision.

After considering these use stories, it is apparent that the DPP is a comprehensive information tool that is nevertheless easily understandable. The idea of having all product data in one place, namely, the DPP, which can be retrieved by scanning a data carrier found on the product or its packaging, means that the product data will be readily available at the customer's fingertips. As such, the DPP presents itself as a convenient and comprehensive information tool that empowers consumers and is reminiscent of EPREL. This hypothesis is weakened by two significant practical matters.

One important limitation to the DPP's effectiveness is that not all consumers will be able to access the DPP: Not those who do not have a device or an internet connection required to download and read the DPP's information, like the less affluent; neither those who do not possess the necessary digital literacy skills to gain access, like some elderly people; nor those with disabilities, like people with a visual impairment, or those with literacy or numeracy difficulties. This wide field of exclusion impacts the DPP's

[60] Recital 44 and Art 13(6)-(7) Regulation (EU) 2023/1542 of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC [2023] OJ L191/1. See also DPP Standardisation Webinar (n 22). On the problems of data carrier presentation, namely, of how to present a data carrier on the product in a way that is durable and allows it to be machine readable, see Colledani and Abdalla (n 53) 20.

[61] Compare Josefin Lövdahl and Sophie I Hallstedt and Jesko Schulte, 'Implications of EU Instruments on Company Capabilities to Design More Sustainable Solutions – Product Environmental Footprint and Digital Product Passport' (2023) 3 Proceedings of the International Conference on Engineering Design 2245, 2250, 2251.

inclusivity and diminishes the DPP's effect of empowering consumers (on which see further 4.3 below).[62]

Even when leaving the inclusiveness issue aside, the act of retrieving the DPP by the customer (scanning data carrier, downloading DPP) is a hurdle that may impair the DPP's effectiveness. This is particularly true at the pre-purchase stage, where the customer is in a physical store. Here, the customer may not have internet access, or neither the time nor the willingness to download the DPP and to browse the information in it.[63] The latter two reasons equally apply to online stores, although here, the hurdle will arguably be lower than in a physical store: Customers have an electronic device at their disposal, which may be specialised equipment or contain assistive technology to enable people with disabilities to use the DPP.[64] Moreover, the DPP can be made accessible through a link on the product's webpage, the clicking of which is an easier action than scanning a QR code. While the retrieval hurdle is a drawback, it can be argued that this effect is generally minor. The average consumer[65] is versed in accessing information online, so scanning a QR code to obtain the DPP and going over the information should not be an inconvenience for most. In addition, many public places offer free internet, which reduces this hurdle. But the fact remains that some consumers may not have a device available to view the DPP. Short of retailers lending consumers devices to do so, or the DPP's information being provided in print, there may be no solution. However, the former does not seem feasible on a global scale, while the latter would not be ecological and thus defeat the DPP's sustainability purpose. Moreover, a printed version of the DPP will not be accessible to consumers with disabilities and no device. Unless consumers have the possibility to consult DPPs at some other place prior to purchase and do so, the DPP will therefore practically remain inaccessible for some consumers at the time of making a purchasing decision.

It ought to be noted that the DPP's effect is not limited to the pre-purchase stage. Its data is relevant for customers after the sale transaction as well. It is convenient when setting up a product, when looking for information on how best to maintain and repair it, and where and how to dispose of it. Similarly, economic operators like repairers, refurbishers, or waste managers may need to access the DPP in order to properly handle the product and update the product's data,[66] eg, where a product is repaired with spare

[62] Beside this, there is of course the general difficulty of consumers to process the information and act on it rationally. This is another, general limit on the empowerment effect of information. A summary of these consumer limitations can be found in Geraint Howells, 'The Potential and Limits of Consumer Empowerment by Information' (2005) 32 Journal of Law and Society 349, 359-362.

[63] In this vein, Adisorn and Tholen and Götz (n 14) note in Section 3.4 that '[i]n order for customers to make sustainable purchasing decisions, information needs to be accessed with least possible effort.'

[64] On these technologies, see Bryan Boyle and Fiachra O'Brolcháin, 'Understanding the Assistive Potential of Consumer Technologies: A Case Example of Smartphones, Smart Speakers, and Internet of Things Technologies' in Alejandro Rafael Garcia Ramirez and Robert Koprowski, *Trends in Assistive Technologies* (IntechOpen 2023) doi: <10.5772/intechopen.105664> accessed 3 November 2025.

[65] cf the cases discussed in the previous paragraph.

[66] See on this Abdalla (n 58) 13, 16-17, 21-22. See also Adisorn and Tholen and Götz (n 14) in Section 3.2.

parts but these 'are used differing [sic] from the original product set up, [then] waste operators could require adjusted product information for recycling purposes.'[67] Nevertheless, the DPP's continued usefulness over the product's lifetime does not do away with the loss of impact at the time of making the purchase decision.

All of this means that while the DPP has the potential to be a powerful and versatile information tool for all economic actors, there are practical limitations that lead to some customers being excluded categorically or situationally from the DPP's benefits (see also Section 4.3 below).

4.2 The Interaction of the DPP and Labels under EU Law

EU law already foresees a range of information tools, with labels being one. Energy labels are a prominent[68] example; quality labels under the Geographical Indications System[69] are another, albeit less conspicuous one.[70] As stated above, energy labels are foreseen as an information requirement under the Energy Label Regulation.[71] This covers 19 product groups ranging from cooking appliances (eg, ovens), over cleaning machines (eg, vacuum cleaners) and heating (eg, space heaters), to electronic products (eg, TVs and smartphones).[72] As these products are also covered by the ESPR and the Energy Label Regulation was not repealed, energy labels and ecodesign labels could potentially appear on these products in parallel, provided the information required under the ESPR cannot be incorporated into the energy label and that the Commission does not dispense with the energy label requirement (Art 16(3) ESPR). Energy labels are said to be 'the default option' over ecodesign labels.[73]

This interaction between the two pieces of legislation, possibly resulting in several labels being placed on products with each bearing a number of different product attributes, brings the risk of a visual and consequently information overload for customers at the point of sale.[74] Rather than informing consumers, the labels may have

[67] Adisorn and Tholen and Götz (n 14) in Section 4.
[68] According to a survey from 2019 (five years after the label's launch), 93% of consumers in the EU recognised the label and 79% referred to it when making a purchase decision, see <https://commission.europa.eu/news-and-media/news/commission-launches-eprel-database-help-consumers-energy-efficient-products-2022-05-17_en> accessed 3 November 2025.
[69] On this system, see <https://agriculture.ec.europa.eu/farming/geographical-indications-and-quality-schemes/geographical-indications-and-quality-schemes-explained_en> accessed 3 November 2025.
[70] The Commission's evaluation of the scheme in 2021 stated that around 3300 geographical indications were registered with a sales value equivalent to 6.8% of the total food and drink sales in the EU in 2017, but that consumer awareness of the scheme is 'generally lower than recognition of national/regional schemes' and remains limited. See Commission, 'Evaluation of Geographical Indications and Traditional Specialities Guaranteed Protected in the EU' SWD (2021) 427 final 13, 16, 36, 40, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2021:427:FIN> accessed 3 November 2025.
[71] A summary of the requirements is provided by Adisorn and Tholen and Götz (n 14) in Section 3.1.
[72] See <https://energy-efficient-products.ec.europa.eu/product-list_en> accessed 3 November 2025.
[73] Ecodesign Working Plan 10.
[74] Compare Han-fen Hua and Anjala S Krishen, 'When is enough, enough? Investigating product reviews and information overload from a consumer empowerment perspective' (2019) 100 Journal of Business Research 27, 28, noting that a number of product attributes or alternatives may cause information overload, because such an overload occurs where

the reverse effect of confusing them, as the consumer may be unsure what each label stands for Section 5.2 offers suggestions for mitigating this risk.

4.3 The DPP and Consumers

As stated above, the ESPR's main objective is to support the development of a circular economy and thus 'contribute to achieving the Union's climate and energy objectives' (Recs 3, 9 ESPR). At the same time, the interests of consumers —sometimes referred to as citizens or customers— are referenced several times in the ESPR's recital. In particular, the possibility for consumers to make informed decisions on sustainable choices through reliable, clear, and non-misleading product information is stressed (Recs 3, 32, 48). As such, the ESPR also pursues consumer protection goals. Indeed, the ESPR's information duties are a classical instrument of EU consumer law,[75] which seeks to empower the consumer.[76]

The ESPR is interesting in terms of its consumer policy in two respects: First, the Regulation seems to signal a further shift in the EU's consumer protection approach as it merges classical consumer law and the protection of businesses (SMEs) by adopting the term 'customer' to encompass both businesses and not just private individuals.[77] Secondly, its approach of empowering consumers rather than protecting them. While the product performance requirements will set minimum values for product parameters and this could be seen as a protection of consumers against ecologically badly performing products, the ESPR's focus is rather on enabling consumers to act, to make sustainable choices.[78] As mentioned, this approach was already adopted in the European Green Deal with respect to the other sustainability initiatives,[79] as well as in the New Consumer Agenda.

This focus on empowerment brings with it the risk of losing sight of the 'protective instinct' of EU consumer law, so that it is accepted that at least some consumers may be harmed in the single market.[80] In this context, the risk is of a disadvantage rather than harm for some consumers: Not being able to act in the sustainable way that a

'the information load exceeds the individual's cognitive capability'. The number and variety of sources of information are a contributing factor to information overload, see Leila Shahrzadi and others, 'Causes, consequences, and strategies to deal with information overload: A scoping review' (2024) 4 International Journal of Information Management Data Insights 100261, <https://doi.org/10.1016/j.jjimei.2024.100261> accessed 3 November 2025.

[75] Information issues were addressed in early EU consumer legislation, like misleading information (Council Directive 84/450/EEC of 10 September 1984 concerning misleading and comparative advertising [1984] OJ L250/17), and information obligations were introduced (Council Directive 85/577/EEC of 20 December 1985 to protect the consumer in respect of contracts negotiated away from business premises [1985] OJ L372/31).

[76] See on this De Almeida and Esposito (n 6) 410. See also Stephen Weatherill, 'Empowerment is not the only Fruit' in Dorota Leczykiewicz and Stephen Weatherill (eds), *The Images of the Consumer in EU Law* (Bloomsbury 2016) 203, 211.

[77] See on this trend Jorge Morais Carvalho and Mateusz Grochowski and Joasia Luzak, 'EU Consumer Law: a Few Prognoses for 2025' [2025] Journal of European Consumer and Market Law (EuCML) 1–2, noting that the traditional distinction between businesses and private persons 'is increasingly blurred'.

[78] Compare De Almeida and Esposito (n 6) 410, discussing consumer empowerment in EU law more generally.

[79] See European Green Deal 8. See also De Almeida and Esposito (n 6) 412.

[80] Weatherill (n 76) 203-204.

consumer may wish. This stems from the flaw that groups of vulnerable consumers (less affluent, elderly, disabled) are seemingly being left out categorically (see Section 4.1 above). Due to their situation, these consumers are excluded from the benefit of the DPP and must rely on other information sources, like labels, scores, and any advertising material provided by the dealer.

The fact that the ESPR's primary objective is ecological, the question arises whether the information requirements under the ESPR generally and the DPP particularly are truly meeting consumer interests or whether these measures serve to digitise and strengthen the internal market further.[81] Since concrete provisions are yet to be laid down in delegated acts, the following observations are necessarily crude. They assume that consumers are interested in acting in a sustainable manner when making purchases, and that they want to make informed choices.[82] On this premise, it would seem that the DPP can 'close the gap between consumer demands for transparency and the current lack of reliable product data',[83] and increase the reliability of green claims.[84] This removes barriers for consumers to take up sustainable purchase options,[85] leading to more sustainable products being purchased and used. At the same time, the DPP facilitates trust in product authenticity and supports consumers when it comes to disposing of their products.[86] Moreover, accessible information will reduce hurdles to engage with a product and may increase the rate of consumers making use of their rights, in particular the newly introduced right to repair.[87] In this way, the DPP will not only empower consumers but help safeguard their rights.

[81] Contrast Bert Keirsbilck, 'Empowering Consumers for the Green Transition: Overview of Directive (EU) 2024/825' [2024] EuCML 205, 206, noting that '[a]rguably, environmental protection is seen by the EU legislature as 'ancillary' to, or as a mere 'by-product' of, the objective of consumer protection, just like consumer protection is traditionally seen as a 'by-product' of the objective of internal market building.' This argument is true for the Directive (EU) 2024/825 of 28 February 2024 amending Directives 2005/29/EC and 2011/83/EU as regards empowering consumers for the green transition through better protection against unfair practices and through better information (2024) OJ L2024/1 (hereinafter 'Green Transition Directive'), which states consumer and environmental protection in its Rec 1; however, the ESPR clearly focusses on environmental protection (see above).

[82] The Commission has stated previously that consumers 'are showing a growing interest in contributing personally to achieving climate neutrality, preserving natural resources and biodiversity, and reducing water, air and soil pollution', see Green Deal 5. This implies an interest in sustainability. Of course, this premise will not apply to all European consumers, either due to their choice, their (financial) needs, or their simple disinterest. Compare Abraham Zhang and Stefan Seuring, 'Digital Product Passport for Sustainable and Circular Supply Chain Management: A Structured Review of Use Cases' (2024) 27 International Journal of Logistics Research and Applications 2513, 2527, pointing out the necessity of the customer's willingness to engage with the DPP at the time of purchase and disposal. See more generally Stefan Grundmann, 'Targeted Consumer Protection' in Leczykiewicz and Weatherill (n 76) 223, 227, noting that consumers with different characteristics have 'diverging interests'.

[83] Anonymous, 'EU's Digital Product Passport: Advancing Transparency and Sustainability' (*European Data*, 27 September 2024) <https://data.europa.eu/en/news-events/news/eus-digital-product-passport-advancing-transparency-and-sustainability>, accessed 3 November 2025.

[84] Compare Lövdahl and Hallstedt and Schulte (n 61) 2247.

[85] See New Consumer Agenda 7.

[86] See Zhang and Seuring (n 82) 2524.

[87] Directive (EU) 2024/1799 of 13 June 2024 on common rules promoting the repair of goods and amending Regulation (EU) 2017/2394 and Directives (EU) 2019/771 and (EU) 2020/1828 [2024] OJ L1799/1 (hereinafter 'Right to Repair Directive'). For a brief comment on this right, see, eg, Keirsblick (n 81) 216; Alberto de Franceshi, 'The Sustainability of Consumer and Market Law: Green Claims, Greenwashing and the Right to Repair' [2023] EuCML 45-48.

For this to come true, however, the DPP's inclusivity will need to be safeguarded so that —ideally— all consumers can have access to the DPP's information (see above). Furthermore, the information needs to be kept simple in order to allow consumers to make sustainable choices; an overwhelmed consumer will not make the 'best' choice. This raises the question whether the DPP can deliver information on which product out of a group selection is 'the most "circular" or sustainable' in a way that is persuasive for customers.[88] This will depend on subsequent regulation.

5 Interim evaluation, improvements, and outlook

The examination of the ESPR's information requirement framework and considerations of some potential issues of these measures allows for an interim evaluation of the ESPR (Section 5.1). To round off the discussion, suggestions for improvements of open problems are made (5.2) and an outlook on the EU's sustainability measures is given by way of a conclusion (5.3).

5.1 Interim Evaluation of the ESPR

The ESPR promises to be a powerful measure with a wide scope that sets minimum performance requirements and sees to the delivery of an array of information to customers through several channels. The DPP is the main communication method, complemented by labels and the traditional document form. For consumers, the DPP will be convenient, as it will put trustworthy information about a product at the consumer's fingertips. This empowerment comes with an essential limitation: Consumers with disabilities, those who do not have the necessary (digital) literacy skills, or those with no access to electronic devices required to view the DPP, will be excluded from this benefit. This has a knock-on effect on the DPP's efficiency as a tool for providing information and for empowering consumers. Nevertheless, the ESPR's goal to foster sustainability can still be said to be successful to the extent that the overall benchmark for sustainable products will be raised: After the ESPR and the delegated acts have come into force, consumers will have less options for making unsustainable choices; there will be only 'more or less sustainable products' to choose from.[89]

From a business perspective, despite the extra effort of its setup and maintenance, the DPP may well turn out to be a beneficial tool for supply chain management that will

[88] Compare Adisorn and Tholen and Götz (n 14) in Section 4.

[89] Compare Keirsblick (n 81) 216. Having said this, consumers can still act unsustainably in other ways, like purchasing more goods than needed, or by disregarding repair or recycling options and replacing items with new ones. On another note, the ESPR contains weak points, namely, a loophole in the form of voluntary industrial agreements and the questionable enforcement of the ESPR against online platforms, both of which may lessen the ESPR's sustainability effect. See on this Cristina Ganapini, 'New Ecodesign for Sustainable Products Regulation (ESPR) – What does it mean for Repair?' (20 June 2024) <https://repair.eu/news/new-ecodesign-for-sustainable-products-regulation-espr-what-does-it-mean-for-repair/> accessed 3 November 2025.

reduce carbon emissions and enhance sustainable production. The administrative burden of creating and maintaining the DPP should not be disproportionate, as businesses are already obliged to collect and provide product data, like energy efficiency. Moreover, seeing as though DPPs will enable customers to compare products based on their sustainability, this will increase competition in the market and, in turn, foster product development (improvement) so that businesses can maintain their reputation and keep their customers.[90] The reliability of the DPP data will also cultivate the consumer's trust in the business.

In terms of the Commission's various deals, agendas and action plans that relate to the ESPR, the DPP will contribute to their achievement: The DPP itself realises part of the CEAP, and this being an initiative of the Green Deal, therefore also materialises part of that goal.[91] For the reasons mentioned, the DPP will also support the Green Transition proposed in the New Consumer Agenda, albeit with the caveat of not managing to include all consumers, irrespective of their financial situation and whether they are vulnerable or average. Nevertheless, the ESPR is a move towards a circular economy in that the DPP will put many —if not most— consumers into a position where they can inform themselves about sustainable product aspects and make corresponding choices both prior to and after the purchase. It has been said that consumers have a duty to contribute to the Green Transition.[92] The DPP will be their tool to do so, although it has limitations.

5.2 Suggestions for Improvements of the ESPR

Despite the ESPR's positive prospects, there are aspects that require further attention. One concerns the ESPR's reach in two ways, namely, its product scope and its inclusiveness of consumers. While delimiting the ESPR's scope is necessary in order for this already broad framework to be workable, the exclusion of the product groups of food and second-hand goods from the ecodesign requirements is an important opportunity that is being missed. Both exclusions are surprising.[93]

With regard to second-hand goods, the Commission deliberated the promotion of 'new consumption concepts and behaviours, such as […] support for repairs through community and social economy organisations actions (eg, repair cafés) and for second-hand markets' in the CEAP.[94] In 2024, 87% of European citizens were engaged in used goods transactions.[95] While the lack of a DPP for second-hand products will not

[90] Compare Zhang and Seuring (n 82) 2526. The authors point out other advantages and challenges for customers and businesses at ibid 2527.
[91] See Lövdahl and Hallstedt and Schulte (n 61) 2246.
[92] De Almeida and Esposito (n 6) 411.
[93] Due to the complexity of the matter both from a regulatory and behavioural economics perspective that deserves deeper consideration, food will not be discussed further in this paper.
[94] CEAP 8.
[95] See Anonymous, 'The latest Figures on Europe's Explosive Second-Hand Market' (*Wavestone*, 15 February 2024) <https://www.wavestone.com/en/news/the-latest-figures-on-europes-explosive-second-hand-market/> accessed 3 November 2025.

discourage those that already purchase such products, providing product information through a DPP may encourage part of the 23% of consumers who are currently not in the habit of purchasing used products: Knowing about things like origin, lifespan, or how to handle a product in terms of its maintenance, repair, and disposal, may reassure consumers and give them the confidence to enter the second-hand market, ie, it will increase the buyer's trust.[96]

The difficulty with used products that are resold is, of course, who ought to be responsible for the establishment of the DPP where none exists, or its update where a DPP is already in place. Unlike with new products, where the DPP's creator will usually be the product's manufacturer, there is no appropriate subject with second-hand products. The seller of the used product would be an obvious candidate; however, private persons, independent stores, and perhaps neither SMEs should be expected to bear the burden of this task. Such a measure is likely to dissuade current second-hand market participants. While an obligatory DPP for second-hand products therefore seems unreasonable, incentives for businesses (particularly online platforms like ebay, momox, etsy, etc) or charities like Oxfam and the British Heart Foundation may persuade these entities to invest in technical infrastructures allowing for the creation of DPPs for these goods. In this case, manufacturers ought to cooperate in the creation process to supply basic product data. Allowances ought to be made for incompleteness of information, which may not be available for all products, depending on their age, origin, or state. The age of a product may also act as a cut-off criterion, so that products over a certain age or those whose the age cannot be determined, need no DPP. As for the storage of the DPP's data, this may need to be centralised, for instance in a European second-hand DPP register. Such a move would truly support circularity and sustainability.

In this respect, the connection of DPPs of original products and the DPPs of their 'second life' form, which may arise through recycling, is an important issue that needs to be addressed. Currently, the ESPR makes no provision for this; however, the Commission is investigating how the transfer of data between DPPs may be possible and for which product-groups this is feasible.[97]

In terms of the ESPR's inclusivity and empowerment, care must be taken to give all consumers potential access to the information that is mandated by the Regulation. Currently, there is a danger that several groups of consumers will be excluded from the benefits of the DPP, which contradicts the aims of the New Consumer Agenda (see 1. above). Nevertheless, it is not clear how this issue can be tackled satisfactorily.

The issue of digital literacy and access to digital devices go beyond the ESPR and ought to be addressed through EU-wide measures. For instance, digital literacy might be raised through incentivised education campaigns across the EU. As for the less affluent

[96] See Zhang and Seuring (n 82) 2523, 2524.
[97] See DPP Standardisation Webinar (n 22).

consumers who do not own digital devices, the Commission might nudge Member States to establish collection and redistribution schemes of unwanted but working digital devices, akin to food banks. This would support sustainability, as devices are reused purposefully. Both measures would promote the New Consumer Agenda's green and digital transitions.

With disabled people, it should not be presumed that they have devices with assistive technology that would enable them to access the information, as several barriers to these technologies exist.[98] Therefore, active measures to support people with disabilities are necessary. Providing consumer information, including labels and instructions in alternative formats, that is, in 'more than one sensory channel', and presented in an understandable and perceivable way, is one strategy that is being realised for specific products and services through Art 4(2) and Art 1 Sec I Annex I Accessibility Act[99]. Accordingly, products like e-readers and 'consumer general purpose computer hardware systems and operating systems for those hardware systems' need to be accessible in this way when placed on the market after 28 June 2025 (Art 2(1)(e) and (a) Accessibility Act). Measures include Braille, audio, and allowing text sizes to be changed (see Annex II Accessibility Act). While the ESPR makes no explicit reference to the Accessibility Act, the DPP ought to be designed so as to be accessible to vulnerable consumers. In other words, the DPP ought to be able to provide the information in alternative formats. This would allow those with reading difficulties, whether due to a visual impairment or poor eyesight, to access the information. Moreover, interoperability with assistive technologies should be ensured. This would support accessibility further, as not only specialised assistive devices, but standard digital consumer devices such as smartphones and tablets can be equipped with assistive technology apps; and Smart Speakers offer accessibility through voice commands.[100]

Another aspect that needs to be addressed carefully is the information load for consumers, particularly at the point of sale. If (all) products in a shop have several labels, stickers, and scores attached to them, this can lead to a visual overload, with the consequence of a confused rather than informed consumer. Accordingly, it would be best to avoid two labels on one product wherever possible and have either an energy label or an ecodesign label. Alternatively, confusion may be avoided by designing the ecodesign labels in a distinctive way from energy labels, eg, by using a different but complementing colour scheme.[101] This will allow consumers to distinguish between them

[98] On these technologies and the barriers to them, see Boyle and O'Brolcháin (n 64).
[99] Directive (Eu) 2019/882 of 17 April 2019 on the accessibility requirements for products and services [2019] OJ L 151/70. On the situation prior to the enactment of this directive, see, eg, Ieva Eskyte, 'Disabled People's Vulnerability in the European Single Market: The Case of Consumer Information' (2019) 42 Journal of Consumer Policy 521-543, particularly 524.
[100] See on this Boyle and O'Brolcháin (n 64).
[101] Where too much of the same colour is used, this can be overwhelming, so complementing and non-clashing colour schemes should be combined, see Anonymous, 'How Colour Affects Consumer Behaviour' (*UKPOS*, January 2020), <https://www.ukpos.com/knowledge-hub/how-colour-affects-consumer-behaviour> accessed 3 November 2025.

at a glance.[102] In either case, information on the labels should be kept to a minimum and as simple as possible to maximise their effect and counteract information overload.[103] Instead of cramming various pieces of information into different labels, the DPP ought to be presented as a comprehensive and yet easy-to-understand data source. Here, overload may be reduced by ordering information according to its importance (highest comes first) and highlighting the most salient pieces of information.[104] Moreover, visualisations in the form of pictograms or graphs should be used rather than information tables whenever possible, as the latter will increase the risk of information overload.[105]

In relation to the repairability score, the price of spare parts is an important factor that has not received sufficient attention: The scoring systems developed by the JRC factor in the price of spare parts; however, only the publication of spare part prices is measured.[106] In other words, the criteria is that *information on* the price of spare parts is published; but there is no regulation of the *price itself*. This conflicts with Rec 30 and Annex I ESPR, which list the price (affordability) of spare parts explicitly as one parameter for repairability scores (see 3.3 above). As has been noted, repair costs of anything over 40% of the purchase price will dissuade users from repairing a product, whereby this includes the price of spare parts and labour costs of the repair.[107] This limit is surpassed by a range of products,[108] yet the duty to provide spare parts at 'reasonable prices' under Art 5(4) Right to Repair Directive will likely not resolve this, as the criteria is not defined.[109] This necessitates regulation of a maximum price for (vital) spare parts in the form of a percentage of the original purchase price that is fixed and published, as apparently originally envisaged by the Commission.[110] This would counteract price

[102] Colour is the first thing a consumer processes, before text or images, see, eg, ibid. See also Daivata Patil, 'Coloring consumer's psychology using different shades the role of perception of colors by consumers in consumer decision making process: a micro study of select departmental stores in Mumbai city, India' (2012) 7 Journal of Business and Retail Management Research 60, 65 <https://www.jbrmr.com/cdn/article_file/i-16_c-135.pdf> accessed 3 November 2025. Patil, ibid, goes on to note at 66 that information retention increases with information in colour over that presented in black and white.

[103] Compare Shahrzadi and others (n 74).

[104] Suggested by Grundmann (n 82) 237.

[105] Compare Lisa Falschlunger and Othmar Lehner and Horst Treiblmaier, 'InfoVis: The Impact of Information Overload on Decision Making Outcome in High Complexity Settings' (2016) Special Interest Group on Human-Computer Interaction (SIGHCI) 2016 Proceedings 3, 4, noting from their study that '[t]ables seem to trigger information overload more frequently than graphs'.

[106] See Cordella and Alfieri and Sanfelix (n 48) 43. cf Spiliotopoulos and others (n 48) 13, where it states that only the availability of spare parts to different groups of people (all end users or professional repairers only) is factored into the score. The reason is that 'the draft ecodesign regulation sets the requirement that the maximum pre-tax price of spare parts […] shall be disclosed and not raised later on'. Sadly, this requirement cannot be found in the ESPR.

[107] See Thomas Opsomer, 'The Price Is Not Right' (*RepairEU*, 7 November 2023), <https://repair.eu/news/the-price-is-not-right/> accessed 3 November 2025. See also Cordella and Alfieri and Sanfelix (n 48) 55, stating 30-40% of the product's value generally and 30% for electronic products to be the upper limit.

[108] See Opsomer (n 107) for examples and an exploration of the possible reasons.

[109] Cf Cristina Ganapini, 'Ecodesign Information Requirements on Original Spare Parts Prices' (White Paper, February 2025) 5, 7 <https://repair.eu/wp-content/uploads/2025/02/White-Paper-on-Price-of-Spare-Parts-Final.pdf> accessed 3 November 2025.

[110] See Spiliotopoulos and others (n 48) 13 and n 106 above. See also Ganapini, 'Spare Parts' (n 109) 5.

fluctuations and extortions, thus contributing to truly informed consumer choices and greater consumer willingness to repair products.[111] Moreover, fragmentation in the single market would be avoided, while including the fact of spare part prices in the repairability score would not only meet consumer expectations but maintain trust in the score.[112] These prices could be included in the DPP so as to be available to customers when making the purchasing decision.[113]

A final improvement is suggested for the DPP Registry or the DPP system: If either allowed for the automatic generation of a data carrier, a label, and a product information sheet, as is the case in the EPREL Compliance system, this would be a cost and time efficient tool for businesses.[114] No such plans seem to exist on the Commission's side, as it has opted for a decentralised data storage approach and will not provide the DPP technical infrastructure;[115] but it is a feature that commercial DPP providers may want to try and include in their services.

5.3 Conclusion and Outlook for EU Sustainability Measures

The ESPR is a remarkable endeavour. It is set to support the interrelated goals and initiatives of the Green Deal, the CEAP, and the New Consumer Agenda, in particular its Green Transition. The ambitious measures include performance requirements and information obligations, which are geared towards making products in the European single market more sustainable. The ESPR manages to target both businesses as the economic operators, as well as customers. The DPP will prove to be a useful tool to achieve the ESPR's aims of enhancing supply chain management and allowing consumers to make sustainable choices across a wide range of products. Nevertheless, it must be ensured that the DPP and other information sources are accessible, so as not to deprive certain customer groups (particularly vulnerable consumers) of the benefits of these sources and the chance to be empowered to make informed and sustainable choices. It remains to be seen from the implementation measures and the DPP service providers how great the ESPR's empowerment effect will be. Irrespective of this, in order to strengthen the Regulation's influence on sustainability further, its range of products could and should be expanded to include — in the form of a voluntary scheme— second-hand goods. While this seems like a radical proposal, this responds to consumer demands and trends and further supports the EU's move towards circularity and sustainability.

By placing the DPP as the primary information source, with labels, scores, and more detailed sources like manuals or data sheets to complement it, information will be

[111] Ganapini, 'Spare Parts' (n 109) 5-6.
[112] See ibid 5, 7-8. Indeed, uniformity on repair is a declared aim of the Right to Repair Directive (see Rec 2).
[113] Cf Ganapini, 'Spare Parts' (n 109) 11, who states that a survey on the best way to make spare part prices available to consumers ought to be conducted, but names accessibility through a QR code as one possibility.
[114] On the EPREL Compliance system and this function, see <https://energy-efficient-products.ec.europa.eu/suppliers/eprel-generated-labels-and-pdfs_en> accessed 3 November 2025.
[115] See DPP Standardisation Webinar (n 22).

bundled. The availability of information will also support customers in being aware and making use of their rights, thus empowering them and safeguarding their rights. Furthermore, by setting performance parameters, the most unsustainable products will leave the market, which indirectly pushes consumers towards sustainable choices. From a business perspective, the bundling of information in one place, namely, the DPP, ought to balance the newly added burden of creating and maintaining the DPP. It will enhance trust in products and move businesses to improve their products. If seen as a tool to differentiate one's own products from competitors, the DPP can also be used to appeal to customers.[116]

The DPP has been criticised for not providing for a move towards transformational change in sustainability, but rather leading to 'products that might be better from a sustainability point of view than the status quo, but that are blind alleys on the way towards full sustainability', since circular products are not necessarily sustainable.[117] It is submitted that while this may be true, the ESPR will set a minimum benchmark of product performance. It will then be up to the market, namely, the competing actors, and, of course, customers, to move further towards sustainability. Similarly, the DPP's sustainability criteria have been criticised for being based 'on either fragmented approaches like circular economy, or some symptoms of unsustainability[; … i]nstead, these instruments should be designed starting from the root-causes of unsustainability'.[118] One example that comes to mind here is (electronic) products breaking wholly or partially relatively quickly. The Commission is aware of this issue of premature obsolescence and has addressed it in the ESPR (Rec 7, Art 5(2)).[119] The effectiveness of these measures will depend on what is laid down in future delegated acts. Irrespective of this, the DPP will facilitate products being repaired rather than being thrown away.[120] Again, it will be on customers and economic operators to change patterns of behaviour.

It has been duly noted that 'the DPP will not be a silver bullet for achieving a circular economy alone, but its realization might make particular sense to form a key instrument in a well-orchestrated policy mix'.[121] Indeed, it is not the perfect answer; however, the DPP is a step forward in that it will support product circularity and sustainability by facilitating improved data flows along the supply chain and enable the transition to a circular and carbon-neutral economy.[122] The Green Transition Directive, the Right to

[116] Compare Bär and others (n 103).
[117] Lövdahl and Hallstedt and Schulte (n 61) 2252. Furthermore, note the weaknesses identified by Ganapini, 'ESPR' (n 89).
[118] Lövdahl and Hallstedt and Schulte (n 61) 2252.
[119] Keirsblick (n 81) 211 notes that the ESPR's premature obsolescence concept conforms with the Green Transition's notion of early obsolescence, which in turn covers planned and functional obsolescence: 'where goods become non-functional or less performant without it being the result of normal wear and tear'. See also ibid 212. The issue has also been tackled by the introduction of the consumer's right to repair (see n 87 above).
[120] The DPP will thus support the consumer's right to repair, see Zhang and Seuring (n 86) 2524.
[121] Adisorn and Tholen and Götz (n 14) in Section 4.
[122] See Zhang and Seuring (n 82) 2514, 2529.

Repair Directive, as well as the Energy Label Regulation among others are other components that together with the ESPR will seek to change consumer behaviour in order to truly bring about a green transition and a circular, sustainable EU economy.[123]

[123] Compare Keirsblick (n 81) 216-217, noting that limitations of consumer choice are necessary to make this successful.

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SPECIAL SECTION

THE BSEF V COMMISSION CASE (T-113/20)

BRIDGING THE ECODESIGN DIRECTIVE AND THE ECODESIGN FOR SUSTAINABLE PRODUCTS REGULATION (ESPR)

Abstract

The judgment in BSEF v Commission (T-113/20) marks a turning point in the development of EU ecodesign policy. This article argues that the case consolidates the legal and conceptual shift from the energy-efficiency-based framework of the Ecodesign Directive to a broader sustainability paradigm now reflected in the Ecodesign for Sustainable Products Regulation (ESPR). It shows how the General Court affirmed the Commission's competence under the Ecodesign Directive to adopt material restrictions – such as the ban on halogenated flame retardants – as legitimate measures to enhance product recyclability and end-of-life outcomes. The judgment also clarifies the relationship between ecodesign, chemicals, and waste legislations, treating these regimes as mutually reinforcing rather than mutually exclusive. By rejecting industry claims of legal uncertainty, disproportionality, and unequal treatment, the Court validated the expansion of ecodesign's regulatory scope beyond energy performance. Situating T-113/20 within the broader evolution of EU product policy, the article reflects on its implications for the design, implementation, and future trajectory of the ESPR.

JEL CLASSIFICATION: K19; K32; K39; K41; L6; L63; L65; L67; Q5

SUMMARY

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 10.13135/2785-7867/12831

1 Introduction

At the crossroads of the EU's environmental, product, and chemicals policy and legislation, the case of *BSEF v Commission* (T-113/20) raised a novel question: can a substance be restricted not because of its hazardousness for the environment and human health, but because it undermines circularity and broader sustainability goals? For the first time, the General Court of the European Union ('Court', 'CJEU') ruled on the scope of Directive 2009/125/EC on establishing a framework for the setting of ecodesign requirements for energy-related products ('Ecodesign Directive'),[1] upholding a targeted ban on halogenated flame retardants ('HFRs') in electronic displays imposed by the European Commission ('Commission'). In doing so, it confirmed that ecodesign is no longer limited to energy efficiency alone: it has become a strategic tool for the green transition, capable of excluding substances in the name of material circularity and high-quality recycling. This ruling stands as a landmark in the development of EU product ecodesign legislation – and offers a preview of the legal and regulatory tensions likely to emerge under the new Regulation (EU) 2024/1781 establishing a framework for the setting of ecodesign requirements for sustainable products ('Ecodesign for Sustainable Products Regulation', 'ESPR').[2]

In the case at hand, the Court delivered its decision on the 16th of March 2022 on the legality of the ban on the use of HFRs in the enclosures and stands of electrical and electronic equipment ('EEE') imposed by the European Commission under the provisions of the Commission Regulation 2019/2021 laying down ecodesign requirements for electronic displays ('Regulation', 'contested regulation').[3] The case was brought before the CJEU by the Bromine Science Environmental Forum ('BSEF'), which argued that the Commission exceeded its legal powers in adopting the contested Regulation, along with violating a series of fundamental principles of the European Union ('EU').

BSEF, a Brussels-based trade association which represents the International bromine industry, was founded in 1997, with the objective of 'foster(ing) knowledge on societal and economy benefits of bromine and its applications'.[4] Bromine is one of the elements found in the periodic table and was discovered in 1826 by Antoine-Jérôme Balard and Carl Löwig.[5] Its name originates from the Greek word 'bromos' ('βρόμος') which translates as 'unpleasant odour', due to the sharp and toxic smell of bromine. Uses of bromine

[1] Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (recast) [2009] OJ L 285, 31/10/09 423.
[2] Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC [2024] OJ L, 28/6/2024.
[3] Commission Regulation (EU) 2019/2021 of 1 October 2019 laying down ecodesign requirements for electronic displays pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EC) No 642/2009 [2019] L 315/241, 5/12/2019 241.
[4] 'BSEF - Bromine: Powering Science and Technologies' (*BSEF*) <https://www.bsef.com/> accessed 13 May 2025.
[5] Royal Society of Chemistry, 'Bromine - Element Information, Properties and Uses | Periodic Table' (*Royal Society of Chemistry*) <https://periodic-table.rsc.org/element/35/bromine> accessed 13 May 2025.

compounds include areas such as water treatment, reduction of mercury emissions, fire safety, energy storage and generation, production of pharmaceuticals and enhanced quality rubber.[6] More specifically, and to the extent relevant for the present analysis, bromine compounds can be used as flame retardants added to furniture foam, plastic casings for electronics and textiles, in order to reduce their flammability.[7]

It was exactly this use of bromine that the Commission targeted with the ban imposed with its Regulation 2019/2021. This Regulation includes restrictions on hazardous substances in electronic equipment, such as HFRs, whose presence in EEE was banned pursuant to Annex II (D)(4) of the same Regulation. BSEF requested its annulment on the basis of seven pleas, which were dismissed by the Court in their entirety as unfounded. The main legal issues brought forward by BSEF concerned breaches of both (i) Ecodesign Directive's provisions, on the one hand because the Commission was lacking competence to adopt Regulation 2019/2021, and on the other hand because the Commission made manifest errors in its assessment, as well as (ii) fundamental EU principles, namely that of legal certainty, proportionality and equal treatment or non-discrimination.

In essence, the Court was called to decide upon the extent to which the European Commission can, under the Ecodesign Directive, ban the use of specific chemical substances – such as HFRs – on the basis of recyclability reasons, without relying on the dedicated legal framework for chemical and waste management regulation. This question touches on several deeper legal and regulatory tensions: (1) whether the Commission has the authority to restrict substances via ecodesign measures or whether this encroaches on competences reserved for waste management and chemical legislation; (2) whether it is legitimate to impose substance restrictions under ecodesign rules – given that they are not primarily designed for chemical safety – rather than through the expressly relevant legislative acts; (3) whether such restrictions are sufficiently clear, justified and proportionate from the perspective of affected industries; and (4) whether, in the crossroads of evolution of EU product ecodesign and environmental law, it is possible to shift toward regulating harmful or non-circular substances 'by design' (i.e. not on account of their direct hazardous effects for the environment and humans, but of their poor or non-recyclability).

The net outcome of case T-113/20 is that the Commission's innovative use of the Ecodesign Directive to ban a category of environmentally unsustainable substances was validated. The Court's dismissal of the industry's claims set a strong precedent that material restrictions can be a lawful component of ecodesign requirements. In other words, this decision signalled that future ecodesign measures – now adopted only under the ESPR – might impose further material bans in support of sustainability goals, and that such measures would likely withstand CJEU's legal scrutiny if properly justified. It also

[6] BSEF, 'What Is Bromine: Uses, Properties, and Origin' (*BSEF*) <https://www.bsef.com/about-bromine/what-is-bromine/> accessed 13 May 2025.
[7] Royal Society of Chemistry (n 6).

serves as a bridge between the old and new regimes: it tested the kinds of actions that the EU is increasingly interested in taking (e.g. removing toxic substances for circularity reasons) and found them compatible with the ecodesign legal framework. As we turn to the ESPR, T-113/20 provides both a legal foundation and a cautionary tale for how the Commission should design future measures.

The present article is organised into three main sections, each subdivided to clarify its progression and analytical approach. Following the Introduction, which sets out the central question – namely, whether the EU's Ecodesign framework can restrict substances based on recyclability – and situates the *BSEF v Commission* judgment within the broader shift from the Ecodesign Directive to the new ESPR, a deep dive in the specifics of the case is provided under Section 2. This section is divided into three subsections: Sub-section 2.1 examines the Court's reasoning on the Commission's competence under Articles 1, 2, and 15 of Directive 2009/125/EC, drawing on a close reading of the contested Regulation 2019/2021, the Commission's impact assessment, and the judgment's references to Annex I of the Directive; Subsection 2.2 maps the relationship between the Ecodesign measure and parallel instruments – namely REACH, RoHS, and WEEE - and Sub-section 2.3 scrutinises how the judgment applies EU general principles – legal certainty (2.3.1), non-discrimination/equal treatment (2.3.2), and proportionality (2.3.3). Throughout Section 2, the methodology used combines doctrinal research (analysing EU regulations, directives, and case law) with a critical reading of the Commission's impact assessment and stakeholders' submissions.

Section 3 first sketches the historical evolution of ecodesign policy in its Sub-section 3.1 – highlighting the shift from energy efficiency to circularity under the European Green Deal's Circular Economy Action Plan - and then turns, in Sub-section 3.2, to how T-113/20's findings inform the ESPR's delegated-act procedure by quoting key ESPR definitions (e.g., 'substance of concern' in Article 2(27)(b)) and explaining how the new framework institutionalises material bans. Methodologically, Section 3 relies on a combined legislative analysis, examination of Commission communications, and secondary literature to assess how past judicial reasoning will shape future regulatory practice. Section 4 concludes with an overview of the main findings of the present analysis.

2 Unpacking T-113/20: case analysis

This section is devoted to an extensive analysis of how the Court addressed the core legal challenges brought by BSEF in its decision on case T-113/20. First, it focuses on whether the Commission acted within its powers under the Ecodesign Directive when banning HFRs in electronic displays - scrutinising Articles 1, 2, and 15 of Ecodesign Directive, the supporting impact assessment, and stakeholder consultations (Sub-section 2.1). Building on that analysis, Subsection 2.2 considers BSEF's argument that the contested Regulation 2019/2021 disregarded parallel instruments (i.e., REACH, RoHS,

WEEE), and shows why the Court viewed those regimes as complementary rather than exclusive (Sub-section 2.2). Finally, it explores how fundamental EU principles, such as that of legal certainty, non-discrimination, and proportionality, were invoked by BSEF and interpreted by the Court to uphold the HFR ban (Sub-section 2.3).

2.1 An affirmation of the Commission's *intra vires* competence to adopt Regulation 2019/2021

The first and main claim made by BSEF touched upon the competence of the Commission to adopt Regulation 2019/2021, thus exceeding the legal scope of its authority granted vis-à-vis the Ecodesign Directive. Although BSEF's argumentation was mainly based on the correlation of the Ecodesign Directive with other legislative acts, namely REACH, RoHS and WEEE – a relationship which will be discussed in more detail under the following sub-section 2.2 – the Court found the Commission's acts being well within the scope of its powers, remaining focused on the Ecodesign Directive's provisions.

Inasmuch as the authority to adopt implementing measures is concerned, the Ecodesign Directive establishes a legal framework for the Commission to set requirements for energy-related products, aimed at ensuring the free movement of such products within the EU internal market. As foreseen in Article 1(2) of this directive, the Commission has the authority to establish requirements that products ought to meet in order to be placed on the market or put into service. The purpose of these measures is to improve energy efficiency, reduce environmental impacts, and contribute to the EU sustainable development goals overall, and as such, include setting ecodesign requirements. Ecodesign is defined by Article 2(23) of the Ecodesign Directive as the 'integration of environmental aspects into product design with the aim of improving the environmental performance of the product throughout its whole life'. Given that the use of HFRs in electronic displays impacts the recyclability of the plastics from which the former are made, it falls directly under the environmental considerations required by the directive.

Moreover, Article 15(1) of the Ecodesign Directive grants the Commission the power to adopt these measures under the specific conditions which are provided by Article 15(2) of the same directive. The list of criteria includes, amongst others, that the 'product shall present significant potential for improvement in terms of its environmental impact without entailing excessive costs' with the 'absence of other relevant legislation or failure of market forces to address the issue properly'. The Court pointed out that, according to the impact assessment supporting the Regulation, the use of flame retardants reduces the quality of the recycled plastic, with the problem being particularly acute with regard to electronic displays, which are 'systematically incinerated'.

The Court also found the contested regulation to be in full alignment with Annex I of the Ecodesign Directive, which outlines the key stages of a product's lifecycle to which ecodesign requirements apply. These include namely raw material selection,

manufacturing, transport, use and end-of-life; the recyclability of materials being a critical aspect of this life cycle approach. Points 1.2(d) and (e) of the Annex focus on the need to consider the expected generation of waste materials and the possibilities for reuse, recycling, and recovery.

In addition to all the elements above, the Commission did, in accordance with Article 15(4)(b) of the Ecodesign Directive, conduct a comprehensive impact assessment, evaluating the environmental, consumer and manufacturing impacts of the contested regulation.[8] This assessment included an assessment of the Commission Regulation's 2019/2021 effect on competitiveness, innovation, market access, costs and benefits for all the stakeholders. At the same time, extensive consultations were conducted with stakeholders, ensuring that the regulation was not developed in isolation, but with useful input from those impacted, as mandated by Article 15(4)(d).[9] Another important point is that the ban imposed was of limited application, meaning that not all HFRs were covered under the prohibition, but merely those used in electronic displays are concerned. This approach ensures that proportionality is respected, without overreaching and overexpanding its scope of application.

Especially with regard to the impact assessment, BSEF contended in its second plea that this was not done appropriately. It claimed that the Commission conducted the Article 15(5)'s assessment as a mere 'box-ticking exercise' without much detail and depth. The Court, however, noted that BSEF referred to the conclusions and not the body of the assessment, which are by nature much more compact and descriptive, concluding that BSEF's argument cannot stand. But most importantly, the Court recalled that the contested regulation's impact assessment had explicitly concluded that REACH and RoHS bans of HFRs are 'not sufficient to achieve the objective pursued', thus the need to legislate farther was imperative. The presence of brominated flame retardants in plastic component constitutes a potential yet insurmountable barrier to the ongoing use re-use and recycling of waste products; uncontrolled recycling of waste polymers containing BFRs leads to the unintentional presence of such chemicals in articles in which their presence is not required, such as food materials, children's toys and polystyrene packaging.[10] This consideration facilitates significantly the understanding of the Court's argumentation in T-113/20, and at the same time foreshadows the broad latitude likely accorded to the Commission under the ESPR.

[8] European Commission, 'Commission Staff Working Document Impact Assessment Accompanying the Document Commission Regulation (EU) .../...Laying down Ecodesign Requirements for Electronic Displays Pursuant to Directive 2009/125/EC of the European Parliament and of the Council, Amending Commission Regulation (EC) No 1275/2008, and Repealing Commission Regulation (EC) 642/2009 (Part 1/3)' (2019) SWD(2019) 354 final.

[9] European Commission, 'Commission Staff Working Document Impact Assessment Accompanying the Document Commission Regulation (EU) .../...Laying down Ecodesign Requirements for Electronic Displays Pursuant to Directive 2009/125/EC of the European Parliament and of the Council, Amending Commission Regulation (EC) No 1275/2008, and Repealing Commission Regulation (EC) 642/2009 (Part 2/3)' (2019) SWD(2019) 354 final, 9 ff.

[10] Daniel Drage and others, 'Halogenated Flame Retardants in Irish Waste Polymers: Concentrations, Legislative Compliance, and Preliminary Assessment of Temporal Trends' (2022) 309 Environmental Pollution 119796.

An argument that is less convincing is that pertaining to the 'blanket ban' being justified by the fact that it is 'not financially viable' for the recyclers to determine which specific HFRs are present in plastics, resulting in incinerating all plastics containing HFRs, without an assessment whether the latter are present therein or not. Although it is true that screening methods are currently not financially viable,[11] with the more accessible ones are lacking at scale and level of accuracy, this argument presented by BSEF was also incidentally tested by the Court under the proportionality test whose rejection was not justifiably rejected on all its aspects.[12]

In conclusion, the Court expressed full support of the Commission's actions, affirming that the Ecodesign Directive was the appropriate framework under which regulation on the matter should have been adopted, and confirming that RoHS, REACH and WEEE operate complementarily rather than exclusively.

2.2 Mapping out the correlations between Ecodesign, REACH, RoHS and WEEE Regulations and Directives

An extension of BSEF's argument on the Commission acting *ultra vires* touches upon the question of whether the contested regulation 'was adopted in disregard of the scope and effectiveness of other EU legal instruments, such as the REACH Regulation, the RoHS Directive and the WEEE Directive'. The Ecodesign Directive in its Article 1(4) clearly states that 'the Directive and its implementing measures adopted pursuant thereto shall be without prejudice to Community waste management legislation and Community chemical legislation (…)'. Its Recital 35 also elicits which other EU legal instruments the directive at hand is complementary to, amongst which WEEE, RoHS and REACH can be found.

Contrary to the interpretation supported by BSEF, the Court confirms the Commission's reasoning according to which the phrases 'without prejudice' and 'complementary to' do not 'exclude the Commission's competence to act under the Ecodesign Directive in cases where it appears that a similar measure could be adopted under another EU legal instrument' but, however, notes that this measure would have 'a different scope' and would be adopted 'further to a different procedure'. In other words, the fact that the use of HFRs can be restricted under chemical regulation such as RoHS or REACH, does not *a priori* preclude the Commission's competence to restrict such use under the Ecodesign Directive. The relationship envisaged by the EU legislator which these legislative instruments is a parallel one. In light of these considerations, the Court deemed necessary to examine whether Commission Regulation's 2019/2021 adoption took place 'in

[11] Martin Sharkey and others, 'POP-BFRS in Consumer Products: Evolution of the Efficacy of Xrf Screening for Legislative Compliance Over a 5-Year Interval and Future Trends' (2022) 853 Science of The Total Environment 158614; Sebastian Strempel and others, 'Screening for PBT Chemicals among the "Existing" and "New" Chemicals of the EU' (2012) 46 Environmental Science & Technology 5680.
[12] See Section 2.3.3.

disregard' of these other legal instruments. An individual look to each of these acts is in this case necessary.

Firstly, Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[13] is a broad regulation controlling the use of chemicals, including substances of very high concern. It imposes restrictions on certain hazardous chemicals, but does not include provisions specifically targeting HFRs in electronic displays. As these products are not explicitly mentioned under REACH's provisions, the Court sided with the Commission's argument according to which, since REACH neither prohibits nor expressly permits the use of HFRs in electronic displays, then room was left for the Commission to act and regulate these substances, even if it is in the context of product ecodesign.

Secondly, Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) (RoHS Directive)[14] aims to reduce the use of certain hazardous substances in EEE, including HFRs like PBDEs (polybrominated diphenyl ethers) and PBBs (polybrominated biphenyls). RoHS sets specific concentration limits for certain substances, but in all EEE. Similarly to what was said above on REACH, RoHS does not contain any provisions either authorising or requiring HFRs to be allowed in electronic displays. Therefore, any ban on HFRs in specific parts of electronic displays, such as the enclosure and stand, is not incompatible with this directive. To the extent that the ban imposed by the contested regulation is also narrower than the scope of RoHS, the view according to which the Commission did not breach RoHS' provisions seems to be reinforced.

Thirdly, as a waste management regulatory instrument, Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)[15] regulates the recycling and disposal of waste electrical and electronic equipment, with a special emphasis on the end-of-life treatment of electronic product. In the view of the contested regulation having as its objective the increase of recyclability of electronic displays, BSEF argues that it should be the WEEE Directive covering this issue, rather than Commission Regulation 2019/2021. The Court, however, did not share this view: it observed that WEEE itself in its Recitals 4 and 11 and Article 4, leaves room for other, parallel solutions to be implemented upstream. In other words, measures that would regulate the design of products before the latter reach their end-of-life stage, in cases where any recyclability problem 'cannot be resolved, or can

[13] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (consolidated version) 2006 (L 396/1).

[14] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) (L 174/88, 1/7/2011).

[15] Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)(recast) (consolidated) 2024 (OJ L 197, 2472012, p 38).

only be so by incurring disproportionate costs, downstream (…)'. As the Court concludes, the contested regulation complements WEEE rather than conflicts with it.

Insofar as tolerance thresholds are concerned, both RoHS and REACH set such thresholds for certain HFRs (e.g., PBDE and PBB in RoHS, and DecaBDE in REACH). The Court confirmed the Commission's argument, stating that tolerance thresholds are not necessary for this type of regulation. Since the Ecodesign Directive focuses on the recyclability yields of electronic displays, thresholds do not apply to this problem posed by HFRs. It distinguished between the need for RoHS and REACH to provide for thresholds for certain HFRs 'having regard to the fact those substances are not hazardous below those thresholds', from the objective of the contested regulation's focus on improving recyclability of plastic compartments of electronic displays.

2.3 Some clarifications on EU general principles

General principles of EU law enjoy a 'constitutional status', thus placed on the same hierarchical rank as the founding Treaties.[16] Consequently, they have the potential of a significant impact on the EU legal order, as tools to interpret or even annul secondary legislative acts.[17] BSEF based its last three claims on the violation of the principles of legal certainty, equal treatment/non-discrimination and proportionality – yet unsuccessfully, since the Court rejected all of BSEF's arguments in that regard for various reasons.

2.3.1 Legal certainty

The principle of legal certainty has a long standing presence in the jurisprudence of the Court,[18] and requires that the 'rules of law be clear, precise and predictable as regards their effects'[19] and 'foreseeable by those subject to them'[20] in order for the latter to 'be able to ascertain unequivocally what their rights and obligations are and take steps accordingly'.[21] This principle entails two dimensions, (i) a temporal one, establishing a prohibition against retroactive application of legislative acts, and (ii) one that pertains to clarity, enabling EU law subjects to clearly perceive their rights and obligations.[22] It is considered an 'umbrella principle' since it covers and brings together several other EU

[16] *Judgement of 15 October 2009, Audiolux SA and Others v Groupe Bruxelles Lambert SA (GBL) and Others (C-101/08)* [2009] Court of Justice of the European Union ECLI:EU:C:2009:626.
[17] Jérémie Van Meerbeeck, 'The Principle of Legal Certainty in the Case-Law of the European Court of Justice: From Certainty to Trust' (2016) 41 European Law Review 275.
[18] *Judgement of 22 March 1961, Société nouvelle des usines de Pontlieue - Aciéries du Temple (SNUPAT) v Haute Autorité de la Communauté européenne du charbon et de l'acier (Joined Cases 42 and 49/59)* Court of Justice of the European Union ECLI:EU:C:1961:5.
[19] *Judgement of 16 February 2012, Marcello Costa and Ugo Cifone (Joined Cases C-72/10 and C-77/10)* Court of Justice of the European Union ECLI:EU:C:2012:80, Court reports – general, 74.
[20] *Judgment of 10 September 2009, Platanol GmbH & Co KG v Hauptzollamt Darmstadt (C-201/08)* 2009 I-08343 European Court Reports.
[21] *Judgement of 10 March 2009, Gottfried Heinrich (C-345/06)* 2009 I-01659 European Court Reports.
[22] Damian Chalmers and others, *European Union Law: Text and Materials* (Cambridge University Press 2006) 411.

principles, such as that of legitimate expectations, vested rights and non-retroactivity.[23] With respect to the elements of clarity and precision, attaining such a level of semantic perfection of legal provisions has been until now found to be unrealistic, especially in the EU multilingual context.[24] In recognition of such impossibility, the Court itself has already admitted that the existence of a 'certain degree of uncertainty regarding the meaning and scope of a rule of law is inherent to that rule'.[25]

The lack of precise identification of the substances covered by the ban brought by Regulation 2019/2021 was, according to BSEF, in violation of the principle of legal certainty. BSEF contended that the fact that there is just a mere reference to a class of substances instead of a detailed list, enumerating the individual substances covered, rendered the Regulation too broad, and thus imposed a 'blanket ban'. The Court, however, sided with the Commission, finding that the definitions of 'electronic display', 'flame retardant' and 'HFR' provided by Regulation 2019/2021 in its Annex I were clear and precise enough, and thus not in violation of the principle of legal certainty. The absence of individually identified substances is not, according to the Court, jeopardising the principle in question, given that the 'contours of the class (i.e., of HFRs) are sufficiently clear'. Insofar as HFRs developed in the future are concerned, the Court pointed out that BSEF failed to demonstrate the ways and the extent to which the identification of such hypothetical new HFRs would be impossible in the future.

The argument of the threshold of minimum concentration of HFRs was put again forward by the BSEF, but the Court found no link with the question of legal certainty. On the contrary, the Court noted that the issue of consistency of the contested Regulation with the REACH Regulation and the RoHS Directive, was already examined under the first plea, and seized the opportunity to underline again that the ban brought by Regulation 2019/2021 does not target HFRs in view of their hazardousness *per se* (whereby thresholds would be necessary), but on account of their impact on recyclability yields of plastic electronic displays.

From a policy perspective, this ruling affirms that legal certainty does not necessarily require minute detail in every regulatory framework, particularly in areas involving complex and evolving technological and environmental considerations, such as the one at hand. It also demonstrates that, within the EU legal system, regulations are interpreted with a certain degree of flexibility, particularly when future developments are difficult to predict. The balance between precision and flexibility in legal texts, especially in dynamic fields such as the one at present, is hard to strike, something which justifies it remaining an ongoing challenge for the Court.

[23] Xavier Groussot, *General Principles of Community Law* (Europa Law Publishing 2006) 24.
[24] Pablo Martín Rodríguez, 'The Principle of Legal Certainty and the Limits to the Applicability of EU Law' (2016) 1 Cahiers de droit européen 115.
[25] *Judgement of 14 April 2005, Kingdom of Belgium v Commission of the European Communities* 2005 I-02801 European Court Reports.

2.3.2 Equal treatment or non-discrimination

Despite the fact that the principle of non-discrimination has outgrown its internal market origins and has been increasingly linked to fundamental rights and equality,[26] its original content is relevant for the purposes of the present case. According to this principle, EU market players have to be treated as equals in case they are in a comparable situation, and conversely, not treated equally when they are in different situations, unless such treatment is dully and objectively justified.[27]

In the case at hand, BSEF claimed that this principle was violated on two separate grounds: first, since the ban targets exclusively the presence of HFRs in electronic displays, the manufacturers of such products are treated disfavourably, in comparison to manufacturers of other products. And second, HFRs are also being discriminated against, when compared to the situation of other chemical substances. To illustrate its argument, BSEF uses the example of cadmium, another substance under Regulation 2019/2021, one which is, however, temporary exempted, according to Annex III of the RoHS Directive, from the restrictions imposed, under the condition that electronic displays containing it are labelled with the cadmium logo. The Court recalled its previous decision *Arcelor Atlantique* and concluded once again in favour of the Commission, by finding that BSEF had 'failed to demonstrate how those products are in a comparable situation', in light of the 'subject matter', the 'purpose of the act which makes the distinction in question' and 'the principles and objectives of the field to which the act relates'.[28]

It is notable that the Court refers to the outdated character of HFRs which are deemed to be no longer necessary, with other alternative solutions being already in place. This was not the case, at the time of the adoption of the contested Regulation, for cadmium-based applications on electronic displays, whose exemption from restrictions was justified in view of accommodating the lack of viable alternatives, respectively. It should be noted in that regard that, following the technological advancements in the field, other alternatives have made their appearance. These evolutions are reflected in the recent Commission Delegated Directive 2024/1416,[29] which amends the cadmium exemption under the RoHS Directive, by specifying that now cadmium can be used in downshifting semiconductor nanocrystal quantum dots directly deposited on LED chips for display and projection applications, under stricter conditions, and with a time horizon of expiration until 2027, following which the industry will have to rely on cadmium-free alternatives.

[26] Koen Lenaerts, 'The Principle of Equal Treatment and the European Court of Justice' (2014) 8 Bulgarian Association for European Law, Evropeiski Praven Pregled 8.
[27] *Judgement of 17 April 1997, Earl De Kerlast V Union Régionale de Coopératives Agricoles (unicopa) and Coopérative du Trieux (C-15/95)* Court of Justice of the European Union ECLI:EU:C:1997:196, 1997 I-01961 European Court Reports.
[28] *Judgement of 16 December 2008, Société Arcelor Atlantique et Lorraine and Others v Premier ministre, Ministre de l'Écologie et du Développement durable and Ministre de l'Économie, des Finances et de l'Industrie (C-127/07)* 2008 I-09895 European Court Reports.
[29] Commission Delegated Directive (EU) 2024/1416 of 13 March 2024 amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in downshifting quantum dots directly deposited on LED semiconductor chips 2024 (L series, 21/5/2024).

2.3.3 Proportionality

Having been characterised as 'the most influential principle of EU law', the principle of proportionality lies at the heart of judicial methodology, constituting a valuable balancing tool.[30] It fulfils a series of functions, which remain distinct but, at the same time, interconnected. What it essentially requires is that a measure is (1) appropriate (suitability test) and (2) necessary to achieve its objectives, and more specifically, if there are other, less restrictive means to achieve the objective pursued (necessity test/the restrictive alternative test).[31] In a more formalised manner, the way in which the proportionality test is put into application involves another part, which entails investigating whether the measure in question is having an excessive effect on the applicant's interests (proportionality *stricto sensu*). These parts constitute a short of communicating vessels, whose inter-relations exist in continuity.[32]

This principle was argued by BSEF to be violated by the ban imposed by the contested regulation. First, BSEF claimed that the Commission exceeded what was appropriate, by dismissing the restrictions provided by REACH and RoHS, and imposing a total ban on HFRs. The Court redrew the attention to the fact that the impact assessment of the contested regulation explicitly discusses how the restrictions imposed by the other two legislative acts are not sufficient in order for the intended purpose to be achieved. Moreover, it recalled that the objective sought by the same regulation is to 'increase the recyclability of certain plastic components of electronic displays' and does not aim at dealing with recycling plastics from all EEE in a broader manner.[33] The issue of suitability of a measure is considered as an easier part of the proportionality test, since it merely requires for the Court to confirm that the measure and its means of achieving the desired objectives are 'reasonably likely' to do so.[34] An inherent element of appropriateness is that of internal consistency; the measure at hand should be, in other words, reflecting a policy concern to achieve the objective pursued 'in a consistent and systematic manner',[35] something crucial in order to ensure effective and better-quality governance overall.[36]

Second, and with respect to the necessary character of the ban at issue, BSEF contended that such ban is not necessary since the stated objectives of the contested regulation 'can and should be achieved under other relevant legislative instruments' such as REACH, RoHS and WEEE. A point on which BSEF insists is that of the justification of the

[30] Takis Tridimas, 'The Principle of Proportionality', *Oxford Principles Of European Union Law: The European Union Legal Order*, vol 1 (Oxford University Press 2018) <https://academic.oup.com/book/41926/chapter/354907422> accessed 15 October 2025.
[31] *Judgement of 4 May 2016, Philip Morris Brands SARL and Others v Secretary of State for Health (C-547/14)* Court reports – general.
[32] Tridimas (n 31) 247.
[33] Commission Regulation (EU) 2019/2021, Recital 15.
[34] Tridimas (n 31) 247.
[35] *Judgement of 8 September 2009, Liga Portuguesa de Futebol Profissional and Bwin International Ltd v Departamento de Jogos da Santa Casa da Misericórdia de Lisboa* Court of Justice of the European Union ECLI:EU:C:2009:519, 2009 I-07633 European Court Reports, pt 61.
[36] Tridimas (n 31) 248.

Commission's decisions to ban HFRs in electronic displays specifically, and not tackle the matter on a more general level. The Court concluded that the ban imposed was not unnecessary, basing itself on the same argumentation it used for the element of appropriateness. An overarching remark that should be made at this point concerns the broad discretion that the Commission enjoys in determining the 'nature and extent of the measures' which it adopts, in the context of complex assessments.

In connection to what was previously said about the different functions that the principle of proportionality can fulfil, the one that is in connection with the present case is that of limiting the scope and intensity of the legislative acts adopted by the EU legislature. In cases where the principle of proportionality is called upon in order to assess a measure adopted on the EU level, the Court relies upon the 'manifestly inappropriate' test in order to conduct its evaluation. In this case, a measure can be repealed by the Court only if it is considered 'manifestly inappropriate' to achieve its objectives. The rationale behind this test is found at the limits between doing politics and the judiciary; in cases where policy choices restrictive of the economic freedom are made, the Court will exercise only a marginal review, respecting the limits of its judicial function.[37] The EU legislature 'must be allowed a broad discretion in areas in which its action involves political, economic and social choices'[38].

As an indispensable component of the necessity test, the existence of less restricting measures that could achieve the same result is crucial.[39] BSEF's argumentation extends to alternative measures that could have been taken either (i) under other legal instruments, or (ii) under Regulation 2019/2021 itself. As for as other legislative acts, BSEF refers again to the triad of legislation to which it has been making references throughout its argumentation. The Court concluded that either the first or the second suggestions made by BSEF would stand. With respect to REACH and RoHS, it acknowledges the possibility of adopting measures under those instruments, but the circumstances under which these measures would apply would differ from the ones under the contested regulation: REACH's objective is not ensuring that recycling of plastic remains cost-effective and that recyclability yields increase, whereas a ban under RoHS would result in a wider scope of application, meaning that HFRs that are not used in the enclosure or stand of electronic displays would be as well included (p136). The Court did not, however, answer specifically to the possibility of establishing such a ban under the WEEE Directive.

The proposed less onerous measures under Commission Regulation 2019/2021 were also addressed by the Court, which examined them one by one and proceeded with not

[37] ibid 251.

[38] *Judgement of the Court, 8 June 2010, The Queen on the application of Vodafone Ltd and Others v Secretary of State for Business, Enterprise and Regulatory Reform (C-58/08)* Court of Justice of the European Union ECLI:EU:C:2010:321, 2010 I-04999 European Court Reports.

[39] See, however, Tridimas (n 30) 247 where it is observed that sometimes the Court will conclude that the measure respects the principle of proportionality without seeking for less restrictive alternative measures, or even in cases where these measures do exist.

upholding any of them. In continuation of its conclusions regarding the second plea, it found that the 'all-around' ban, as well the absence of a tolerance threshold, are justified by the cost-inefficiency of identification of the presence of HFRs in plastics – which are as discussed above, otherwise incinerated directly – and the objective of the contested regulation, which is the increase of recyclability rates and not the protection against the environmental hazard itself posed by HFRs.

Interestingly enough, the argument on the marking measure proposed by BSEF, whereby plastic components would bear a marking, accompanied by detailed information on the type and quantity of HFRs was rejected *quasi en passant* by the Court. It found that such a measure would as well fail to achieve the objective pursued because 'most of those plastic components are shredded and incinerated rather than dismantled'. More critically, the Court's position contrasts sharply with its earlier justification for the blanket ban on HFRs, which rested on the economic infeasibility of detecting specific flame retardants during recycling. If the information were already available via manufacturer-applied labels, as BSEF proposed, the cost and complexity of identification would shift away from recyclers, thus directly addressing the very rationale invoked to support the ban. By failing to engage with this dimension – namely, that labelling could obviate the need for costly downstream testing – the Court left a significant gap in its proportionality analysis. The absence of any discussion of potential dismantling strategies, cost-benefit considerations, or comparative regulatory efficacy renders the rejection of the labelling proposal insufficiently reasoned.

As far as the measure proposed to impose product requirements that would facilitate the separate collection of WEEE plastics containing HFRs is concerned, the Court sided with the Commission's findings that 'separation would still be necessary, and recycling would be made more difficult than in the absence of HFRs'. This wording is, however, unclear, probably referring to the dismantling of WEEE to plastic components containing (or not) HFRs.

With respect to the imposition of standardised external power supplies as a way of limiting the use of HFRs was also found to be unjust for those manufacturers that had already managed to fade-out HFRs use in the enclosure or stand of electronic displays. Although flame retardants are needed for electronics and electrical equipment, they do not necessarily need to be halogenated;[40] ENFIRO project which showed that many BFRs can be replaced by other FRs (e.g. non-halogenated OPFRs, metal-based and other inorganic FRs).[41]

Finally, the last alternative measure proposed by BSEF consisted in requiring the use of 'complementary recycling techniques' such as chemical dissolution techniques, used for

[40] Jacob De Boer, Stuart Harrad and Martin Sharkey, 'The European Regulatory Strategy for Flame Retardants – the Right Direction but Still a Risk of Getting Lost' (2024) 347 Chemosphere 140638.
[41] Adrian Beard and Pim EG Leonards, 'Life Cycle and Risk Assessment of Environment-Compatible Flame Retardants: ENFIRO, a Prototypical Case Study'.

polymer discovery in plastic, and the removal of additives or the destruction of legacy substances was not rejected for substantial reasons by the Court, but due to lack of proof provided from BSEF.

3 From the Ecodesign Directive to the ESPR: the journey from energy efficiency to a more inclusive sustainability framework

This section traces how the EU's ecodesign regime has transformed from a narrowly energy-efficiency instrument into a comprehensive, lifecycle-oriented sustainability framework and shows how T-113/20 provides guardrails for this transition. It outlines the shift from the 2005/2009 Ecodesign Directive—which focused on reducing electricity consumption and standby losses—toward a circular-economy mindset embodied in the 2024 ESPR, where measures now address durability, repairability, recyclability, and the elimination of substances that impede material recovery (Subsection 3.1). Building on that policy history, it draws on the Court's findings in *BSEF v Commission* to identify key lessons for ESPR implementation: confirmation that material-ban powers lie squarely within ecodesign (competence), the need for robust impact assessments to satisfy proportionality, the importance of clear definitions to secure legal certainty, and the acceptability of stepwise, product-by-product action under the principle of equal treatment (Subsection 3.2). Together, these insights show that the ESPR - backed by Digital Product Passports ('DPPs') and explicit 'substance of concern' criteria - can lawfully and effectively extend ecodesign from energy efficiency-related provisions to full-fledged product circularity.

3.1 The evolution of the EU Ecodesign framework

When the Ecodesign Directive was first adopted in 2005 (with its later recast in 2009), its policy focus was relatively narrow; it was conceived as a tool to improve the energy efficiency of products as part of the EU's climate change mitigation strategy. Recital 4 jointly with Article 1(2) of that directive stressed reducing energy consumption and enhancing energy security as key goals, reflecting the priorities of the mid-2000s (e.g the Kyoto Protocol commitments[42] and concerns over energy efficiency). In essence, ecodesign was seen at the time as an energy policy instrument – with environmental ancillary benefits – targeting all types of measures that would cut electricity use, such as stand-by power losses and efficiency standards of electronic and electrical appliances.

Over time, awareness started growing with regard to the fact that many of the environmental impacts of products occur outside the use-phase energy consumption. With the full life-cycle - from raw material extraction to manufacturing and disposal – involving significant resource use, pollution and waste, the EU began along with that realisation to

[42] Kyoto Protocol to the United Nations Framework Convention on Climate Change 1997, notably Article 2(1)(a)(i).

emphasise circular economy concepts, aiming to design out waste and hazardous substances and keep materials in use for longer. By the late 2010s, still operating under the Ecodesign Directive, some implementing regulations started to incorporate requirements like durability (e.g. minimum lifetimes for lighting products[43]), repairability (e.g. availability of spare parts, ease of disassembly in appliances[44]), and recyclability (e.g. labelling of plastic parts, removability of certain components[45]). These moves signalled a shift from pure energy efficiency toward a more holistic approach to product sustainability. However, such requirements were still introduced on a case-by-case basis and primarily for energy-related products, since that was the Directive's limit.

It should be emphasised, however, that this shift certainly did not happen overnight; the above-mentioned implementing regulations aside, Recital 13 of the Ecodesign already had acknowledged in the lifecycle thinking that comes with ecodesign conceptualisations. On the basis of the Commission's (then Commission of the European Communities) communication on Integrated Product Policy, all environmental impacts from raw material selection to end-of-life were linked to the improvement of a product's environmental performance in a cost-effective way.[46]

A major inflection point in policy came in March 2020 with the EU's adoption of the Circular Action Plan (CEAP).[47] Already announced in the EU Green Deal in 2019,[48] CEAP explicitly recognised that product design lies at the heart of the EU circular economy, and flagged the need for a 'comprehensive set of requirements to ensure that all products placed on the EU market become increasingly sustainable and stand the test of circularity'. In other words, it noted that the current framework did not cover enough products or sustainability aspects of such products in a manner that would suffice to drive

[43] Commission Regulation (EU) 2019/2020 of 1 October 2019 laying down ecodesign requirements for light sources and separate control gears pursuant to Directive 2009/125/EC of the European Parliament and of the Council and repealing Commission Regulations (EC) No 244/2009, (EC) No 245/2009 and (EU) No 1194/2012 (OJ L 315/209, 5/12/2019) which requires that LED modules and certain other light sources meet a minimum rated lifetime (e.g. nominal hours of operation before reaching a defined lumen depreciation) in order to remain on the market. It also establishes independent test methods to verify that a lamp actually endures at least this long under normal operating hours (see Annex V on Functionality after endurance testing).

[44] Commission Regulation (EU) 2019/2023 of 1 October 2019 laying down ecodesign requirements for household washing machines and household washer-dryers pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EU) No 1015/2010 (OJ L 315, 5122019, p 285), which foresees that spare parts of these machines need to be available for at least 10 years after the former are place n the market, and that these spare parts be replaceable with commonly available tools without bringing permanent damage to the appliances (see Annex II on ecodesign requirements). See also Commission Regulation (EU) No 66/2014 of 14 January 2014 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for domestic ovens, hobs and range hoods (OJ L 29, 3112014, p 33).

[45] ibid.

[46] Commission of the European Communities, 'Communication from the Commission to the Council and the European Parliament - Integrated Product Policy Building on Environmental Life-Cycle Thinking' (2003) COM/2003/0302 final.

[47] European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - A New Circular Economy Action Plan for a Cleaner and More Competitive Europe' (2020) COM/2020/98 final.

[48] European Commission, 'Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions - The European Green Deal' (2019) COM2019/640 final.

the much needed systemic change. More concretely, the target set out by the Green Deal to double the circularity of material use in the EU and achieve climate neutrality by 2050 requires tackling how products are made, what they contain, and how they are disposed of. This led to the proposal of the Sustainable Products Initiative,[49] whose centrepiece is the ESPR, described as the 'cornerstone' of the EU's approach to a more environmentally sustainable and circular economy.

The ESPR's rationale, therefore, is to embed sustainability and circularity 'by design', ensuring products are conceived from the outset to minimise resource use, facilitate repair and reuse, eliminate substances that block high-quality recycling, and deliver longer lifespans. Its objectives are fourfold: first, to reduce the overall environmental and climate impacts of all physical goods placed on the EU market; second, to foster a genuine circular economy by keeping materials in use and recovering them at end-of-life; third, to drive innovation and competitiveness in EU industry by harmonising ecodesign requirements across sectors - thereby avoiding fragmented national rules - and stimulating demand for durable, repairable, and non-toxic products; and fourth, to empower consumers through greater transparency so they can compare products based on their sustainability attributes. By integrating requirements on durability, reparability, recycled content, and banning substances of concern that impede recycling, the ESPR aligns with broader EU ambitions to shift away from a take-make-dispose model and toward a regenerative economy in which products support circular material flows, reduce greenhouse gas emissions across their lifecycle, and contribute to resource security and social well-being.

Especially with respect to the introduction of DPPs, these will significantly aid, among other things, in operationalising the material restrictions envisaged by the ESPR. Constituting a type of digital identity card[50] for products placed on the market or put in service in the EU, DPPs are designed to include information to support products' sustainability and enhance their circularity, particularly regarding their composition and the materials used for their manufacturing. The information contained therein will be accessible electronically via a data carrier (Article 9(1)(b) ESPR) to all ESPR actors, with manufacturers being the ones responsible for providing the primary information on products' compositions.[51]

This means that in case there is a restricted or banned material pursuant to a delegated act, compliance will be considerably facilitated and monitored with every product's passport providing the information necessary to verify compliance therewith. This greatly strengthens enforcement compared to the Ecodesign Directive era, making material bans

[49] European Commission, 'Sustainable Products Initiative - Inception Impact Assessment' (2020) Ref. Ares (2020)4754440.
[50] See also Hendro Wicaksono and others, 'Digital Product Passport (DPP) Technological Advancement and Adoption Framework: A Systematic Literature Review' (2025) 253 Procedia Computer Science 2980.
[51] However, as the nature and purpose of the interaction with DPPs is different for each of them, the degree of their engagement differs as well, along with their access rights and the information available to each of them.

more practically effective, thus maximising material efficiency.[52] In essence, DPPs will turn what was a design requirement on paper into a traceable attribute of each product in the EU market. Case T-113/20 showcased the industry's demands for clarity and practicality, and the DPP is one way that the EU is delivering that, by systematising the ways in which information about materials is handled.

In summary, the transition from the Ecodesign Directive to the ESPR marks the broadening of the EU policy on product design from a narrow energy-efficiency tool to a comprehensive sustainability framework. This shift of the political impetus and the regulatory mandate to act on all product lifecycle stages in a more systematised and comprehensive manner also reflects lessons learned under the Ecodesign Directive: having seen that certain 'non-energy' requirements (like durability and composition) can be effectively implemented, scaling up across more products can (and should) follow the same trajectory.

3.2 Lessons learned from T-113/20 and implications for ESPR enforcement

The Court's ruling on case T-113/20, as it was extensively analysed above, touched on a series of fundamental legal issues – competence, proportionality, legal certainty, and equal treatment – which are equally relevant to the implementation of the ESPR. It essentially constitutes a jurisprudential bridge between the two regimes, that of the Ecodesign Directive, and that of the ESPR. Going forward, it appears necessary not only to be aware of the main outcomes and conclusions of the Court on this case but most crucially, foresee in what ways this case offers guidance on how these conclusions might play out under the ESPR.

3.2.1 On the Commission's competence, scope of delegated acts and legislative complementarity

Under the ESPR, the Commission now has a clear mandate to adopt delegated acts setting ecodesign requirements for almost all physical products.[53] Given the ESPR's broad subject matter and scope, requirements on material composition and even horizontal measures in that regard are expressly included. At any rate, case T-113/20 has already confirmed that such material-focused measures fall well within the concept of 'ecodesign' as improving the environmental performance over products' lifecycle.

A concept, already having appeared in REACH, but now defined in ESPR for the first time in a more complete manner is that of 'substance of concern' ('SoC'). Article 2(27)(b)

[52] Recital 23 ESPR; Foivos Psarommatis and Gökan May, 'Digital Product Passport: A Pathway to Circularity and Sustainability in Modern Manufacturing' (2024) 16 Sustainability 396, 2.
[53] Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC 2024 (OJ L, 2862024), Article 1(1) and (2).

ESPR defines SoC as any substance falling under specific categories, one of which is 'a substance negatively affecting the reuse and recycling of materials in the product in which it is present'.

Surely in practice the Commission will still have to ensure that it respects boundaries with other chemical or waste management legislation, but the legal basis in the ESPR for such action sees now itself firmly established. Criteria for ecodesign requirements are bound to be defined by Article 4 ESPR (and related provisions, such as Article 8, 72-73 ESPR). Strictly in relation to the case at hand, recyclability is listed as one of the product aspects which are relevant in the context of ecodesign requirements adopted pursuant to Article 4 ESPR, next to other fundamental aspects of product sustainability (e.g. durability, reliability, reusability, upgradability, repairability, etc.). Thus, any competence challenge against an ESPR measure (for example, claiming the Commission is *de facto* regulating chemicals or waste beyond its remit) would likely fail if the measure can be tied to product sustainability, especially when considering the fact that the Court upheld such measures under the previous, narrower regime of the Ecodesign Directive.

More notably, Article 6 ESPR is very explicit in the interaction of this regulation with other community legislation on chemical safety, clarifying that the restrictions imposed under its provisions should not be based on chemical safety considerations. Risks for human health or the environment can surely be taken into consideration, but specifically in order to avoid duplicating or replacing restrictions covered under chemical or electronic waste management, Recital 26 is very clear in drawing this line and emphasising the complementary relationship of ecodesign with the above-mentioned areas of legislation. Following the Court's decision on case T-113/20, concerns were voiced by industry, particularly in regard to double regulation of chemicals, calling for the case of the ban of HFRs under the Ecodesign Regulation 'not to be repeated'.[54] Amongst the recommendations put forward was the REACH and RoHS remaining the primary legislation for chemicals, the development of policies on a risk-basis, and not a hazard one, and the replacement of SoC only with less harmful ones. This claim merits a closer look, due to the fact that it runs counter to the core rationale of the ESPR. Various arguments which were used throughout this analysis can be regrouped in order to respond to this claim.

First, these regulations have fundamentally different objectives and scopes: REACH regulates the production, marketing and use of chemical substances across all sectors, focusing on human health and environmental risks through a centralised system of registration, evaluation and authorisation of substances. In turn, RoHS provides restrictions for the use of certain hazardous substances in electrical and electronic equipment, with the primary objective of limiting toxic waste. The ESPR, by contrast,

[54] Orgalim, 'Position and Recommendations from Europe's Technology Industries on the Proposed Ecodesign for Sustainable Products Regulation' (2022) <https://orgalim.eu/wp-content/uploads/Position-and-recommendations-from-Europes-technology-industries-on-the-proposed-Ecodesign-for-Sustainable-Products-Regulation_010622.pdf> accessed 15 September 2025.

targets product design, and aims to improve the environmental performance of products over their entire lifecycle. The HFR ban was imposed by the contested regulation not because of hazardousness, but because it significantly hindered materials' recycling.

Second, there was no substance conflict with existing REACH/RoHS restrictions at the time that the contested regulation was adopted. Most HFRSs used in electronic displays were not restricted under REACH or RoHS: the Commission had explicitly assessed whether there was an overlap, and found that there was no EU legislation that prohibited or restricted (or prohibited the restriction of) the use of the substances targeted by the contested regulation. And third, these instruments function complementarily, with ecodesign providing a targeted and flexible tool that REACH cannot always match quickly in specific products contexts – especially when the environmental harm lies in material recovery, not direct toxicity.

In conclusion, while Regulation 2019/2021 – and by extension, the ESPR – operates in 'neighbouring fields' with REACH and RoHS, it cannot be viewed as constituting a legal or policy duplication. It reflects a complementary layer of regulation, allowing the EU to target sustainability obstacles that chemical legislation alone cannot always address. The Court in T-113/20 firmly upheld this view, reinforcing the idea that ecodesign regulation serves as a legitimate, independent regulatory route for addressing substances that impede environmental goals, especially in the context of the circular economy.

While REACH will still handle substance-by-substance risk assessments and restrictions, the ESPR can act faster in certain cases by setting more generic requirements. Instead of waiting for a class of chemicals to be restricted via lengthy REACH procedures, the Commission can now use a delegated act to ban substances in products, if they hamper circularity or sustainability; exactly as it happened in the case of the HFR ban, based on their functionality (flame retardancy) and composition. One candidate which is in the last years frequently discussed is PFAS (per- and polyfluoroalkyl substances), in products like textiles and cookware. PFAS are often described as 'forever chemicals' that persist and pollute. Certain categories of PFAS have been either already restricted (perfluocarboxylic acids (C9-14 PFCAs), their salts and related substances[55]) or will be facing restrictions in the near future (Undecafluorohexanoic acid (PFHxA), its salts and related substances[56]).

As a matter of fact, information about the presence of PFAS in textiles is limited, due to the fact that countries from which the biggest percentage of textiles is imported, regulate chemicals more loosely.[57] During their end-of-life phase, textiles are to the

[55] Commission Regulation (EU) 2021/1297 of 4 August 2021 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain (C9-C14 PFCAs), their salts and C9-C14 PFCA-related substances (Text with EEA relevance) 2021.
[56] Commission Regulation (EU) 2024/2462 of 19 September 2024 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards undecafluorohexanoic acid (PFHxA), its salts and PFHxA-related substances 2024.
[57] European Environment Agency, 'EU Exports of Used Textiles in Europe's Circular Economy' (2023) Briefing 01/2023 <https://www.eea.europa.eu/publications/eu-exports-of-used-textiles/eu-exports-of-used-textiles/download.pdf.static> accessed 31 May 2025.

largest extent incinerated, or exported to third continents (e.g. Africa and Asia), where they are reused, recycled, dumped in landfills, or incinerated. Overall, PFAS in textiles hinder circularity, since their reuse and recycling bears significant contamination and release risks.[58] On a more general level, numbers are striking: out of 450 million tonnes of plastic produced in 2021, only 3,4% of fluopolymers (a substance which falls under the PFAS category) was recycled.

A REACH restriction covering a wider range of PFAS is currently under discussion,[59] but the ESPR could, for example, ban PFAS-based coatings in apparel as a design requirement for textiles, pushing the industry toward better alternatives. The key (differentiating) element is that the ESPR enables group approach restrictions aligned with circular economy goals, which were not the case under the Ecodesign Directive. By embedding such rules in product design legislation, the EU sets the conditions necessary to implement a belt-and-suspenders approach, whereby chemicals that are hazardous and/or constitute an obstacle to product ecodesign, can be tackled from two angles – both product and chemicals legislation. This dual approach is powerful and, as it was already established above, considered totally acceptable by the Court.

While not explicitly mentioned in T-113/20, two of the key principles of the Commission's Better Regulation were indirectly tested: stakeholder consultation and impact assessment. [60] The ESPR adds another layer of scrutiny through the introduction of the Ecodesign Forum (Article 19 ESPR), a multi-stakeholder group with 'balanced and effective participation' in, *inter alia*, the preparation of ecodesign requirements. Member States-designated experts, along with all other parties with the interest in the specific product or product group targeted by potential requirements.

3.2.2 On the principles of proportionality, legal certainty and fairness

Proportionality of ecodesign requirements will be expected, however, to remain a central test for any ESPR delegated act. In T-113/20, the Court scrutinised proportionality, mainly basing its argumentation on the Commission Regulation's 2019/2021 impact assessment and placed considerable weight on the procedural requirements set out by the Ecodesign Directive when adopting an implementing measure. This underscores exactly the importance of impact assessments and scientific evidence when designing such requirements. Accordingly, the ESPR process of adopting delegated acts will involve detailed impact assessments (Article 5(10)(b) ESPR), based 'on the best available evidence' and 'taking due consideration of all aspects of the life cycle of the product',

[58] European Environment Agency, 'PFAS in Textiles in Europe's Circular Economy' (2024) Briefing no. 11/2024.
[59] European Chemicals Agency (ECHA), 'Next Steps for PFAS Restriction Proposal' <https://echa.europa.eu/de/-/next-steps-for-pfas-restriction-proposal> accessed 3 April 2025.
[60] European Commission, 'Better Regulation Guidelines' (European Commission 2021) SWD(2021) 305 final.

along with stakeholder consultations.[61] It is worth considering, however, that, as the Court repeatedly recalled, the Commission enjoys wide discretion in technical matters; the Court took a clear stance whereby it did not second-guess any policy decisions of the Commission, and was satisfied by a mere demonstration by the Commission that the relevant factors were thoroughly examined and no major risks were ignored.[62]

Even though the Court did have a particular difficulty in rejecting BSEF's argument with respect to legal certainty of certain terms included in Regulation 2019/2020, the risk of definitional ambiguity will be even greater under the ESPR due to the equally higher degree of complexity of the new framework. In order to avoid challenges, definitions and metrics need to be clear and harmonised; industry groups have already recommended that terms be well-defined, ideally aligned with standards.[63] For example, the ESPR mandates under its Article 7 for products to include, among other things, a 'repairability score' and a 'recyclability score' which are not defined in the text of the ESPR, thus requiring delegated acts to provide the necessary details (Article 4 ESPR).

Only with the exception of certain categories of products, the ESPR applies to the 'broadest possible range of products' (Recital 5) placed on, or put into service in, the EU market regardless of their provenance, i.e. whether they were manufactured in the EU or in a third country. This ensures non-discrimination between domestic and imported goods; more subtle equal treatment issues could, however, arise between product categories. Were the Commission to ban a particular substance in one product group but not (or not yet) in another where the same substance is also used, companies might question this; exactly as it was the case in T-113/20. The Court created a very clear precedent in that regard, by accepting that the Commission can regulate stepwise, and that different product categories are not necessarily in a 'comparable situation', if the regulatory context or scientific evidence differs.

In that regard, a very interesting component of the EU ecodesign regulation framework is systematised in the ESPR, which is devoted to prioritisation and planning of products' ecodesign requirements. According to Article 18 ESPR, the Commission sees itself granted the discretionary power to prioritise products to be covered by ecodesign requirements, by 'analysing the contribution of those products' to the different EU climate and environmental objectives, as well as the functioning of the EU market and its economic resilience. This analysis cannot be arbitrary, since the Commission is obliged to take into

[61] Recital 22 ESPR, although strange this does not appear in Article 5 ESPR as well. Stakeholder consultations are only explicitly mentioned in case of adoption of implementing measures for common specification measures (Art 42).
[62] In that regard, see also Camille Lanssens, 'The Court of Justice of the European Union's Review of Uncertain Scientific Appraisals: What Role for the Impact Assessment Guidance?' (2023) 16 Review of European Administrative Law 79, where the author differentiates between legislative acts and delegated or implementing acts on the account of the fact that judicial review of legislative and non-legislative acts brings up different types of questions and in that legislative acts can provide for a specific impact assessment procedure for the adoption of delegated and implementing acts differing from the IA Guidance. Especially with respect to T-113/20 she notes that even if the Court was asked to review an alleged infringement of the Article 15(1) of the Ecodesign Directive as well as an infringement of the BR Guidelines it only assessed compliance of the act to the Ecodesign Directive.
[63] Orgalim (n 55).

consideration different criteria such as any disproportionate costs brought by the adoption of any potential ecodesign requirements, volume of sales and trade, the distribution across the value chain of the environmental impacts of these products, and the need for regular review and adaptation of these measures. It is evident that this provision is directly aiming at safeguarding the Commission's actions against claims of discriminatory regulation of some products (and not of some others), as the ones raised by BSEF in T-113/20.

4 Conclusion

In the unfolding narrative of EU environmental and product ecodesign policy, the *BSEF v Commission* judgment demonstrates the EU's growing ambition to embed circular economy goals directly in product design. By endorsing the Commission's ban on HFRs not because of their inherent toxicity but because they hinder high-quality recycling, the Court reaffirmed that ecodesign has matured beyond mere kilowatt-hour savings. T-113/20 thus stands both as a capstone for the Ecodesign Directive's most ambitious application and as a herald of the ESPR. The Court's reasoning on the Commission's competence under Article 15, its nuanced reconciliation of parallel regimes (REACH, RoHS, WEEE), and its measured application of EU general principles - legal certainty, proportionality, equal treatment - collectively provide a blueprint for how the ESPR can and is likely to face similar tensions in the years ahead.

Looking forward, the ESPR 'codifies' what T-113/20 suggested in practice: that product ecodesign can target any substance that undermines circularity, irrespective of whether that substance poses a direct chemical risk. By embedding criteria such as durability, reparability, recyclability, and substances of concern into a single, unified framework, the ESPR transforms ecodesign from a patchwork of case-by-case measures into a coherent, lifecycle-wide strategy. A very promising ESPR tool, that of DPPs, promises to play a pivotal role in ensuring that bans or restrictions truly take root in production lines and recycling streams. The prioritisation mechanisms and procedural safeguards - rigorous impact assessments, stakeholder consultations, and the Ecodesign Forum's oversight - draw directly on the Court's insistence that technical discretion be balanced by transparency and robust evidence.

In a broader sense, this journey - from the narrow, energy-centric vision of 2005 to today's holistic, circular-economy approach - mirrors the EU's own evolution from a union seeking only to temper energy consumption to one striving for climate neutrality and systemic resource efficiency. The ESPR does not discard energy efficiency; it integrates it into a wider tapestry of environmental objectives, thereby underscoring that every stage of a product's life - from raw material extraction to end-of-life - deserves equal scrutiny. As the EU legislator prepares future delegated acts under the ESPR, the lessons learned from T-113/20 offer valuable insights: first, that material bans for recyclability are lawful

when grounded in life-cycle evidence; and second, that any restriction must be transparent and well-calibrated under EU law's core principles.

Ultimately, *BSEF v Commission*, read alongside the ESPR, signals the advent of a new phase in EU product ecodesign policy and lawmaking - one in which ecodesign operates not merely as a defensive mechanism against environmental degradation but as a proactive instrument for advancing the circular economy. In this emerging paradigm, ecodesign assumes a constitutive role in shaping environmental outcomes: by embedding recyclability and resource efficiency into the very conception of products, the EU seeks not only to depart from the linear model of production and consumption but also to institutionalise circularity as a foundational market principle. As the legislative, and potentially judicial, dimensions of this transition continue to evolve under the ESPR framework, the judgment in T-113/20 will remain as the moment in which ecodesign transcended its energy efficiency origins to follow a genuinely comprehensive product ecodesign direction.

*Valerio Giovannini**

SPECIAL SECTION

REGULATORY BURDENS UNDER CBAM AND ESPR IN EU LAW WITH A FOCUS ON PROPORTIONALITY AND EXTRATERRITORIALITY

Abstract

This article examines the complex legal and economic interplay between two key instruments of the European Union's environmental regulatory framework: the Carbon Border Adjustment Mechanism (CBAM) and the Ecodesign for Sustainable Products Regulation (ESPR). While each serves a distinct objective, CBAM aims to prevent carbon leakage through border carbon pricing, and ESPR promotes product circularity and sustainability via ecodesign requirements, their concurrent application may result in a disproportionate regulatory burden, particularly for non-EU exporters.

The analysis highlights how the EU's regulatory power generates a de facto extraterritorial effect, often referred to as the "Brussels Effect," by imposing substantial compliance obligations on third-country producers. These include granular emissions reporting, product traceability, and potential redesigns to meet EU market standards. Drawing on the case law of the Court of Justice of the European Union (CJEU), the article explores the legal foundations for this extraterritorial influence, rooted in the territorial nexus of market access, while also underscoring the complex legal questions that arise when EU rules govern production processes entirely situated outside the Union.

The article further scrutinises the proportionality and cost-effectiveness of CBAM and ESPR, particularly with respect to their impact on EU consumers. It evaluates the principle of proportionality in EU law and the legal requirement for comprehensive impact assessments, with reference to BSEF v Commission to illustrate the CJEU's rigorous scrutiny of regulatory balance.

In conclusion, the article reflects on the broader tension between the EU's environmental ambitions and the practical constraints faced by international trading partners and EU citizens. It proposes recommendations for improving regulatory coherence, ensuring that the EU's global standard-setting role is exercised with legal clarity, procedural fairness, and sensitivity to the cumulative burden imposed on global supply chains and consumers.

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10.13135/2785-7867/12833

JEL CLASSIFICATION: K32

SUMMARY

1 Introduction

The European Union is advancing its regulatory framework to support the transition toward a more sustainable, climate-resilient economy. This process is increasingly shaped by the interaction of legal instruments aimed at transforming the way goods are produced and marketed within the internal market. Two of the most prominent of these instruments, the Ecodesign for Sustainable Products Regulation (ESPR)[1] and the Carbon Border Adjustment Mechanism (CBAM)[2], reflect the Union's dual approach: fostering sustainability within its internal market through stringent product standards, while also addressing the carbon intensity of imported goods.

Although each regulation is significant in its own right, their simultaneous application gives rise to a complex set of legal questions. This article explores the intersection of ESPR and CBAM, analysing the extent to which they may impose overlapping obligations, particularly on non-EU companies. It further investigates the extraterritorial dimensions of EU law and the resulting impact on both international commerce and EU consumer welfare.

The ESPR, replaces and expands the scope of the Ecodesign Directive[3]. It moves beyond the focus on energy-related products and applies to a broad range of consumer and industrial goods. The Regulation establishes a legal framework for setting ecodesign requirements applicable to products placed on the Union market. In accordance with Article 5(1)[4], such requirements may relate to specific aspects related to sustainability

[1] Council Regulation (EC) 2024/1781 of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Council Directive (EU) 2020/1828 of 25 November 2020 and Council Regulation (EU) 2023/1542 of 12 July 2023 and repealing Council Directive 2009/125/EC of 21 October 2009 (Text with EEA relevance).
[2] Regulation (EU) 2023/956 of the European Parliament and of the Council of 10 May 2023 establishing a carbon border adjustment mechanism (Text with EEA relevance).
[3] Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (recast) (Text with EEA relevance).
[4] The ecodesign requirements that may be set under the ESPR are the following: (a) durability, (b) reliability, (c) reusability, (d) upgradability, (e) repairability, (f) the possibility of maintenance and refurbishment, (g) the presence of substances of concern, (h) energy use and energy efficiency, (i) water use and water efficiency, (j) resource use and resource efficiency, (k) recycled content, (l) the possibility of remanufacturing, (m) recyclability, (n) the possibility of

and circularity of products. Furthermore, the Regulation imposes comprehensive information obligations, most notably the requirement to establish a Digital Product Passport, as defined in Article 2(12) of the ESPR. Implementation will follow a staged approach. Working Plans (non-binding communications) will be adopted, each identifying priority product groups. These will then be subject to delegated acts specifying detailed ecodesign criteria.

The first of these Working Plans, adopted in April 2025, identifies a range of products for which delegated acts will subsequently establish ecodesign requirements, in line with the criteria set out in Article 5(1) of the ESPR. Among the priority products listed, steel is designated as a high-priority intermediate product. A delegated act regulating steel is expected to be adopted by the fourth quarter of 2026. This development is of particular significance, given that steel is already subject to domestic carbon regulation under the EU Emissions Trading System (ETS)[5] and is simultaneously classified as a CBAM good when imported into the Union. Since this article addresses the potential for an excessive regulatory burden on economic operators under both legal frameworks, particularly with regard to the extraterritorial implications, the example of steel, which may in theory become subject to dual requirements, is especially pertinent and illustrative of the concerns raised in this analysis.

CBAM, established under Regulation (EU) 2023/956 and adopted in April 2023, is intended to equalise the carbon cost borne by EU producers, which are subject to the ETS mechanism, with that borne by international competitors. The regulation imposes a financial charge on the embedded emissions of imported goods of the categories listed in Annex I of the CBAM Regulation, including steel, as mentioned above, thereby mitigating the risk of carbon leakage and incentivising foreign producers to adopt cleaner technologies. CBAM will be phased in gradually, beginning with reporting requirements and culminating in full financial liability by January 2026.

As this article will argue, the simultaneous application of the ESPR and CBAM may create a unique and potentially burdensome regulatory challenge. For example, the regulation of intermediate products such as steel under both frameworks may result in overlapping compliance obligations. Specifically, non-EU exporters of steel may be subject to carbon pricing requirements under CBAM as well as detailed ecodesign requirements under the ESPR. Notably, the ESPR applies regardless of the product's origin, while CBAM, as discussed further below, produces legal and practical effects extending to economic operators located outside the European Union. This regulatory overlap raises important legal questions about the extraterritorial reach of EU law and the legitimacy of imposing

the recovery of materials, (o) environmental impacts, including carbon footprint and environmental footprint, and (p) the expected generation of waste.

[5] Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC (Text with EEA relevance).

significant compliance burdens on businesses operating beyond the EU's territorial boundaries.

The economic implications of the concurrent application of the ESPR and CBAM are also considerable. If the combined effect of these two regulatory frameworks results in a significant increase in the cost of imported goods, it may reduce market competition within the European Union and lead to higher prices for end consumers. Such an outcome raises important consumer protection concerns and prompts an inquiry into the legal remedies available to affected parties under EU law.

The ESPR will apply directly and indirectly to consumer products (once the delegate acts on selected products will be adopted), and current indications suggest that the scope of CBAM may soon be expanded to include finished products incorporating goods already covered by CBAM. As a result, consumers are likely to bear the financial burden associated with the increased compliance costs arising from the simultaneous application of both regulatory regimes.

Based on this framework, the article will focus in particular on the extraterritorial implications of these two legal instruments and their compatibility with the principle of proportionality under EU law. It will examine whether the combined application of these frameworks, which impose additional regulatory burdens on third-country operators, can be legally justified under the EU legal principles supporting the extraterritorial reach of Union regulations. The article will also explore the broader implications for EU consumers, assessing the proportionality of the new measures, analysing the relevant jurisprudence of the Court of Justice of the European Union, and considering the legal avenues available to consumers for the protection of their interests.

For the sake of clarity, the analysis will not address the broader implications of these measures under international law, focusing instead on their legality under EU law, including the obligations imposed on third-country operators.

2 The Legal Nature and Function of CBAM

At its core, CBAM is an environmental measure conceived to incentivise global decarbonization while simultaneously safeguarding the competitiveness of EU industries subject to the EU Emissions Trading System (ETS). The ETS, a cornerstone of the EU's climate policy since 2005, operates on a cap-and-trade principle, obliging energy-intensive industries within the EU to acquire allowances for their greenhouse gas (GHG) emissions. This internal carbon price, while effective in driving decarbonization within the Union, inadvertently places EU producers at a competitive disadvantage against producers in third countries that do not face comparable carbon costs.

The objective of the CBAM is clearly articulated in recital 14 of the Regulation, which states that "*the objective of the CBAM is to prevent the risk of carbon leakage*". According to the text of the law the Regulation "*would also encourage producers from*

third countries to adopt technologies that are more efficient in reducing greenhouse gas emissions, thereby generating fewer emissions. For this reason, [it is expected that] the CBAM [will] effectively support the reduction of greenhouse gas emissions in third countries."

This latter aspect, namely the incentivization of emissions reduction in third countries, is a particularly important consideration for the purposes of this analysis. Indeed, it is precisely this environmental protection objective and support for global environmental strategies that will argue may serve as the foundation for justifying the CBAM both as a non-protectionist measure and as a basis for its extraterritorial reach. Moreover, it provides a rationale for the potential compliance burdens that consumers may ultimately bear.

The narrative surrounding CBAM often oscillates between its characterisation as an environmental measure and its perception as a "protectionist" instrument. From the EU's perspective, the mechanism is fundamentally about environmental protection and a crucial tool for reaching EU climate objectives[6]. However, as previously explained, it must equally be acknowledged that the mechanism is designed to counteract the competitive disadvantage faced by EU producers subject to the ETS, thereby preventing carbon leakage and safeguarding the integrity of the Union's climate objectives. This inherently "protectionist" dimension, understood within the broader context of preserving domestic competitiveness in a decarbonising economy, creates a fundamental dichotomy with the environmental protection objective, which, from a legal perspective, as further explored below, and particularly in relation to the extraterritorial reach of EU law, cannot be overlooked.

The mechanism operates on the principle of "equivalence", whereby the charge on the embedded emissions of imported goods is intended to correspond to the charge imposed on domestic goods under the ETS. This design feature further supports the characterisation of CBAM as an environmental measure rather than a protectionist trade barrier, a distinction that is crucial for ensuring its compatibility with World Trade Organization (WTO) rules. However, as will be discussed below, the delicate balance between environmental ambition and trade compliance inherent to CBAM remains a continuous subject of legal and political scrutiny.

Academic debate has addressed the legal characterisation of this mechanism, particularly whether it can be considered, in substance, a form of taxation. Notably, the analysis by Klotz and others[7], which explored the question of whether CBAM constitutes a

[6] This environmental protection function, and the role of CBAM as an instrument for achieving both EU and global climate objectives, is clearly affirmed in recital 20 of the CBAM Regulation, which states: *"(…) the mechanism is intended to address the need to curb greenhouse gas emissions, in line with the binding environmental target under Union law, set out in Regulation (EU) 2021/1119, to reduce the Union's net greenhouse gas emissions by at least 55% compared to 1990 levels by 2030 and the objective to reach economy-wide climate neutrality at the latest by 2050."*

[7] S Klotz, SL Probst and O Hulliger, 'The Carbon Border Adjustment Mechanism – A Tax in Disguise?' (2022) 62 European Taxation 306.

disguised tax, was published even prior to the adoption of Regulation (EU) 2023/956, underscoring the significance of this question. In this context, CBAM has been described as an environmental policy instrument which nonetheless exhibits alignment with several core principles of tax law[8]. Although the European Union does not officially classify CBAM as a tax, the mechanism reflects key fiscal principles such as neutrality, legal certainty, and the polluter-pays principle, elements typically associated with taxation regimes[9]. An additional indicator suggesting a shift toward a tax-like character is the transfer of institutional responsibility for the instrument from the Directorate-General for Environment (DG ENV) to the Directorate-General for Taxation and Customs Union (DG TAXUD), the EU body responsible for taxation and tariff policy.

2.1 Objectives and Legal Design

Concretely, CBAM requires EU importers to purchase "CBAM certificates" corresponding to the embedded GHG emissions of the imported goods. The price of these certificates is directly linked to the weekly average trading price of EU ETS allowances, expressed in euros per metric tonne of CO_2 equivalent emitted[10]. This dynamic pricing mechanism ensures that the carbon cost faced by importers fluctuates in tandem with the EU's internal carbon market, maintaining the principle of equivalence. This direct linkage ensures that the cost burden on imports precisely mirrors the domestic carbon price, reinforcing the non-discriminatory argument.

The initial scope of CBAM covers a limited, yet strategically significant, number of product groups, identified through Combined Nomenclature (CN) codes. These "CBAM goods" include: (1) cement, (2) electricity, (3) fertilisers, (4) iron and steel, (5) aluminium, and (6) hydrogen[11]. This selection targets sectors with high carbon intensity and significant trade flows, maximising the impact of the mechanism in its nascent phase. The regulation explicitly provides for a review and potential expansion of product coverage by 2030, aiming to eventually include all product groups currently falling under the ETS. Article 30(3) of the CBAM Regulation specifically highlights the review of potential expansion to downstream products, such as washing machines made from steel, with a final selection expected in 2025 and a legislative proposal in Q1 2026. This potential expansion is crucial, as it would significantly broaden the scope of affected businesses and heighten the dual regulatory burden discussed later.

The CBAM is being implemented in two distinct phases to allow stakeholders sufficient time to adapt. The transitional period (1 October 2023 to 31 December 2025) is limited to

[8] S C Rodrigues Aldeia, 'The European Union Carbon Border Adjustment Mechanism as a Green Tax Policy Instrument' (2025) 12 Central European Economic Journal 85, 86-97.
[9] ibid.
[10] Article 3 (1) (24): (24) '"*CBAM certificate' means a certificate in electronic format corresponding to one tonne of CO2e of embedded emissions in goods.*"
[11] Annex I of the CBAM Regulation includes a table listing all specific CN codes corresponding to goods that fall within the product categories identified in the regulation.

reporting obligations. During this phase, importers are required to declare the greenhouse gas emissions embedded in their imports, without being subject to any financial payments. This period is intended to facilitate adaptation to the new requirements for data collection and reporting. The definitive period will commence on 1 January 2026. From that date, importers will be legally obliged to purchase and surrender CBAM certificates corresponding to the embedded emissions of their imported goods. The price of these certificates will reflect the average cost of allowances under the EU Emissions Trading System (EU ETS). Also, to avoid the risk of double carbon charges, the CBAM Regulation will provide for adjustments in cases where a carbon price has already been paid in the country of origin[12].

Crucially, CBAM applies to both direct emissions (GHG emissions from the production process of the goods) and, initially for the goods listed in Annex I, indirect emissions (emissions from the generation of electricity used in the production of the goods). This comprehensive approach aims to capture the full carbon footprint embedded in the imported products. A critical component of the CBAM mechanism, which is of particular relevance to this analysis, is the requirement for the accurate determination of embedded emissions associated to imported CBAM goods. Non-EU producers are expected to monitor and collect data relating to the emissions generated during the manufacturing of CBAM goods subsequently exported to the European Union, as this product-specific information must be submitted to the authorised CBAM declarant at the time of importation. The methodology for calculating embedded emissions, which accounts for the diversity of production processes and the complexities associated with electricity consumption, is set out in the CBAM Implementing Regulation[13] applicable during the transitional period.

2.2 Compliance Burden on Economic Operators

In the context of an analysis focused on the compliance burden placed upon economic operators, it cannot be overlooked that, despite its robust design and clearly articulated objectives, the CBAM mechanism continues to operate within a legal and practical framework marked by unresolved ambiguities, particularly as it progresses towards full implementation. These persisting uncertainties generate significant financial and compliance-related exposure for affected undertakings.

A primary concern remains the future cost of CBAM certificates. While linked to EU ETS allowance prices, the volatility of the carbon market introduces a significant variable that directly affects financial planning, investment decisions, and long-term compliance

[12] An ongoing legislative proposal (Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2023/956 as regards simplifying and strengthening the carbon border adjustment mechanism COM (2025) 87 final) aimed at simplifying the CBAM mechanism introduces a modification whereby the carbon price paid in a third country may be taken into account when calculating the number of CBAM certificates to be surrendered.

[13] Commission Implementing Regulation (EU) 2023/1773 of 17 August 2023 laying down the rules for the application of Regulation (EU) 2023/956 of the European Parliament and of the Council as regards reporting obligations for the purposes of the carbon border adjustment mechanism during the transitional period (Text with EEA relevance).

strategies for importers and, indirectly, for their third-country suppliers. The lack of a predictable pricing trajectory complicates risk management and hinders accurate cost projections.

A critical and largely unresolved issue concerns the precise methodology and criteria for recognising carbon pricing systems in third countries. The CBAM Regulation allows for a reduction in the number of certificates to be surrendered if an equivalent carbon price has already been paid in the country of origin. It is worth noting that the Proposal for a Regulation to simplify CBAM[14], which has been endorsed[15] by both co-legislators but not yet published in the Official Journal at the time of writing, will broaden this to allow the carbon price to be recognised more generally if paid in any "third country." However, the key point is that the exact standards for assessing equivalence, the process for negotiating bilateral agreements, and the mechanisms for verification remain largely undefined. This lack of clarity presents a significant challenge for countries with emerging or developing carbon pricing systems that aim to avoid the full CBAM burden on their exports to the EU.

Apart from the requirements related to purchasing CBAM certificates, which will come into force during the definitive phase starting January 2026, the obligation for third-country operators to collect and report embedded emissions data, even during the transitional phase, using often complex methodologies mandated by EU law, raises significant questions of extraterritoriality and proportionality. These rules, while technically imposed on EU importers, necessitate significant investments and changes in practices for non-EU entities operating outside the EU's direct territorial remit. While these obligations did not initially result in financial payments, they have already created economic exposures for companies needing to establish new systems for data collection and reporting[16]. In addition, the risk of sanctions introduced under Article 16(2) of Commission Implementing Regulation (EU) 2023/1773 must be taken into account. This provision establishes penalties ranging from EUR 10 to EUR 50 per tonne of unreported emissions, with fines subject to adjustment based on the European consumer price index. Against this background, although no systematic data are yet available to quantify the economic impact on affected businesses during the transitional phase, it has been observed that the added administrative complexity alone may disincentivise some importers from sourcing certain goods from outside the EU[17].

The administrative costs for small importers, excluding the actual costs associated with CBAM compliance through the purchase of certificates, were estimated, in the 2025 impact assessment accompanying the Commission's proposal for simplifying CBAM, to

[14] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2023/956 as regards simplifying and strengthening the carbon border adjustment mechanism, COM (2025) 87 final.
[15] At the time of writing, the co-legislators have reached a provisional agreement during interinstitutional (trilogue) negotiations. The text of the agreement now awaits formal endorsement by both the European Parliament and the Council through their respective internal procedures.
[16] Elisabetta Cornago, Aslak Berg, 'Learning from CBAM's transitional phase: Early impacts on trade and climate efforts' (Centre for European Reform 2024) 3.
[17] ibid 2-3.

range from EUR 5,440 to EUR 6,900 per year, for imports valued at approximately EUR 1,600[18]. These costs appear disproportionate relative to the overall value of goods imported into the EU by small operators. This concern has constituted the principal rationale for the recently proposed simplification measures, which envisage the introduction of a new de minimis rule: a CBAM threshold exemption of 50 tonnes per year. The effect of this threshold would be to exempt approximately 90% of current imports which, under the existing regulatory framework, would otherwise fall within the scope of the CBAM mechanism.

As the definitive phase approaches, and these initial efforts translate into substantial financial commitments, the question of whether such stringent pre-obligations for non-EU entities are entirely proportionate will likely gain increasing prominence in legal discourse. The framework established by the mechanism, which demands significant involvement from third-country operators, combined with regulatory uncertainties arising both from the complexity of the legislative framework, including an excessive reliance on secondary legislation even for core aspects of the Regulation, is creating an excessive regulatory burden for both EU and non-EU companies. These factors acquire particular relevance for the present analysis insofar as they affect the justifiability of such burdens and their potential susceptibility to legal challenge, both in relation to the extraterritorial scope of the obligations imposed and their broader impact on third parties beyond the business sector, including consumers.

3 The ESPR and the Expansion of Product Regulation

The ESPR marks a significant development in the European Union's product policy framework, shifting the focus from primarily energy efficiency to broader circular economy goals. It repeals and replaces Directive 2009/125/EC[19] (the Ecodesign Directive), which had mainly applied to energy-related products. The Regulation substantially broadens the scope of regulated goods and introduces more rigorous sustainability requirements, with key provisions expected to take effect between 2027 and 2028. The most salient innovation introduced by the ESPR is the significant broadening of its material scope. Whereas the former Directive applied only to energy-using and energy-related products, such as lighting, household appliances, and electronic displays, the ESPR is intended to cover "almost all goods" placed on the EU market. Only a limited number of goods are expressly excluded under the Regulation, as specified in Article 1(2), including motor vehicles, food and feed products, and medicinal products.

[18] Commission Staff Working Document accompanying Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2023/956 as regards simplifying and strengthening the carbon border adjustment mechanism, SWD(2025) 58 final, para 2.1.
[19] Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (recast) [2009] OJ L 285, 31.10.2009, p. 10.

This near-universal coverage reflects the Union's ambition to integrate sustainability considerations systematically into product design across the internal market and evidences a policy commitment to comprehensive lifecycle regulation. The regulatory framework established under the ESPR has been deliberately structured to ensure adaptability and responsiveness to evolving market conditions and technological developments.

The ESPR operates through a two-tiered model. Products subject to specific ecodesign requirements are not enumerated within the Regulation itself. Rather, the European Commission will adopt triennial "Working Plans," identifying priority product groups based on criteria such as environmental impact, potential for improvement, and economic significance. The first ESPR Working Plan (2025–2030), formally adopted in April 2025, outlines the Commission's strategic orientation for the initial implementation phase. It includes both final and intermediate goods, as well as horizontal sustainability requirements.

Based on these Working Plans, the Commission will adopt delegated acts that establish binding ecodesign requirements for designated product categories, in accordance with the list set out in Article 5(1) of the ESPR. These acts will specify standards related to durability, reparability, recyclability, and the disclosure of product information, among other criteria.

The first Working Plan (2025–2030) identifies the following priority areas:

- **Final Products**: High-volume consumer goods such as textiles (including clothing and footwear), furniture, tires, and mattresses.
- **Intermediate Products**: steel, and aluminium. These materials will initially be subject to mandatory information requirements concerning their sustainability attributes.
- **Horizontal Requirements**: Cross-cutting measures applicable to multiple product groups. These include:
  - **Repairability**: Especially in relation to consumer electronics and household appliances, intended to extend product lifespan and reduce waste.
  - **Recycled Content and Recyclability**: Especially for electrical and electronic equipment, with a view to facilitating the use of secondary raw materials and promoting circular material flows.

The ESPR represents a significant shift in EU product regulation by placing circularity at the core of legal requirements for goods marketed within the Union. Its broad scope, emphasis on the entire product lifecycle, and mix of general and product-specific rules are poised to reshape how products are designed, manufactured, and sold. Manufacturers, including those outside the EU, will need to familiarize themselves early with these new obligations and take proactive measures to ensure compliance in order to maintain access to the EU market. Notably, the ESPR introduces stringent sustainability requirements across a wide range of product categories, impacting not only companies based within the EU but also third-country producers who must adhere to these rules to sell their goods in the Union.

3.1 Compliance Burden on Economic Operators

As observed in relation to the CBAM mechanism, the ESPR likewise entails the risk of imposing an excessive burden on economic operators falling within its scope, including those established in third countries seeking to export products to the European Union. In this regard, it is noted that such operators, in the absence of comparable domestic legislation mirroring the ESPR, may lack the requisite production and monitoring mechanisms necessary to ensure the circularity of goods.

A key point is that the regulation itself acknowledges the risk of imposing a disproportionate administrative burden on economic operators. This concern arises specifically in connection with Article 5(1), which allows for limitations based on the product's circularity due to the presence of so-called "substances of concern." This is expressly addressed in Recital 31, final paragraph, which provides as follows: "*In order to take into account the criteria to be met by ecodesign requirements, and in particular to avoid a disproportionate administrative burden for economic operators, the Commission should be able, as appropriate for the product group concerned, to set thresholds on the concentration of substances in the product or relevant components triggering the tracking requirement, set differentiated application deadlines and, in duly justified cases, provide derogations from the tracking requirement.*"

This reference is indicative of the legislator's awareness of the potentially burdensome nature of environmental compliance obligations. This concern is reiterated in the operative part of the Regulation, notably in Article 5(10)(f), which expressly states that no disproportionate administrative burden should be imposed on manufacturers or other actors in the value chain.

However, while the Regulation acknowledges the risk of such burdens being placed on economic operators, it does not provide concrete mechanisms to mitigate this risk, nor does it offer any form of redress or exemption in cases where the obligations ultimately prove to be unduly onerous. Economic operators will be required to comply with an as-yet undetermined number of ecodesign requirements, across the thematic areas identified in Article 5(1), which are formulated in broad and generic terms and could therefore give rise to far-reaching obligations.

As mentioned above, this regulatory burden is further compounded by overlapping obligations stemming from other EU environmental legislation, most notably the CBAM, raising the risk of duplicative regulatory coverage of the same final or intermediate goods.

Using steel once again as a representative example, it is evident that such an intermediate product may be subject to circularity-related requirements under the ESPR, such as minimum recycled content, resource efficiency criteria, or disclosure obligations concerning substances of concern, while simultaneously being captured by the CBAM due to its emissions profile and carbon intensity.

4 The Extraterritorial Reach of EU Environmental Law: Unpacking the 'Brussels Effect' of CBAM and ESPR

The simultaneous introduction and application of CBAM and ESPR give rise to a complex and unprecedented intersection of legal frameworks. Although each instrument is designed to pursue distinct yet complementary environmental objectives, their concurrent application, particularly in relation to specific categories of goods, creates the risk of a cumulative regulatory burden.

The concurrent application of CBAM and ESPR to producers located outside the European Union raises fundamental questions about the extraterritorial reach of EU law. Although these manufacturers operate beyond the Union's direct jurisdiction, they are effectively compelled to comply with stringent EU standards and data-collection requirements. To maintain access to the EU market, non-EU exporters must align their production processes and information-management systems with the regulatory framework established by these measures. This phenomenon, commonly referred to as the "Brussels Effect"[20] or the European Union's regulatory power, arises from the considerable size and appeal of the EU internal market, which compels multinational corporations to adopt EU regulatory standards as *de facto* global norms.

As observed by Anu Bradford, the European Union establishes global regulatory benchmarks across various sectors, including food safety, chemical regulation, competition law, and data protection, exerting a tangible influence on the daily lives of individuals not only within the European Union but also across the globe[21]. The EU justifies this reach on the basis of preventing carbon leakage (for CBAM – see recital 10 of the CBAM Regulation) and promoting sustainable consumption within its market (for ESPR – see recital 7 of the ESPR), implying that these are legitimate environmental objectives that necessitate a border adjustment or product standard, irrespective of the product's origin.

However, the cumulative impact of CBAM and ESPR compliance costs could lead to significant market distortions and effectively create *de facto* trade barriers for non-EU exporters. For some non-EU companies, particularly smaller enterprises or those from developing countries with less developed environmental infrastructures, the combined compliance burden might be prohibitively high. This could lead them to opt out of exporting to the EU altogether, thereby increasing entry barriers for certain products and reducing diversity of supply. This could inadvertently stifle economic development in certain regions and limit global trade flows.

The extraterritorial impact of CBAM is perhaps the most evident. While the direct legal burden for reporting and surrendering carbon certificates rests with the EU importer, this necessarily creates a significant economic and administrative impact on third-country

[20] This definition was given by A Bradford, 'The Brussels Effect' (Columbia Law School Scholarship Archive 2012) <https://www.almendron.com/tribuna/wp-content/uploads/2018/08/the-brussels-effect.pdf> accessed 20 June 2025.
[21] ibid 3.

producers. For multinational groups with subsidiaries in Europe, the impact is direct, as an EU-based company within the corporate structure bears the financial and reporting obligations for goods imported from its non-EU sister companies. However, even where there is no corporate affiliation, the introduction of a carbon tariff on imported goods intrinsically raises their cost. This regulatory-induced price increase makes products manufactured in third countries economically less attractive, creating a strong market incentive for non-EU producers to reduce their embedded emissions, effectively aligning their production processes with EU carbon pricing principles, regardless of their geographical location.

Beyond the financial implications, third-country operators are indirectly subjected to stringent reporting obligations. The requirement to track and verify embedded emissions, often necessitating adherence to complex methodologies detailed in EU implementing acts (such as those for the CBAM transitional period), has already posed considerable challenges[22]. These difficulties, arising from EU-mandated methodologies for data collection and reporting (informed by Annex IV of the CBAM Regulation), are highly likely to persist into the definitive period. The very precise and intricate requirements for determining embedded emissions, for instance, demand a level of data granularity and verification processes that may not exist in all third countries, forcing non-EU operators to adopt EU-centric accounting and monitoring practices. This creates a *de facto* administrative burden that transcends geographical borders.

A similar rationale applies to the ESPR. While the specific ecodesign criteria are yet to be fully specified through delegated acts, it is clear that any entity wishing to market goods in the EU will have to make additional efforts to comply with these new sustainability requirements. Be it an economic effort (e.g., investing in new materials or production techniques to meet recycled content targets), an administrative effort (e.g., establishing systems to track Substances of Concern throughout the supply chain for the Digital Product Passport), or both, new processes will have to be implemented outside the EU's geographical territory, solely in response to a law adopted within the Union. This means that a factory in Asia or the Americas, producing goods in scope of the ESPR (e.g., textile and tyres) destined for the EU market, must effectively integrate EU ecodesign principles into its product design, material sourcing, and information management systems. The market access leverage exerted by the EU effectively externalises its regulatory standards globally.

[22] As discussed above, even in the absence of official economic data quantifying the impact, several commentators have drawn attention to the challenges faced by companies already during this transitional phase. For a detailed analysis, see Elisabetta Cornago and Aslak Berg, 'Learning from CBAM's Transitional Phase: Early Impacts on Trade and Climate Efforts' (Centre for European Reform 2024).

4.1 Territorial Extension in EU Law

The discussion surrounding the extraterritorial reach of EU law is not new, particularly in the realm of competition law[23]. This phenomenon has recently gained traction in the context of environmental legislation, particularly in relation to CBAM, which has attracted significant scrutiny for its contribution to longstanding debates concerning the legality of unilaterally imposed trade-related measures. In this context, CBAM has been described as giving rise to a form of "territorial extension," and, by implication, as having potentially coercive effects under World Trade Organization (WTO) law[24].

It has been observed that[25], in the EU context, the term *extraterritoriality* lacks a common or settled definition. Rather, it remains an ambiguous and contested concept. Legal literature frequently employs the term inconsistently, often using it to refer to a range of divergent legal phenomena[26]. For the purposes of this analysis, we will distinguish between pure extraterritoriality and territorial extension, in line with established legal scholarship. As Joanne Scott explains[27], a measure is regarded as extraterritorial when it imposes obligations on persons who lack any meaningful territorial connection to the regulating state. By contrast, *territorial extension* refers to situations where the application of a legal measure is contingent upon a territorial link, such as access to the domestic market, while the substance of the obligations it imposes is determined, as a matter of law, by conduct or circumstances occurring outside the territory of the regulating state. It is this latter category of territorial extension that forms the core focus of the present analysis, which examines the normative and structural justifications for the application of EU law beyond the Union's borders. The regulatory frameworks established by the ESPR and the CBAM exemplify this model. Their application is triggered by a territorial nexus, namely, the placing of goods on the EU internal market, yet the content of the obligations under both instruments is shaped by extra-EU factors, particularly the production processes and emissions profiles of third-country operators.

[23] See for example: Lena Hornkohl, 'The Extraterritorial Application of Statutes and Regulations in EU Law' (2022) MPILux Research Paper Series 1/2022 <https://www.mpi.lu/fileadmin/mpi/medien/research/WPS/MPILux_WP_2022_1__Extraterritorial_Application_LH.pdf> accessed 15 September 2025, and Marek Martyniszyn, 'Extraterritoriality in EU Competition Law' in Nuno Cunha Rodrigues (ed), *Extraterritoriality of EU Economic Law* (Springer 2021); and Hannah L Buxbaum, 'The Extraterritorial Application of U.S. and E.U. Competition Law: A Comparative Analysis' (2009) 29 Northwestern Journal of International Law & Business 33.

[24] Ilaria Espa, Joseph Francois and Harro van Asselt, 'The EU Proposal for a Carbon Border Adjustment Mechanism (CBAM): An Analysis under WTO and Climate Change Law' (2022) WTI Working Paper No 06/2022 4. On this matter, see also: review of European Community and International Environmental Law 131; Reinhard Quick, '"Border Tax Adjustments" in the Context of Emission Trading: Climate Protection or 'Naked' Protectionism?' (2008) 3(5) Global Trade and Customs Journal 163; and Joel P Trachtman, 'WTO Law Constraints on Border Tax Adjustment and Tax Credit Mechanisms to Reduce the Competitive Effect of Carbon Taxes' (2017) 70(2) National Tax Journal 469.

[25] Hornkohl (n 23).

[26] ibid.

[27] Joanne Scott, 'Extraterritoriality and Territorial Extension in EU Law' (2014) 62 (1) American Journal of Comparative Law 87, 90.

This conceptual distinction is not merely academic. As Hannah L. Buxbaum has observed, notions of territoriality and extraterritoriality are legal constructs that serve to "reinforce or resist claims to authority."[28] The inherent fluidity of these concepts highlights the contested nature of jurisdictional assertions, especially where the threshold for a sufficient territorial connection is open to interpretation. As Scott also notes[29], territorial extension is often embedded within the very design of EU legislative instruments. One strategy employed by the Union to shield such measures from legal challenge, or to provide a normative justification for their extraterritorial effects, is to ensure that those effects are structurally integrated into the legal framework from the outset, rather than introduced as incidental or post hoc consequences[30].

Scholars have argued that the EU's capacity to project its legal norms beyond its borders rests on the size and attractiveness of its internal market, combined with its regulatory expertise and institutional capacity[31]. The EU has become a global regulatory actor, shaping, both deliberately and inadvertently, markets and governance regimes in diverse areas such as competition policy, digital regulation, public health, and environmental protection[32]. According to this approach, this regulatory gravitation enables the EU to impose legal obligations on third-country actors that, while not territorially situated within the Union, maintain a substantial economic interest in accessing its market[33]. This regulatory dynamic is especially pronounced under the European Green Deal (EGD), which forms the cornerstone of the EU's ambition to lead in global climate governance. Beyond the CBAM and ESPR, this ambition is reflected in other legislative initiatives, such as the extension of the EU Emissions Trading System (ETS) to maritime transport, the Deforestation Regulation, the Corporate Sustainability Due Diligence Directive, and the Methane Regulation, all of which incorporate elements of extraterritorial application[34].

In this broader setting, some scholars have posited that the concept of the EU's regulatory power offers a useful framework for observing the Union's attempts to influence greenhouse gas emissions and other regulatory domains beyond its jurisdictional borders[35]. By adopting ambitious legislative instruments with effects extending beyond the EU, the latter actively seeks to harness the "Brussels Effect" to foster the global diffusion of its regulatory standards[36]. As a result, even in the absence of binding legal

[28] Hannah L Buxbaum, 'Territory, Territoriality, and the Resolution of Jurisdictional Conflict' (2009) 57 Americn Journal of Comparative Law 631, 635.
[29] Scott (n 27) 107.
[30] ilbid.
[31] Sebastian Otto, 'The External Impact of EU Climate Policy: Political Responses to the EU's Carbon Border Adjustment Mechanism' (2025) 25 International Environmental Agreements 177,180.
[32] ibid.
[33] ibid.
[34] ibid.
[35] Goldthau A and Sitter N, 'Regulatory or Market Power Europe? EU Leadership Models for International Energy Governance' in J M Godzimirski (ed), *New Political Economy of Energy in Europe* (Springer 2019) 27–47, 30.
[36] Sebastian Otto, 'The External Impact of EU Climate Policy: Political Responses to the EU's Carbon Border Adjustment Mechanism' (2025) 25 International Environmental Agreements 177, 180.

obligations, there may be both *de facto* and *de jure* extensions of EU law[37]. Multinational corporations may align with EU standards voluntarily to retain market access, and non-EU jurisdictions may converge towards EU norms to avoid regulatory divergence[38]. The European Green Deal has marked a significant evolution of this strategy. As Smith, Overland, and Szulecki have observed, the EGD is distinctive in articulating a binding commitment to carbon neutrality and in integrating climate policy objectives across a wide range of internal and external policy domains, having the potential to consolidate the Brussels Effect in climate and environmental governance[39]. However, the real test of the EU's global regulatory aspirations lies in the practical implementation of the EGD and the extent to which its institutional capacity, and the underlying political consensus, can match its ambitions for leadership in the green transition[40]. This observation is especially relevant in relation to the justification for the territorial extension embedded in the regulatory instruments under discussion. If the normative and institutional basis for such extraterritorial effects were to be weakened, whether through inconsistent implementation, inadequate enforcement, or loss of legitimacy, the EU's capacity to impose obligations on private entities located outside its territorial jurisdiction would be significantly undermined. Ultimately, the legitimacy of extending the reach of EU law beyond the Union's borders rests primarily on the credibility, coherence, and effectiveness of the EU's broader environmental and climate policy framework, first and foremost within the Member States, and, through the mechanism of territorial extension, for those external actors seeking access to the EU internal market.

Although not directly within the scope of the present analysis, it is useful to note, for the sake of completeness, that under customary international law, there are generally recognised bases upon which a state may assert extraterritorial jurisdiction. These principles include nationality, territoriality, and universality. In simplified terms, the nationality principle allows a state to exercise jurisdiction when its nationals, whether individuals or corporations, are either the victims (passive nationality) or the perpetrators (active nationality) of certain conduct[41]. The territoriality principle may be invoked when the conduct in question occurs within a state's borders (subjective territoriality) or when its effects are felt within those borders (objective territoriality)[42]. The universality principle is typically limited to serious international crimes such as piracy, genocide, and crimes against humanity[43]. These bases for extraterritorial jurisdiction are, as is evident

[37] ibid.
[38] Bradford A, *The Brussels Effect: How the European Union Rules the World* (OUP 2020).
[39] Smith, I D, Overland I and Szulecki K, 'The EU's CBAM and Its "Significant Others": Three Perspectives on the Political Fallout from Europe's Unilateral Climate Policy Initiative' (2023) 62 (2) Journal of Common Market Studies 603.
[40] See also Bloomfield J and Steward F, 'The Politics of the Green New Deal' (2020) 91 The Political Quarterly 770; Katharina Rietig and Claire Dupont, 'Climate Policy Integration in the EU: Policy Effectiveness and Coherence' in Tim Rayner and others (eds), *Handbook on European Union climate change policy and politics* (2020).
[41] Danielle Ireland-Piper, 'Extraterritorial Criminal Jurisdiction: Does the Long Arm of the Law Undermine the Rule of Law?' (2012) 13 Melbourne Journal of International Law 9.
[42] ibid.
[43] ibid.

from their characterisation, predominantly relevant in the field of criminal law. Moreover, they pertain primarily to questions of jurisdictional competence rather than to the matter of the territorial extension of substantive regulatory rules. As such, their direct applicability to the present analysis remains limited.

4.2 Judicial Approaches to Extraterritoriality: From Competition Law to Environmental Regulation

The CJEU has historically grappled with the boundaries of its prescriptive jurisdiction, employing various interpretative approaches to justify the reach of EU law beyond its strict geographical confines or beyond cases typically falling under direct EU competence.

In competition law, outside the area of merger control, the CJEU has largely endorsed an "implementation" test, under which the EU may exercise jurisdiction when an anticompetitive agreement, decision, or concerted practice is implemented within the EU, even if carried out by companies not established in the Union. For example, in *Ahlström Osakeyhtiö and Others v. Commission* (Woodpulp I)[44], the Court asserted jurisdiction over non-EU undertakings based on the impact of their anti-competitive practices on the EU market. It is worth noting, however, that the Advocate General Darmon in *Woodpulp I* advocated a more restrictive approach, requiring that the effects be "*direct, substantial and foreseeable*" to justify the assertion of jurisdiction[45].

This concept has been clearly articulated by the CJEU, not explicitly in *Woodpulp I*, but in other judgments which have similarly recognised that effects-based jurisdiction aligns with principles of public international law where foreign conduct produces "*immediate and substantial effects*" within the EU (see, for example, Case T-102/96 *Gencor*)[46].

The CJEU further developed, in an earlier judgment, a test focused on assessing the effects of a single undertaking that is part of a larger group. This test permits the attribution of the presence of one undertaking within the EU to related firms located abroad, thereby enabling the Court to establish jurisdiction over the latter, based on the effects on the EU market of that single undertaking (Case 48/69 *ICI v. Commission*)[47].

These precedents in competition law demonstrate a nuanced approach, generally seeking to tie EU competence to activities that directly manifest or produce effects within the EU legal order. The EU's preference for territorial extension over pure extraterritoriality is significant because it reflects a commitment on the part of the EU to respect the limits on prescriptive jurisdiction laid down by public international law. As

[44] A. Ahlström Osakeyhtiö and others v Commission Joined Cases C-89/85, C-104/85, C-114/85, C-116/85, C-117/85 and C-125/85 to C-129/85 [1993] ECR I-1307.
[45] Opinion of AG Darmon, Joined Cases C-89/85, C-104/85, C-114/85, C-116/85, C-117/85 and C-125/85 to C-129/85 [1988] ECR 5193, para 53.
[46] Gencor Ltd v Commission Case T-102/96 [1999] ECR II-753, Para 90.
[47] Imperial Chemical Industries Ltd v Commission Case 48/69 [1972] ECR 619. Para 127 -146.

such, and notwithstanding the unilateral nature of many of the measures at stake, it forms part of the broader international orientation which pervades EU measures of this kind.

In fields outside competition law, the territorial extension that grounds the applicability of European law generally relies not on effects, as previously discussed, but rather on an objective territorial connection to the beneficiary of a right or a person deserving protection, or on a territorial nexus justifying the applicability of a European legislative framework with all its attendant legal consequences and interests involved. The first of these scenarios, protection of persons holding a legitimate interest or otherwise deserving protection, is exemplified by the CJEU's judgment in Case C-561/20, *Q, R & S v United Airlines Inc.*[48], which further clarified this expansive approach in the context of consumer protection. Notably, the CJEU confirmed that Regulation (EC) No 261/2004, concerning air passenger rights, applies to passengers departing from an airport located within an EU Member State, even where the operating air carrier is non-EU, and subsequent travel occurs outside the Union. The Court held that departure from an EU airport establishes a sufficient territorial connection, irrespective of any effects within the EU (paras 47–49). It further clarified that such an application does not constitute an extraterritorial effect, as the relevant link is established at the point of departure from EU territory (para 53). The second scenario concerns the full applicability of an EU legislative framework, with all its associated legal implications, and does not aim primarily to protect an individual or specific interest. In *Case C-366/10, Air Transport Association of America and Others*[49], which addressed the inclusion of aviation activities in the EU Emissions Trading System (EU ETS), the Court confirmed that Directive 2008/101/EC validly applies to flights departing from or arriving at EU airports, including flights to or from third countries. The Court's justification rested on the fact that charges for emissions are levied within the EU (paras 125–129) and that the regulatory scope is limited to emissions linked to operations at EU aerodromes (paras 143–147, 151–156). While acknowledging the global nature of emissions, the Court emphasised the territorial connection to EU airspace.

Another important angle to consider, drawing upon both regulatory frameworks and judicial interpretation, is the territorial extension of EU law as articulated in Article 3 of the General Data Protection Regulation (GDPR)[50], which expressly defines the territorial scope of the Regulation. Under Article 3(1), the GDPR applies to the processing of personal data "in the context of the activities of an establishment" of a controller or processor in the Union, regardless of whether the processing itself takes place within the EU. This reflects the intention on the part of the EU to extend the reach of EU data protection law

[48] Q and Others v United Airlines Inc (C-561/20, ECLI:EU:C:2022:269).
[49] Air Transport Association of America and Others v Secretary of State for Energy and Climate Change Case C-366/10 [2011] ECR I-13727.
[50] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance) [2016] OJ L 119/1.

beyond the Union's physical territory, where a sufficient functional connection exists with an EU-based entity[51].

This provision has also been examined by the CJEU in earlier case law under the Data Protection Directive (DPD)[52], the predecessor of the GDPR. In the landmark *Google Spain* judgment (Case C-131/12) [53], the CJEU held that data processing carried out by a search engine operator established outside the EU could nonetheless fall within the scope of EU data protection law if it occurred "in the context of the activities" of an EU-based establishment (paragraph 50). In that case, Google Spain, the EU-based establishment, promoted and sold advertising space in Spain. The Court found these activities to be "inextricably linked" to the data processing carried out by Google Inc. in the United States (the search engine operator and controller), as they rendered the search engine economically viable (paragraph 56). The Court thus embraced a broad construction of the territorial nexus, anticipating the principle subsequently codified in Article 3(1) of the GDPR. It affirmed that even an indirect, yet economically significant, connection may suffice to bring data processing activities conducted outside the EU within the scope of EU data protection law.

This case constitutes a significant illustration of the extraterritorial application of EU regulatory norms and offers a useful point of comparison. However, it is submitted that the model developed in *Google Spain* may have limited direct relevance to the frameworks established under CBAM and ESPR. The Court's reasoning in *Google Spain* relied on the existence of a direct and functional relationship between the non-EU entity and an EU-based establishment. Such a relationship is not necessarily present in the context of CBAM, where the connection between a third-country exporter and an EU-based importer may exist in practice but is not inherent to the regulatory design. The analogy is even less applicable under ESPR, where the legal focus is on the placing of products on the EU market. In such cases, the involvement of an EU-based importer is not strictly required for the transaction to take place, thereby weakening the territorial nexus that underpinned the *Google Spain* judgment. Second, and perhaps more importantly, the GDPR expressly codifies its extraterritorial scope in Article 3(1), reflecting a deliberate and explicit regulatory choice. By contrast, neither the ESPR nor the CBAM frameworks contain similarly clear provisions extending their application beyond EU borders, indicating a more implicit or functional approach to territorial reach.

A further legislative development deserving close attention is the Artificial Intelligence Act (AIA)[54]. Like the GDPR, the AIA adopts a functional and effects-based approach to

[51] See on this point Christopher Kuner, 'Territorial Scope and Data Transfer Rules in the GDPR: Realising the EU's Ambition of Borderless Data Protection' (Working Draft, April 2021) Paper No 20/2021, 11.
[52] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJ L 281/31.
[53] *Google Spain SL v Agencia Española de Protección de Datos (AEPD)* C-131/12, ECLI:EU:C:2014:317.
[54] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU)

territorial scope. Under Article 2(1)(a), (c), the AIA applies not only to providers and users of AI systems located within the Union, but also to those established in third countries where the output of the AI system is used in the EU. What matters, therefore, is not the physical location of the provider or the user, but the place of deployment or use of the AI system's output. This approach is notably a-territorial, as it does not distinguish between actors located within or outside the EU for the purposes of establishing regulatory jurisdiction[55].

That said, although the AIA may provide a valuable benchmark for the future territorial extension of EU law, including potentially for the ESPR and CBAM, two key limitations must be acknowledged. First, as previously noted in relation to the GDPR, neither the ESPR nor the CBAM frameworks currently contain explicit provisions addressing territorial extension, which limits the direct applicability of the AIA as a comparator. Second, while the AIA is an adopted and binding legal instrument, its interpretation by the Court of Justice or other judicial bodies remains pending. Further judicial clarification will therefore be crucial to ascertain how its territorial scope will be construed and applied in practice, and to determine whether such judicial interpretation could serve to justify a similar territorial extension of EU law within the regulatory frameworks considered in this article.

4.3 The Unique Challenge of CBAM and ESPR: Beyond Direct Territorial Nexus

The case law and regulatory framework analysed support the proposition that EU regulatory obligations may validly extend beyond the Union's borders where a concrete territorial nexus exists. As discussed above, in the field of competition law this jurisdictional reach has been grounded in the existence of effects within the internal market. By contrast, in other areas of EU law, extraterritorial application has been justified through a more objective territorial link, either to the person entitled to protection under the legislation or to the activity to which the regulatory framework is addressed.

This distinction is critical when considering the instruments examined in this contribution. Unlike in competition law, where "effects" refer to distortions of the competitive structure of the internal market, CBAM and ESPR do not concern anticompetitive conduct by undertakings operating outside the EU. Rather, these instruments impose regulatory obligations on entities in third countries simply by virtue of their intention to place goods on the EU market. In principle, one might argue that CBAM indirectly addresses a competitive imbalance by ensuring that imported goods reflect carbon costs comparable to those borne by EU producers under the EU Emissions

2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) [2024] OJ L, 2024/1689.

[55] See H Ruschemeier, 'AI as a challenge for legal regulation – the scope of application of the artificial intelligence act proposal' (2023) 23 ERA Forum 361, 371.

Trading System (ETS). However, while not wholly unfounded, this argument appears analytically weak: the link to competition law's effects-based reasoning is tenuous at best.

Instead, the more plausible jurisdictional basis for both CBAM and ESPR lies in the territorial connection created through the importation or placing on the market of goods within the EU. In the case of CBAM, this connection is constituted by the act of importing goods into the EU customs territory. As in *Case C-366/10*, where the CJEU upheld the application of the EU ETS to flights arriving at or departing from EU airports, the Court considered emissions occurring outside the Union to be relevant because the charging event, takeoff or landing, occurred within the EU. Similarly, the trigger for CBAM obligations is the importation of goods into the EU, notwithstanding that the production process, including emissions generation, occurs entirely outside EU territory.

The same logic applies to the ESPR, where the placing of a product on the EU market activates compliance obligations, including with respect to product design and information disclosure. Again, it is the destination of the goods, the EU market, that supplies the territorial connection necessary to justify the application of Union law.

However, the analogy to the cases cited above has limits. In both *C-561/20* and *C-366/10*, the relevant activity began or ended with a tangible territorial anchor: physical departure from an EU airport or the occurrence of emissions within EU airspace. By contrast, CBAM and ESPR regulate products whose core attributes and production processes are determined entirely outside the EU, prior to any interaction with the internal market. While the EU undoubtedly possesses jurisdiction to regulate access to its market, the more controversial aspect lies in the depth and reach of the obligations it imposes on third-country operators merely seeking to place goods on that market.

This is where the truly extraterritorial dimension arises. The legal issue is not the imposition of conditions for market access per se, which is within the EU's competence, but rather the extent to which the Union may demand compliance with complex and resource-intensive procedures, such as emissions accounting or sustainability disclosures, from entities over which it exercises no prescriptive authority outside of the importation act itself. In this respect, the territorial connection created by the mere arrival of a product in the EU may be a necessary condition for jurisdiction, but arguably not a sufficient one to justify such expansive regulatory demands.

Put differently, the extraterritorial dimension of CBAM and ESPR raises more complex legal questions as to whether importation or market placement alone constitutes a sufficiently robust territorial nexus to justify the imposition of far-reaching obligations under EU law, especially in cases where the regulated conduct takes place entirely outside the Union and prior to the product's entry into the EU market.

Given that the territorial connection underpinning CBAM and ESPR may be considered relatively weak, some scholars[56] have argued that the legal justification for the EU far-

[56] Scott (n 27) 124-125.

reaching extraterritorial implications should not rest exclusively on immediate jurisdictional links. Rather, it may more plausibly lie in the global objectives these instruments seek to pursue. These objectives, while not confined within territorial boundaries, reflect pressing global concerns and are increasingly recognised in international environmental governance.

Scott has observed that the legitimacy of regulatory measures with extraterritorial effects may derive from their alignment with global or transboundary problems for which there exists international consensus regarding the importance of the underlying objectives[57]. In her view, such alignment may justify the EU's regulatory intervention, not as an attempt to export its standards, but as part of a broader effort to initiate interactive processes with third countries[58]. According to the author, these processes aim to identify and evaluate the various approaches that might be adopted to achieve shared regulatory goals[59].

From this perspective, the EU's assertion of jurisdiction through instruments like CBAM and ESPR can be seen not merely as unilateral action but as a contribution to the development of transnational regulatory dialogue in service of collectively endorsed environmental imperatives. This rationale is overtly manifest across numerous legislative files within the EU's Green Deal political strategy, particularly the "Fit for 55" package. In this context, the EU positions itself as a global leader, exporting its regulatory standards as a means to achieve broader environmental goals, such as those enshrined in the Paris Agreement. The underlying premise is that global problems require global solutions, and the EU, through the power of its single market, can be a catalyst for such solutions.

Crucially, the presence of these measures serving to address global or transboundary problems (such as climate change), in relation to which international agreement on the importance of the underlying objective has been reached, becomes the very justification for such territorial extension, thereby buttressing its legality.

However, it must be noted that recent political developments, and more concretely the legislative turn represented by the so-called *omnibus proposals*[60], reflect a discernible shift in the EU's strategic priorities towards enhancing the competitiveness of European industry. This reorientation, arguably at the expense of some core ambitions of the European Green Deal, raises questions about the continued credibility of the Union's historical role as a normative leader in global environmental governance.

If the Union's emphasis transitions from the export of universal environmental standards to the protection of domestic industrial interests, the normative clarity and

[57] ibid 124.
[58] ibid.
[59] ibid 125.
[60] We're specifically referring here to the proposals within the Omnibus I package, dated 26 February 2025. These include: Commission, Omnibus I COM(2025) 80 (26 February 2025); Commission, Omnibus I COM(2025) 81 (26 February 2025); Commission, Omnibus I COM(2025) 87 (26 February 2025); Commission, Omnibus I – Annexes COM(2025) 87 (26 February 2025).

perceived legitimacy of its external regulatory influence may become increasingly contested. This tension is particularly evident in the case of the CBAM, which, although formally grounded in environmental objectives, functions in practice as an instrument to protect EU industries from the risk of carbon leakage. In such a context, the EU's claim to act as a global standard-setter motivated by collective environmental concerns may appear, at least in part, self-interested.

Nonetheless, it must also be acknowledged that the design of CBAM includes a provision to exempt imports from countries where a comparable carbon price has been effectively paid. This feature, while arguably reflecting a strategic economic interest in incentivising alignment with EU standards, simultaneously contributes to the global diffusion of carbon pricing mechanisms. As such, CBAM's impact extends beyond market protection, fostering convergence with EU regulatory objectives in a manner that, even if pragmatically motivated, may still serve broader climate policy goals.

To conclude, while the case law of the Court of Justice of the European Union, such as *Case C-561/20* and *Case C-366/10*, demonstrates an evolving acceptance of extraterritorial effects where a clear territorial nexus exists, the application of these principles to instruments such as CBAM and ESPR presents a novel and legally complex frontier. In the case of both CBAM and ESPR, it will be difficult to argue that a sufficient territorial connection is present, particularly where production occurs thousands of kilometres outside the European Union and involves companies with no physical or legal presence within the Union. In such instances, the European Union's normative leverage may instead rest, as some have argued[61], on its role as a global leader in achieving environmental objectives, particularly where those objectives are reflected in international agreements or treaties.

As discussed above, the GDPR and the AIA, particularly in light of case law on data protection, such as *Google Spain*, offer a different perspective on extraterritoriality, broadening the concept beyond its traditional scope. While the limits of this approach in the present case have already been noted, the extension of such norms to non-EU entities nonetheless raises potentially significant developments. This is especially true when considering the rationale underlying *Google Spain*, namely the presence of an economic interest linked to activities taking place within the EU. By analogy, it could be argued that the placing of products on the EU market constitutes a comparable scenario, insofar as it reflects a direct and substantial connection between the non-EU operator's activity and the EU's internal market.

That being said, it cannot be overlooked that the European Union is increasingly orienting its regulatory tools toward protecting the competitiveness and interests of its own industries. This shift risks undermining the Union's environmental objectives and diminishing its legitimacy in imposing obligations with extraterritorial effects.

[61] See for example Scott (n 27) 124-125.

Justifications for such obligations, as previously noted, rely heavily on the European Union's normative leadership in global environmental governance. It is therefore foreseeable that the tension between the European Union's environmental ambitions and the established principles of international jurisdiction will become a focal point of legal scrutiny in the coming years.

5 Proportionality in EU Law and Possible Avenues for Consumer Protection

Another important issue that requires careful analysis is the potential burden these regulatory measures may place on consumers, particularly in relation to reduced purchasing power and the extent of available legal protections. This concern may materialise if high compliance costs discourage non-EU exporters from entering the EU market. A decline in the number of suppliers could weaken competitive pressure, leading to increased market concentration among EU-based producers or a limited selection of compliant non-EU sellers. This reduction in competition may result in higher prices for consumers within the Union, undermining the internal market principles of open competition and fair pricing. The simultaneous application of the CBAM and the ESPR raises not only considerable compliance challenges for businesses but also important legal questions regarding the proportionality and broader economic implications of these instruments. In this context, it becomes essential to examine the role of proportionality as a general principle of EU law, the legal obligations surrounding the conduct of impact assessments, and relevant case law concerning sustainability-related regulation.

The principle of proportionality constitutes a fundamental general principle of Union law, serving as an indispensable safeguard against legislative or administrative actions by EU institutions that might exceed what is permissible[62]. As enshrined in Article 5(4) TEU, it mandates that "*the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties*. The proportionality principle applies both to legal acts adopted by EU institutions and to those of the Member States when implementing Union law. However, its application differs depending on the level at which it is invoked, with distinct thresholds and interpretative approaches employed in assessing proportionality at the EU and national levels[63]. In support of this interpretation, De Búrca and Jans have argued that the proportionality principle can be employed with varying degrees of judicial deference, depending on the context and nature of the measure under review[64].

[62] Schwarze considers proportionality to be the most significant general principle in the realm of EU economic law, particularly given the absence of a comprehensive EU administrative law framework. In his view, the principle serves as a standard for evaluating the relationship between the objective pursued and the means employed. See Schwarze J, *European Administrative Law* (revised edn, Sweet & Maxwell 2006) 664–65.

[63] Wolf Sauter, 'Proportionality in EU Law: A Balancing Act?' (2013) 20 Maastricht Journal of European and Comparative Law 440.

[64] de Búrca G, 'The Principle of Proportionality and its Application in EC Law' (1993) 13 Yearbook of European Law 105, 126.

As observed by Vasiliki Kosta, the principle of proportionality in EU law is a constitutional principle invoked to review the legality of any Union action, whether legislative, administrative, or executive in nature[65]. Its constitutional character is also emphasised by Sauter, who argues that proportionality, as a constitutional principle, enables courts to reconcile conflicting rights and norms through a process of balancing. This involves assessing the relative weight of competing interests and applying requirements such as necessity and the least restrictive means (LRM) test[66].

The definition of "proportionality" offered by Alison L Young and Gráinne de Búrca provides a clear and comprehensive account of this principle, particularly in explaining the relationship between the objective pursued and the rights that may be limited in the process. The authors argue[67] that proportionality is primarily aimed at controlling outcomes by ensuring that any restriction on rights is justified and balanced. Specifically, it requires that the benefits and burdens of a measure are proportionately distributed, and that, in pursuing a legitimate objective, the chosen means impose the least possible restriction on the affected rights, or, put differently, that the least restrictive means necessary to achieve the intended outcome are employed[68].

Their definition is grounded in the general principle underlying proportionality in EU law, namely that any act or measure must not exceed what is appropriate or necessary to achieve a legitimate objective. This implies that, where multiple means are available to pursue a given objective, the EU is required to adopt the least onerous option capable of achieving the intended result[69]. Within this framework, the Court of Justice of the European Union (CJEU) plays a central role in conducting both procedural and substantive reviews of proportionality. Procedurally, the Court ensures that the institution or body adopting the measure provides a reasoned justification for its chosen means. Substantively, the CJEU assesses whether the evidence relied upon is factually accurate, internally consistent, and sufficiently robust to support the conclusions reached[70].

Kosta further elucidates that the principle acts as a "*tool that assesses the legality of the exercise of power where a legitimate aim is pursued but another interest deserving of legal protection (typically a right) is damaged.*"[71] Crucially, proportionality necessitates a balancing of conflicting interests, as it is "*not an independent principle of review, since it refers not to any particular free-standing substantive value*"[72]. This inherent requirement for balancing conflicting interests forms the bedrock of the present

[65] Vasiliki Kosta, 'The Principle of Proportionality in EU Law: An Interest-based Taxonomy' [2017] SSRN 1 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3368867> accessed 15 September 2025.
[66] Sauter (n 63) 439.
[67] Alison L Young and Gráinne De Búrca, 'Proportionality' in Stefan Vogenauer and Stephen Weatherill (eds), *General Principles of Law. European and Comparative Perspectives* (Hart Publishing 2017) 137.
[68] ibid.
[69] ibid 138.
[70] Vasiliki Kosta, 'The Principle of Proportionality in EU Law: An Interest-based Taxonomy' in Joana Mendes (ed), *EU Executive Discretion and the Limits of Law* (Oxford University Press 2017) 1.
[71] ibid 2.
[72] ibid1.

analysis. Indeed, there is a legitimate concern that, in the context of environmental legislation, the aforementioned balancing act risks erring in favour of environmental objectives, potentially at the expense of other equally or more deserving interests, such as those pertaining to consumers.

To ascertain compliance with the principle of proportionality, a three-pronged test is generally applied by Union courts, as outlined by Kosta:

- **Suitability (or Appropriateness):** The action or measure must be suitable for pursuing a legitimate aim.
- **Necessity:** The action must not extend beyond what is necessary to achieve the legitimate aim; that is, no less-restrictive yet equally effective means should be available.
- **Proportionality *stricto sensu* (or Balancing):** Even if the action is suitable and necessary, the interference with a protected right or interest must be justified in light of the gain resulting from pursuing the legitimate aim[73].

his third limb, proportionality *stricto sensu*, requiring that the interference with a protected right or interest be justified by the legitimate aim pursued, is particularly susceptible to future legal challenges concerning measures such as the ESPR and CBAM. These instruments, *inter alia*, are likely to increase, at best, the price of products sold within the EU. The potential resultant diminution of consumers' purchasing power may leave them without adequate protection, thereby arguably undermining the proportionality of the measures.

As Kosta aptly notes regarding Article 5(4) TEU, stating that "*the form and content of Union action shall not go beyond what is necessary to achieve the objectives of the Treaties*," such a formulation, in isolation, "*does not make much sense as it fails to identify what interest it serves*."[74] This underscores the contention that merely adhering to the Treaties does not inherently ensure a balanced assessment of all interests at stake. This author concurs with Kosta's assertion that "*the fact that there exists proportionality as a free-standing heading of judicial review in EU law (free-standing proportionality) makes it difficult to identify what interest it serves*."[75] Similarly, Sauter contends that the application of the proportionality test in EU law lacks consistency. He characterises the principle as a balancing act, not only between competing legal principles but also across different levels of governance, between the residual competencies of Member States and the integrative aims of the Union, and between policy objectives and the protection of individual rights[76].

Consequently, judicial clarification remains paramount. It will therefore likely fall upon consumers or consumer associations, subject to the limitations discussed below regarding the admissibility of actions brought by consumers under Articles 263 or 267 TFEU[77], to

[73] ibid 3.
[74] ibid 6.
[75] ibid 21.
[76] Sauter (n 63) 466.
[77] Treaty on the Functioning of the European Union (TFEU) [2008] OJ C115/47.

potentially initiate legal challenges against ESPR and CBAM measures to seek protection. Indeed, EU courts consistently review Union measures, including environmental and product regulations, for their adherence to the principle of proportionality. While the EU legislature enjoys a broad margin of discretion, particularly in policy areas involving complex economic, social, and environmental choices where scientific uncertainty may prevail, this discretion is not unconstrained. The courts will intervene where a measure is found to be manifestly disproportionate, that is, demonstrably unsuitable, unnecessary, or imposing an excessive burden, or where the Union institution has committed a manifest error in its assessment of the relevant facts or in the balancing of the competing interests.

5.1 Judicial Oversight in Proportionality Assessments

Our analytical inquiry into the proportionality of Union measures, particularly those stemming from environmental and product policy, necessitates a direct examination of the statutory provisions mandating impact assessments. This is a crucial feature prominently observed within the legal frameworks under analysis, especially concerning the rules setting ecodesign requirements.

Specifically, the Ecodesign Directive (Directive 2009/125/EC) explicitly stipulates the European Commission's obligations when preparing a draft implementing measure. Article 15(4)(b) of that Directive provides that the Commission shall: "*carry out an assessment, which shall consider the impact on the environment, consumers and manufacturers, including [small and medium-sized enterprises (SMEs)], in terms of competitiveness – including in relation to markets outside the [EU] – innovation, market access and costs and benefits*."

These provisions are integral to ensuring that the principle of proportionality is effectively embedded within the legislative process. They compel the Commission to undertake a comprehensive evaluation of a broad spectrum of effects before adopting legally binding requirements. Article 15(4)(b) of the Ecodesign Directive unequivocally demonstrates a deliberate legislative intent to balance multiple, and often competing, objectives by explicitly requiring consideration of environmental, economic, and social concerns. Crucially, it makes clear and express reference to the interests of consumers.

However, it is pertinent to note that while Directive 2009/125/EC expressly mandates a detailed assessment of the impact on consumers as part of its regulatory framework, the legislative text of its successor, the ESPR, although it makes repeated references to the principle of proportionality, particularly in relation to economic operators and with explanatory emphasis in Recital 31, does not consistently articulate an equally explicit concern for consumer protection in evaluating the proportionality of its measures. While the Regulation refers to the need to avoid imposing disproportionate administrative

burdens on manufacturers and other actors in the value chain, such considerations are not uniformly extended to the impacts on end-users[78].

This distinction highlights a potential area of ambiguity regarding the precise weight accorded to consumer interests within the broader proportionality assessment, particularly when economic burdens are considered, which may form a basis for future legal scrutiny.

In the sphere of European Union regulatory compliance, the principles of proportionality (Article 5(4) TEU) and the stringent statutory requirement for comprehensive impact assessments (notably Article 15(4)(b) of Directive 2009/125/EC, the Ecodesign Directive) constitute pivotal benchmarks through which not only industry stakeholders, but also consumers and their representative associations, may seek judicial review of EU legislative measures. Challenges frequently contend that the European Commission has failed to adequately reconcile ambitious environmental objectives with the attendant economic burdens placed upon businesses and, crucially, with potential adverse ramifications for consumer welfare and purchasing power.

A salient illustration of the General Court's jurisprudential approach in this domain, particularly regarding the vital role of consumer impact assessment, is *Case T-113/20, Bromine Science Environmental Forum (BSEF) v European Commission*, delivered on 16 March 2022[79]. In this action, BSEF, representing producers of halogenated flame retardants (HFRs), sought the annulment of Commission Regulation (EU) 2019/2021, which imposed a ban on HFRs in the enclosure and stand of electronic displays. Crucially for our analysis, BSEF alleged that the Commission had failed to adequately assess the impacts on consumers, particularly concerning fire safety, and the overall cost-effectiveness of the ban.

The judgment is of particular interest for this analysis as it scrutinised the Commission's fulfilment of its obligations concerning impact assessments and proportionality. The Court underscored that ecodesign measures must be predicated upon robust technical, economic, and environmental analyses, necessitating a delicate balance between environmental factors and considerations of competitiveness and product functionality. The Court recalls in the judgment that *"(…) according to Article 15(4)(b) of the Ecodesign Directive, 'in preparing a draft implementing measure the Commission shall … carry out an assessment, which shall consider the impact on the environment, consumers and manufacturers, including SMEs, in terms of competitiveness – including in relation to markets outside the Community – innovation, market access and costs and benefits'. Furthermore, pursuant to Article 15(5)(a) of the Ecodesign Directive, implementing measures are to meet the criterion that 'there shall be no significant negative impact on the functionality of the product, from the perspective of the user'"* (paragraph 95).

[78] According to article 5 (10) (f) "there shall be no disproportionate administrative burden on manufacturers or other actors in the value chain, including SMEs, in particular microenterprises".

[79] *Bromine Science Environmental Forum (BSEF) v European Commission* T-113/20, EU:T:2022:154.

The *BSEF* judgment serves as a robust affirmation of the EU courts' disposition to uphold ambitious environmental legislative measures, provided that they are within the scope of the empowering directive. Concurrently, the judgment reaffirms the stringent judicial oversight of the Commission's adherence to procedural requirements, particularly regarding comprehensive impact assessments and proportionality analyses. In this judgment, the Court ultimately upheld the Commission's measure, confirming the ban's relevance to the legitimate ecodesign objectives of resource efficiency and recyclability. While cost-effectiveness and consumer impact remain potent grounds for legal challenge, the Court ultimately deferred to the Commission's broad technical and policy discretion, dismissing the applicant's claims as unfounded[80]. What is noteworthy for the purposes of this analysis is that, although the Court ultimately found the Commission's intervention to be proportionate, its reasoning places particular emphasis on the interests of consumers when assessing the proportionality of a measure. At the same time, the judgment offers another important insight: even where consumer impacts are recognised as highly relevant, the threshold for establishing a manifest error of assessment sufficient to justify annulment remains high.

Crucially, in the context of emerging legislation such as the CBAM and the ESPR, the insights drawn from the BSEF judgment become especially relevant for consumer protection. As previously observed, while Directive 2009/125/EC expressly required a detailed assessment of consumer impact pursuant to Article 15(4)(b), the successor regulation, the ESPR, noticeably reduces this emphasis. It lacks an equally explicit reference to consumer interests in the proportionality assessment of its measures. The CBAM framework appears to offer even less direct consideration of consumer-related proportionality concerns.

This legislative posture suggests that, at present, the likelihood of consumers or their representative organisations successfully challenging these frameworks on the grounds of disproportionate impact may be limited and legally complex.

Nonetheless, the reasoning adopted by the Court in BSEF underscores the importance that can be placed on consumer interests when evaluating the proportionality of legislative intervention. It therefore cannot be excluded that similar legal challenges might in the future arise in relation to the ESPR and CBAM frameworks analysed in this paper.

It is also important to consider that judicial interpretation evolves in response to changing societal priorities and political developments. We are currently observing a potential shift in the regulatory landscape, where environmental protection, although still paramount, is increasingly examined in light of its socio-economic implications. Given that the Court of Justice is ultimately responsible for interpreting and applying the principle of proportionality, it is conceivable that future rulings, influenced by these evolving

[80] ibid paragraph 145.

concerns, could create new legal opportunities for contesting certain provisions on the basis of consumer protection. The final determination as to whether the Commission's balance is proportionate will continue to rest with the judiciary.

5.2 Admissibility of Legal Actions Brought by Consumers

It should also be noted that there exists a significant issue regarding the admissibility of legal actions brought by_ consumers that must be taken into account in this context. Specifically, under the current legal framework, consumers as such may not be considered as having standing (locus standi) to bring actions directly before the CJEU. The TFEU provides two principal mechanisms for judicial review aimed at ensuring that the institutions, bodies, offices, and agencies of the Union act within the limits of their legal authority. These mechanisms are set out in Article 263 TFEU, which governs direct actions for annulment, and Article 267 TFEU, which establishes the preliminary reference procedure for indirect judicial review via national courts[81]. The TFEU not only permits EU institutions to challenge the legality of Union acts but also grants access to so-called "non-privileged" applicants, including natural and legal persons, under the conditions set out in Article 263(4) TFEU. According to this provision, non-privileged applicants may only bring an action for annulment if they meet one of the following criteria: (1) they are the addressee of the contested act; (2) the act is of direct and individual concern to them; or (3) the challenge is brought against a regulatory act that is of direct concern to them and does not entail implementing measures[82].

In order to determine whether an individual or a group of individuals, such as consumer associations, meets the conditions set out under Article 263(4) TFEU, the Court of Justice of the European Union has developed a specific legal test. This was articulated in the Judgment of 15 July 1963 in Case 25/62, *Plaumann & Co. v Commission*, and is commonly referred to as the Plaumann test. According to this test, an applicant is considered to be individually concerned by a measure if it affects them "*by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons*".[83]" This is a particularly stringent standard, and it is precisely this threshold that consumer associations generally fail to meet. In particular, it may prove difficult for consumer associations to demonstrate the existence of specific attributes or circumstances that are unique to them, since their membership consists of a broad and shifting group of individuals whose identities and situations vary over time. As a result,

[81] Peers S and Costa M, 'Court of Justice of the European Union (General Chamber) Judicial Review of EU Acts after the Treaty of Lisbon; Order of 6 September 2011, Case T-18/10 Inuit Tapiriit Kanatami and Others v. Commission & Judgment of 25 October 2011, Case T-262/10 Microban v. Commission' (2012) 8 European Constitutional Law Review 82, page 1.
[82] Kucko M, 'The Status of Natural or Legal Persons According to the Annulment Procedure Post-Lisbon' (2017) 2 LSE Law Review 101.
[83] *Plaumann & Co v Commission* 25/62 [1963] ECR 95, page 108.

they are rarely able to demonstrate the level of individual concern required to establish standing under Article 263(4) TFEU.

However, where applicants do not meet the standing criteria under Article 263(4), an alternative route for legal redress remains available under Article 267 TFEU[84]. In such cases, individuals or associations may bring proceedings before national courts, arguing that a particular provision of EU law adversely affects their rights. National courts may then refer questions to the CJEU for a preliminary ruling under Article 267(b) TFEU, which specifically allows the Court to assess the validity and interpretation of acts of the institutions, bodies, offices or agencies of the Union. This mechanism thereby offers an indirect, but nonetheless meaningful, pathway for judicial scrutiny of Union acts that may otherwise be insulated from direct review by non-privileged applicants.

Against this backdrop, it should also be noted that certain strands of legal scholarship have criticised the Plaumann case law as excessively restrictive, arguing that it fails to provide adequate access to justice[85]. These critiques have been particularly prominent in the context of climate change, a phenomenon that affects all individuals, including both current and future generations. In such cases, the general nature of the harm results in a paradoxical outcome: the more serious and widespread the damage, the less likely it is that the corresponding legal acts can be challenged under the Plaumann test[86]. The paradox lies in the notion that the gravity and universality of the impact may itself preclude standing under Article 263(4) TFEU. This line of reasoning has prompted growing calls for a reconsideration of the current standing criteria, particularly in cases involving global environmental challenges. A potential shift in judicial approach, especially in litigation related to climate change, could have important implications for access to justice more broadly, including the possibility of extending standing to consumer associations in appropriate cases.

6 Conclusion

The CBAM and the ESPR represent ambitious expressions of the European Union's intent to lead the global transition to a sustainable, low-carbon economy. These regulatory instruments are not solely directed at decarbonizing the internal market; they are designed to exert external influence, encouraging global convergence around higher environmental standards, what is often termed the Brussels Effect.

However, this assertive normative posture raises increasingly complex legal, political, and economic questions. The very legitimacy of the EU's extraterritorial regulatory

[84] Among the established case law on the matter see: *Telefónica SA v European Commission* C-274/12 P, ECLI:EU:C:2013:852, para 59.
[85] Lena Hornkohl, 'The CJEU dismissed the People's Climate Case as inadmissible: the limit of Plaumann is Plaumann' (*European Law Blog*, 6 April 2021) <https://www.europeanlawblog.eu/pub/the-cjeu-dismissed-the-peoples-climate-case-as-inadmissible-the-limit-of-plaumann-is-plaumann/release/1> accessed 15 September 2025.
[86] ibid.

ambitions, particularly when they impose *de facto* obligations on third-country operators, hinges on a delicate equilibrium between environmental necessity, proportionality, and respect for the sovereignty of external jurisdictions.

The success of this ambitious regulatory project will depend not only on the robustness of the legislative texts, but on the quality of implementation, the clarity and transparency of secondary legislation, and the degree of cooperation secured with international partners. Equally vital will be the capacity of the EU to maintain internal cohesion and external credibility.

We find ourselves at a pivotal juncture in the history of EU regulatory governance. Increasingly, the rigor of the EU's environmental legislation is being questioned not only by third countries but from within the Union itself. This is evidenced by a growing tendency toward de-regulatory recalibration, as exemplified by the emergence of multiple omnibus legislative packages currently under adoption. These developments are not merely political in nature, they also carry substantial legal implications.

Politically, this recalibration may signal a retreat from the EU's previously undisputed role as a global leader in environmental rulemaking. The Green Deal, once the flagship of the Union's international agenda, now appears more fragile, its credibility challenged both by shifting domestic priorities and mounting external resistance.

Legally, the implications are profound. The EU's authority to project its environmental norms beyond its territory, through instruments like CBAM and ESPR, has thus far been predicated on the assumption that such measures serve a legitimate environmental objective, recognized and respected by the international community. If that perception of environmental leadership wanes, the foundational justification for the extraterritorial application (or, more precisely, extension) of EU law weakens considerably.

In such a scenario, CBAM risks being perceived less as an instrument of environmental governance and more as a mechanism of disguised protectionism, raising serious concerns under WTO law and principles of international comity. Similarly, ESPR, if it goes too far in prescribing detailed design and compliance requirements for goods originating in fundamentally different industrial and economic contexts, may be challenged as an overreach, potentially incompatible with international trade norms.

This raises a fundamental legal and normative question that lies at the heart of the EU's global regulatory strategy: In the absence of sustained international recognition of the EU's environmental leadership, can the Union still justify the imposition of legally binding obligations on jurisdictions and actors that, subject to legal interpretation, may be considered to fall outside its legal competence? The answer to this question will shape not only the future trajectory of CBAM and ESPR, but the very viability of the EU's broader attempt to leverage market power into regulatory influence on the world stage.

The European judiciary will inevitably play a central role in navigating this uncertain terrain. It will fall to the Court of Justice of the European Union to assess whether these

instruments respect the limits of EU competence, comply with principles of proportionality, and are underpinned by sufficiently rigorous impact assessments.

In conclusion, the EU must approach this moment not with complacency, but with critical self-awareness and strategic foresight. Its continued ability to act as a credible and effective global standard-setter depends not only on the ambition of its environmental agenda, but on its commitment to legal precision, procedural fairness, and regulatory humility.

*Martina Mastrodomenico and Remigio Graziani**

SPECIAL SECTION

LCA AND ECO-DESIGN BETWEEN INNOVATION AND RESPONSIBILITY

The role of Life Cycle Assessment and eco-design in environmental policies and consumer protection

Abstract

The evolution of environmental regulation and consumer protection law is driving a profound transformation of production and commercial models, gradually orienting them towards sustainability and social responsibility. This regulatory development raises a structural challenge: how to reconcile the reduction of environmental impacts with the parallel need to strengthen consumer protection. Life Cycle Assessment (LCA) and eco-design emerge as essential tools in this respect: LCA makes it possible to analyse environmental effects throughout a product's life cycle, thereby providing a scientific basis for policies on responsible consumption and production, while eco-design integrates sustainability criteria at the design stage, fostering durability, repairability and recyclability.

This transition is increasingly reflected in binding legal instruments. The Eco-design for Sustainable Products Regulation (ESPR) introduces stricter design requirements; Directive 2019/771 on legal guarantees reinforces the right to durable and repairable goods; and the proposed Green Claims Directive seeks to regulate environmental claims, preventing greenwashing and ensuring that information provided to consumers is verifiable and transparent. International standards such as ISO 14040 and ISO 14044 provide methodological guidance for LCA, while principles like Extended Producer Responsibility (EPR) and the precautionary principle impose regulatory obligations on producers to manage end-of-life processes and adopt preventive measures to minimise risks.

The emerging right to repair further consolidates this approach, requiring manufacturers to provide spare parts and ensure access to information necessary for maintenance and repair.

* This article is the result of a joint effort by the authors: 1 Fundamentals and Regulatory framework - 1.1 Introduction: The history and definition of Life Cycle Assessment (LCA)- 1.2 Life Cycle Thinking as the Conceptual Basis of LCA – 1.3 Methodological Approaches to Life Cycle Assessment– 1.4 LCA as a Tool for Measuring Environmental Impacts and its Regulatory Evolution – 1.5 From LCA to Policy: the ESPR and the European Regulatory Framework- 1.6 Extended Producer Responsibility and LCA: From Policy Principle to Regulatory Instrument– 1.7 Standardising LCA for Legal and Regulatory Use: The Role of ISO 14040 and ISO 14044] were written by Dott.ssa Martina Mastrodomenico, from the University of Teramo; while 2 Environmental sustainability as a transversal metanorm within consumer law - 2.1 The Precautionary Principle and Its Application in Environmental and Consumer Protection Policies – 2.2 The Impact of the Eco-Design Principle in Consumer Law - 2.3 Critical perspectives and regulatory implications were written by Dott. Remigio Graziani, University of Teramo.

10.13135/2785-7867/12834

Nevertheless, significant challenges remain: the methodological complexity of LCA, the absence of harmonised standards, and the risk of unreliable or incomplete data may undermine the effectiveness of this framework, while the proliferation of unregulated labels contributes to misleading practices.
These difficulties, however, should not be regarded as insurmountable, they call instead for targeted regulatory measures: tax incentives for companies adopting eco-design practices and reliable certifications; stricter controls and sanctions against misleading claims; and the integration of LCA criteria into sustainable public procurement policies.
The adoption of LCA and eco-design represents a strategic challenge for reconciling technological innovation, environmental protection and consumer rights; to maximise their effectiveness, a joint effort by institutions, businesses and civil society is required in order to build a coherent regulatory framework capable of ensuring a transition towards a sustainable economy firmly grounded in both environmental responsibility and the effective enforcement of consumer law.

JEL CLASSIFICATION: K32, Q56, Q58

SUMMARY

1 Fundamentals and Regulatory Framework

1.1 Introduction: The history and definition of Life Cycle Assessment (LCA)

The environment, in the current context, has now a great relevance, especially considering the consequences that climate change is causing in many countries. More and more frequently, phenomena such as persistent rain, floods but also extreme heat and desertification continue to spread on a large scale and with great vehemence: concerns for the future regarding "the environmental issue" have led politicians and businesses to support as much as possible the strategies aimed at protecting the environment. One example was the very introduction of the 17 goals for sustainability (SDGs)[1] within the

[1] UN Resolution A/RES/70/1, "Transforming our world: the 2030 Agenda for Sustainable Development," adopted on 25 September 2015. *Ex multis*: Adenle A A, Chertow M R, Moors E H M, Pannell D J, *Science, Technology, and Innovation for Sustainable Development Goals* (Oxford University Press 2020); Bennich T, Weitz N, Carlsen H, 'Deciphering the scientific literature on SDG interactions: A review and reading guide' (2020) 728 The Science of the total environment 1; Biermann Fand others, 'Scientific evidence on the political impact of the Sustainable Development Goals' (2022) 5 Nature Sustainability 795; Cohen B and others, 'Cobenefits and trade-offs of climate change mitigation actions and the

framework of Agenda 2030[2]: the United Nations brought together governments, society and the entire scientific community with the goal of undertaking a series of initiatives and new strategies aimed at achieving climate neutrality by 2050. These objectives created the urgency to implement forms of environmental impact measurement: on one hand a constant estimate of emissions is required, on the other a study on new technologies serving monitoring is needed.

In less suspect times, particularly at the end of the 1960s, a study aimed to evaluate the environmental impact of products: historically, the origins of what would later become LCA can indeed be traced back to the analysis of Coca Cola packaging, initially called Resource and Environmental Profile Analysis (REPA)[3]. At the same time, in Europe, these issues began to be discussed through energy analyses: the European equivalent of REPA was called "Ecobilancio" (from the German name of Life Cycle Assessment, Ökobilanz). In this period, indeed, the awareness of the finiteness of resources and the impossibility of sustaining the unconditional exploitation rhythms that had been established also began to spread.

At the beginning of the 1970s, many companies began to analyse their products in a similar way, although a great difficulty caused by the scarcity of available industrial data. Only in the 1980s did the EPA (the American Environmental Protection Agency) published its LCA 101[4], a document supporting this emerging methodology that explains the fundamental concepts of LCA, its applications, benefits and limitations. Not being regulated by shared technical standards, each company could carry out the LCA according

Sustainable Development Goals' (2021) 26 Sustainable Production and Consumption 805; Dzebo A and others, 'The Sustainable Development Goals viewed through a climate lens' (SEI publications 2018) <https://www.sei.org/publications/the-sustainable-developmentgoals-viewed-through-a-climate-lens/> accessed 25 Sepptember 2025; Pizzi S and others, 'Management research and the UN sustainable development goals (SDGs): A bibliometric investigation and systematic review' (2020) 276 Journal of Cleaner Production 10.

[2] *Ex multis*: Idowu S O, Schmidpeter R, Zu L, *The Future of the UN Sustainable Development Goals: Business Perspectives for Global Development in 2030* (Springer 2020); Mohieldin M, Wahba S, Gonzalez-Perez M A, Shehata M, *Business, Government and the SDGs: The Role of Public-Private Engagement in Building a Sustainable Future* (Palgrave Macmillan 2023); Persaud N, Ruby D, 'The United Nations: 2030 Sustainable Development Goals Agenda' in *The Role of Monitoring and Evaluation in the UN 2030 SDGs Agenda* (Palgrave Macmillan 2021); Yusha'u, Muhammad Jameel, Jan Servaes (eds), 'Beyond the SDGs: From 2030 to 2050 Agenda for Development' in *The Palgrave Handbook of International Communication and Sustainable Development* (Springer International Publishing 2021); Weitz N, Carlsen H, Nilsson M, Skånberg K, 'Towards systemic and contextual priority setting for implementing the 2030 Agenda'(2017) 13(2) Sustainability Science 531; Weitz N, Carlsen H, Skånberg K, Dzebo A, 'SDGs and the Environment in the EU: A Systems View to Improve Coherence' (SEI Publications 2019) <https://www.sei.org/publications/sdg-synergies-environment-eu/> accessed 15 September 2025 ; Weitz N, Carlsen H, Trimmer C, 'SDG Synergies: An Approach for Coherent 2030 Agenda Implementation' (SEI Publications 2019) <https://www.sei.org/ publications/sdg-synergies-factsheet/> accessed 25 September 2025; Weiland S, Hickmann T, Lederer M, Marquardt J, Schwindenhammer S, 'The 2030 Agenda for Sustainable Development: Transformative Change through the Sustainable Development Goals?' (2021) 9 Politics and Governance 90.

[3] The Resource and Environmental Profile Analysis (REPA) represents one of the earliest systemic methodologies developed to assess the environmental impacts associated with the life cycle of products. Introduced in the United States in the late 1960s and early 1970s, REPA was used to analyze resource use and environmental emissions from the extraction of raw materials to the final disposal of products. This methodology laid the foundation for the subsequent development of Life Cycle Assessment (LCA), as acknowledged by the United States Environmental Protection Agency (EPA) and the Society of Environmental Toxicology and Chemistry (SETAC).

[4] U.S. Environmental Protection Agency, "LCA 101: Introduction to Life Cycle Assessment", EPA/600/R-02/139F, 2002.

to its own methodologies, arbitrarily choosing the boundaries of the analysed system, data sources and evaluation criteria. In particular, they began citing results derived from LCA studies to promote a "green" or ecologically responsible image. The growing concern about the misuse of LCA led to the need to develop international standards to ensure consistency and reliability: a crucial role was played by the Society of Environmental Toxicology and Chemistry (SETAC). In 1990, during the SETAC congress held in Vermont (USA)[5], the first definition of LCA was given as "*an objective process of evaluating the environmental loads associated with a product, process or activity, conducted through the identification and quantification of energy and materials used and wastes released into the environment, to assess the impact of these uses of energy and materials and releases into the environment, and to examine and implement opportunities for environmental improvement. The assessment includes the entire life cycle of the product, process or activity, including raw material extraction and processing, manufacturing, transportation and distribution, use, reuse, maintenance, recycling and final disposal*" (SETAC,1991). The standardisation process of the method continued, leading to the publication of manuals by various research groups, up to the publication in 1997 of the first ISO standards, updated in 2006 (ISO 14040, 2006; ISO 14044, 2006). With the beginning of the new millennium, the urge of a strategy aimed systematically and proactively addressing environmental issues related to products throughout their entire life cycle began to consolidate: the Integrated Product Policy (IPP) was born. This strategy was officially launched with the 2001 Green Paper and structured with Communication COM (2001)68. The particularity of this strategy lies in its innovative and cross-cutting nature: it does not merely impose regulatory constraints but promotes active collaboration among producers, consumers and public institutions. The goal is to build a system in which eco-innovation and environmental responsibility become fundamental criteria in design, production and purchasing decisions, as stated in the same communication.

One of the key principles of IPP is the life cycle approach: every product must be evaluated taking into account not only its final characteristics, but also the processes and resources that led to its creation; this allows, for example, to avoid the paradox whereby a product apparently "ecological" during the use phase turns out to be highly impactful in the production or disposal phase.

To make these principles operational, IPP uses a series of tools; among the most relevant are the Life Cycle Assessment (LCA), which allows the quantification of the environmental impacts of a product in a scientifically based manner; ecological labeling, such as the Ecolabel [6], which helps consumers identify more sustainable alternatives; and

[5] SETAC, 'A Technical Framework for Life-Cycle Assessment' Workshop Report (Vermont 1991).
[6] Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel, which establishes a voluntary ecolabelling scheme for products and services with reduced environmental impact throughout their entire life cycle.

Green Public Procurement (GPP), which introduces environmental criteria in public administration purchases, steering the market toward more virtuous options.

1.2 Life Cycle Thinking as the Conceptual Basis of LCA

At the base of Life Cycle Assessment as it is understood and defined today, there is a holistic and philosophical conception called Life Cycle Thinking[7]. It is, even before being a technique, a true cultural attitude; an invitation to move away from a fragmented vision of environmental problems to consider them as a whole, recognising how every design, production, or consumption choice affects multiple levels, at different times in the life cycle of a good. It is an approach that aims to make visible what often remains hidden behind the surface: it therefore leads us to question, for example, what will happen to a product once it has been used, how many natural resources were needed to make it, what emissions were generated during transportation.

To turn abstract thinking into concrete action, it is necessary to have suitable tools: one of the most important is Life Cycle Assessment, that is, the evaluation of the life cycle. Unlike Life Cycle Thinking, which is a qualitative approach, LCA is a structured methodology, based on concrete data and regulated by international standards, and it is used to measure, with scientific rigor, the environmental impacts associated with a product throughout all phases of its existence. In summary, Life Cycle Thinking is the vision, Life Cycle Assessment is its practical translation. One provides the cultural framework within which to operate, the other the tools to make conscious and verifiable choices. Both contribute to building an economy more attentive to the environment, based on knowledge, transparency, and responsibility.

1.3 Methodological Approaches to Life Cycle Assessment

Among the methodologies recognised at the international level for evaluating the environmental impacts of the phases that make up a production chain, a leading role is held by Life Cycle Assessment (LCA), standardised as ISO 14040[8]. It consists of an analytical approach, predominantly quantitative, whose objective is to measure the environmental

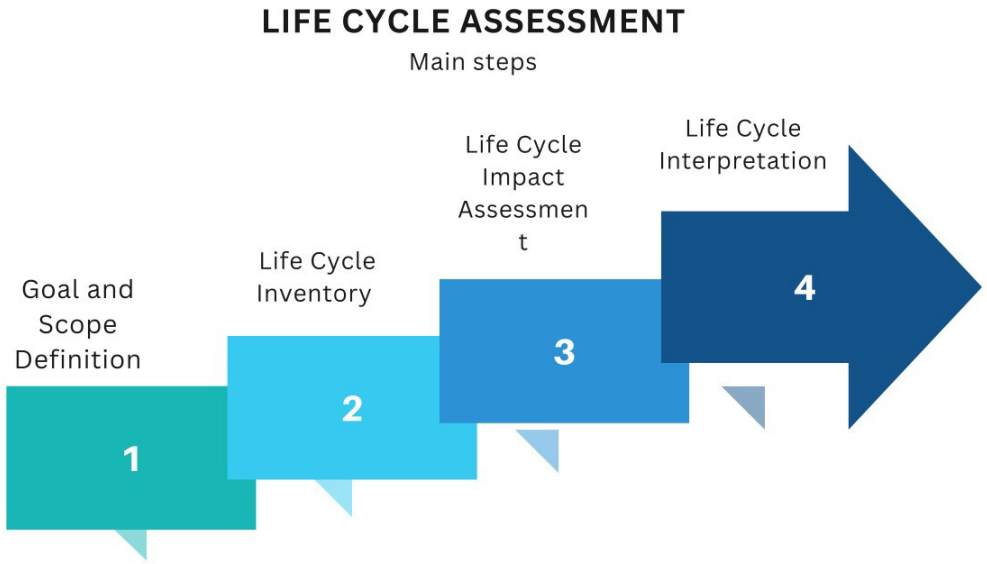
[7] «Life Cycle Thinkingis is a mostly qualitative discussion to identify stages of the life cycle and/or the potential environmental impacts of greatest significance, e.g. for use in a design brief or in an introductory discussion of policy measures. The greatest benefit is that it helps focus consideration of the full life cycle of the product or system; data are typically qualitative (statements) or very general and available-by-heart quantitative data»: Christiansen K (ed), 'Simplifying LCA: Just a Cut? Final report from the SETAC EUROPE LCA Screening and Streamlining Working Group' (SETAC Europe, Brussels 1997).

[8] Finkbeiner M, 'The international standards as the constitution of life cycle assessment: the ISO 14040 series and its offspring' in *Background and future prospects in life cycle assessment* (Springer 2014) 85-106; Schaubroeck T, 'Sustainability assessment of product systems in dire straits due to ISO 14040–14044 standards: Five key issues and solutions' (2022) 26 Journal of Industrial Ecology 1600-1604; Brandão M, Busch P, Kendall A, 'Life cycle assessment, quo vadis? Supporting or deterring greenwashing? A survey of practitioners' (2024) 17 Environmental Science: Advances 266-273; Klöpffer W, 'The critical review of life cycle assessment studies according to ISO 14040 and 14044: origin, purpose and practical performance' (2012) 17(9) The International Journal of Life Cycle Assessment 1087-1093.

consequences associated with the complete life cycle of a product or service, in relation to its specific function. Regardless of the nature of the system analyzed, the LCA considers various indicators, including: greenhouse gas emissions, the consumption of natural and energy resources, the impact on ecosystems, the impact on human health, water pollution, and waste production. This methodology allows an objective estimation of the environmental and energy burdens linked to a good or service, throughout the entire arc of its existence. This type of approach is commonly defined as "from cradle to grave" and aims to provide a complete picture of the interactions between the product and the environment, also allowing for the identification of possible improvement strategies. Although considered by the European Commission as one of the most suitable methodologies for evaluating environmental impact, the LCA does not have the purpose of establishing whether or not a good should be produced: its function is purely descriptive.

The entire process is divided into four main phases:

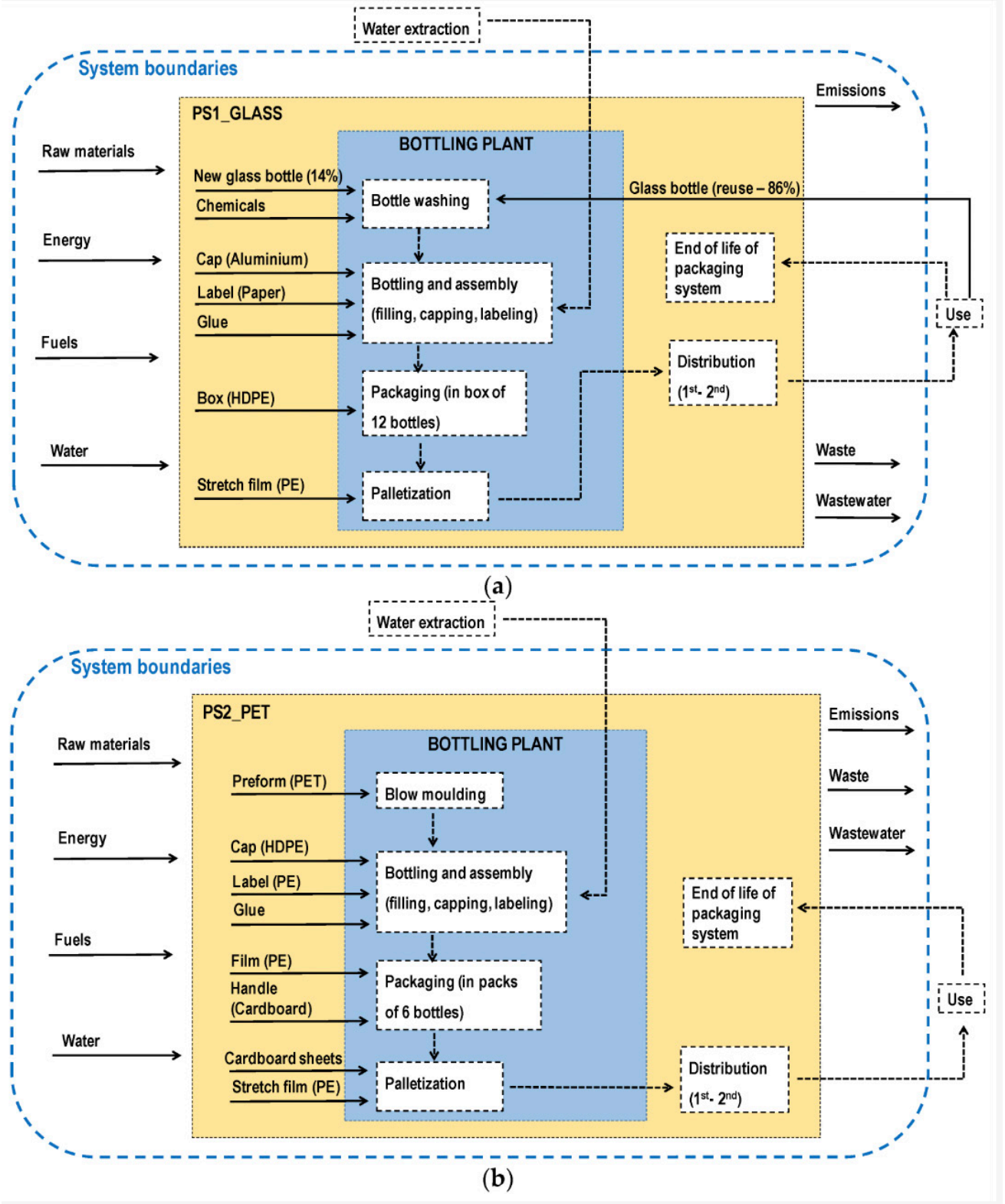
1. The first consists of defining the objectives and scope (Goal and Scope Definition): the purposes of the study, the reference functional unit, the system boundaries (in temporal, geographical, and technological terms), and the quality criteria for the data collected are identified;
2. Follows the inventory analysis (Life Cycle Inventory), during which all flows of material and energy entering and leaving the system are recorded and quantified. This phase, apparently technical, requires great accuracy: the omission even of a single relevant process can compromise the entire analysis;
3. The third phase is the impact assessment (Life Cycle Impact Assessment), in which the data collected are associated with specific environmental impact categories: this takes place through a series of sub-phases: classification, characterization, normalization, and weighting. The operation is supported by specialised software that allows the raw data to be translated into readable environmental results;
4. Finally, the interpretation (Life Cycle Interpretation) allows a critical reading of the results obtained, relating them to the initial objectives. At this specific moment, the critical phases of the production chain emerge and possible corrective actions are outlined, also through a redesign of the goods or processes involved.



A clear example of practical LCA application is the comparison between beverage bottles made of glass and those made of recycled PET.

At first sight, glass might appear to be the more sustainable option due to its reusability and "natural" image; however, LCA demonstrates that in well-structured recycling systems, recycled PET can have a lower environmental impact.

This is due to its lighter weight, reduced transportation emissions, and lower energy requirements for recycling compared to glass. This case highlights how LCA enables us to move beyond intuitive perceptions and rely instead on objective data to inform more sustainable design and policy decisions. In such contexts, eco-design finds its full expression, steering companies toward innovative solutions grounded in integrated, systemic environmental thinking.


Water extraction
System boundaries
Emissions
PS1_GLASS
BOTTLING PLANT
Raw materials
New glass bottle (14%)
Chemicals
Bottle washing
Glass bottle (reuse – 86%)
Energy
Cap (Aluminium)
Label (Paper)
Glue
Bottling and assembly
(filling, capping, labeling)
End of life of packaging system
Use
Fuels
Distribution
(1st- 2nd)
Box (HDPE)
Packaging (in box of 12 bottles)
Water
Waste
Stretch film (PE)
Palletization
Wastewater
(a)
Water extraction
System boundaries
PS2_PET
Emissions
Raw materials
BOTTLING PLANT
Waste
Preform (PET)
Blow moulding
Energy
Wastewater
Cap (HDPE)
Label (PE)
Glue
Bottling and assembly
(filling, capping, labeling)
End of life of packaging system
Fuels
Film (PE)
Handle (Cardboard)
Packaging (in packs of 6 bottles)
Use
Water
Cardboard sheets
Stretch film (PE)
Palletization
Distribution
(1st- 2nd)
(b)

The comparative diagram of PS1 (reusable glass bottles) and PS2 (single-use PET bottles)[9] clearly illustrates the systemic complexity captured by LCA methodologies and highlights how environmental performance cannot be assessed through material type by itself.

Indeed, while glass benefits from a high reuse rate, it entails significant energy and water consumption for washing and a heavier environmental burden during transport.

PET, though single-use, shows lower impacts in logistics and production, particularly when recycled effectively. This juxtaposition challenges common-sense assumptions about sustainability and reinforces the necessity of LCA as a scientific tool guiding eco-design decisions.

More importantly, it reveals how design choices must be aligned with broader systems of collection, reuse, and regulatory frameworks, particularly under the Extended Producer Responsibility principle. Eco-design, therefore, must be approached not in isolation but as an integrated practice informed by technical, legal, and environmental interdependencies.

1.4 The Role of LCA as a Tool for Measuring the Environmental Impact OF A Product and Its Evolution

LCA plays a crucial role in measuring the environmental impact of products, providing a quantitative and objective evaluation of environmental performance throughout the entire life cycle. This "cradle to grave" approach allows the avoidance of impact transfers from one phase of the life cycle to another or from one type of environmental impact to another.

The LCA methodology has subsequently been applied to specific environmental themes: in particular, the so-called Organizational LCA (OLCA) has been developed, regulated by the technical specification ISO/TS 14072:2014, which allows the overall environmental impact of an entire organization to be assessed, going beyond the analysis limited to individual products. In parallel, thematic standards have emerged such as the Water Footprint (ISO 14046:2014) and the Carbon Footprint (ISO 14060) dedicated to the issue of greenhouse gas emissions.

International attention to climate change mitigation has, on one hand, accelerated the development of specific standards for the analysis of environmental data, on the other hand, a tendency has emerged to focus on individual aspects and consequently a partial and simplified approach, in contrast to the systemic and multi-indicator approach that characterises LCA: the substantial difference between the methodologies lies, in fact, precisely in the one-dimensional nature of such methods that focus essentially on a single environmental indicator, thus opposing one of the fundamental principles of life cycle assessment.

[9] Ferrara C, De Feo G, Picone V, “LCA of Glass Versus PET Mineral Water Bottles: An Italian Case Study” (2021) 6(3) Recycling 50.

Despite interpretative complexity, the introduction of new standards has stimulated methodological debate and enriched environmental evaluation tools. From the systemic vision of the product life cycle, known as Life Cycle Thinking (LCT), several analytical methodologies have taken shape that reflect the three fundamental pillars of sustainability: environment, economy, and society. Among these, Life Cycle Assessment (LCA), Life Cycle Costing (LCC) [10], and Social Life Cycle Assessment (SLCA)[11] represent the main tools used to investigate respectively the environmental impacts, economic costs, and social consequences of goods and services throughout their life cycle.

1.5 From LCA to Policy: the ESPR and the European Regulatory Framework

The growing importance attributed to environmental sustainability in community and international policies has led to a progressive and necessary convergence between scientific methodologies for assessing environmental impacts and legislative production. In this scenario, Life Cycle Assessment (LCA) has established itself as one of the most recognised tools to support the regulatory framework, guiding the product innovation process and making environmental communication transparent. The relationship between LCA and regulatory sources, both at the European and international levels, is not limited to mere coexistence: rather, it is a dynamic interaction and mutual exchange, in which standards help to structure and legitimise the use of the method, while LCA provides the technical-scientific basis to build more effective regulations grounded in verifiable data.

A clear example of this link is provided by Regulation (EU) 2024/1781, also known as the Ecodesign for Sustainable Products Regulation (ESPR), which has introduced an innovative and more ambitious framework than the previous ecodesign directive, extending the application of sustainability criteria to a wide range of consumer goods[12]. The approach adopted by the European legislator is explicitly based on the need to consider the entire life cycle of products to promote their durability, reparability, recyclability, and more generally, the reduction of overall environmental impact. In this context, the use of LCA is not only encouraged, but also becomes a technical prerequisite to justify the environmental requirements imposed at the regulatory level. In fact, the LCA methodology makes it possible to identify the most critical phases of the life cycle of a product, namely those that generate the greatest environmental load, and therefore allows targeted interventions.

[10] UNEP, 'Compilation and evaluation of all costs associated with a product over its entire life cycle, from production to use, maintenance, and disposal' (SETAC 2009).
[11] UNEP, 'An impact assessment technique that aims to evaluate the social and socio-economic aspects of products and their actual and potential positive and negative impacts across the entire life cycle' (SETAC 2009).
[12] Cfr. Regulation (EU) 2024/1781 of the European Parliament and of the Council, Article 1(2), which extends the scope of ecodesign requirements to any physical good, including components and intermediate products, with the exclusion of food, medicines, regulated vehicles, and other specific cases. See also Article 5, which lists the relevant aspects for design requirements (e.g. durability, reparability, energy efficiency, recyclability), and Article 18(5), which identifies priority product groups (e.g. textiles, furniture, metals, tyres, chemicals, electronics).

The ESPR regulation also promotes the creation of the "digital product passport", an information tool that accompanies each good throughout its entire existence and must contain, among other things, information on environmental performance[13]. Also in this case, LCA is configured as one of the main tools available to producers to collect and transparently communicate this data, thus helping to avoid misleading greenwashing practices and to strengthen consumer trust in environmental claims. A significant innovation is also represented by the ban on the destruction of unsold goods, introduced to limit resource waste and encourage more virtuous practices in surplus management[14]. This ban initially applies to sectors such as fashion, where it will be mandatory to publicly report quantities and the fate of unsold products. Therefore, large companies will be required to publish precise data annually on their website regarding the disposal of stock, promoting recovery through recycling, donation or reintroduction into the market.

This obligation is also consistent with LCA logic, which aims to assess and optimise environmental impact throughout the product's life cycle, including waste and surplus management phases.

Another European legislative act that, although addressing different aspects, is related to the topic of LCA is Directive (EU) 2019/771 on the conformity of consumer goods. Apparently, this is a measure closer to consumer law than to environmental regulation; however, the principle of product durability[15], which represents one of the key elements of the directive, finds empirical foundation precisely in the evaluations conducted according to the life cycle approach.

LCA studies demonstrate, in fact, that extending the useful life of a good – through the right to repairability and the possibility of reuse – represents one of the most effective strategies to reduce overall environmental impact. The regulation therefore strengthens the link between sustainability and consumer rights, implicitly laying the groundwork for greater use of LCA methodologies in the definition of industrial and consumer policies, especially with regard to the "end-of-life" phase of the product. Particularly interesting is the relationship between LCA and the proposed Green Claims Directive[16]: the aim of this legislative act is to regulate voluntary environmental claims made by companies, in order

[13] It should be noted that other recent legislative acts mandate the introduction of a digital product passport in specific sectors. This is the case with the new Construction Products Regulation (CPR), which requires a DPP for construction materials with a high environmental impact. Similarly, the Battery Regulation and textile strategies already include mandatory traceability and environmental transparency through digital tools. In each of these contexts, the Life Cycle Assessment (LCA) methodology serves as the cornerstone for the collection and certification of information.

[14] Regulation (EU) 2024/1781, Articles 23–25: the ban on the destruction of unsold goods, applicable from 19 July 2026 for large enterprises (and from 2030 for medium-sized ones), concerns the products listed in Annex VII (e.g. clothing, footwear). Exemptions are provided for micro and small enterprises. Article 24 also introduces transparency obligations regarding destroyed unsold goods, which must be reported annually on the operator's website.

[15] Cfr. Regulation (EU) 2024/1781, Article 5, which includes durability among the aspects subject to ecodesign requirements; see also Annex I, where durability is defined through parameters such as technical lifetime, resistance to use, and mean time between failures. These elements aim to extend the useful life cycle of products, in line with the objectives of the circular economy.

[16] Proposal for a Directive of the European Parliament and of the Council on the substantiation and communication of explicit environmental claims, COM (2023)166 final.

to combat the phenomenon of greenwashing and protect consumers from misleading messages. The proposal establishes that every environmental claim must be based on a solid, verifiable methodology grounded in scientific data. It is therefore appropriate to note that, even in this context, LCA is clearly identified as the reference methodology to justify and validate environmental claims about products. Companies will therefore be required to provide documented evidence and, in many cases, to submit their evaluations to independent verification, with methodological standards directly inspired by ISO 14040 and ISO 14044.

1.6 Extended Producer Responsibility and Lca: From Policy Principle to Regulatory Instrument

Another area of development that deserves attention is the relationship between the LCA methodology and extended producer responsibility (EPR), an environmental principle that places on the producer the burden of managing the product even in the post-consumption phase. This principle, already adopted in various national legislations through regulations on WEEE, packaging, batteries, and end-of-life vehicles, is also playing an increasing role at the European level, especially with the evolution of waste directives and the implementation of the Green Deal[17].

In this sense, the ESPR represents a decisive policy step, since it explicitly links product design to sustainability criteria and relies on EPR schemes to translate such requirements into operational and incentive-based mechanisms.

LCA, in this sense, is configured as the privileged tool to quantify the environmental impacts connected to the end-of-life phase of products, providing an objective basis for defining responsibilities, environmental contributions, and eco-design criteria. The integration between EPR and LCA meets the need to avoid distortions, such as the arbitrary allocation of burdens not proportionate to the actual environmental impact of the product. An evaluation based on LCA data, therefore on environmental performance, instead allows the modulation of environmental fees based on actual performance, rewarding lower-impact products and encouraging circular and innovative solutions.

An interesting example is offered by France, which with the AGEC law (Anti-Gaspillage pour une Économie Circulaire)[18] has introduced eco-design obligations and contribution modulation based on documentable environmental criteria, paving the way for a

[17] Sikora A, 'European Green Deal-legal and financial challenges of the climate change' (2020) 21 Era forum 681. Krämer L, 'Planning for climate and the environment: The EU green deal' (2020) 17(3) Journal for European Environmental & Planning Law 267; Schoenefeld J J, 'The European Green Deal: What prospects for governing climate change with policy monitoring?' 2021 9(3) Politics and Governance 370; Wendler F, 'Climate change policy in the EU: From the Paris agreement to the European Green Deal' in *Framing Climate Change in the EU and US After the Paris Agreement* (Springer Nature 2022) 65-117.

[18] French Law No. 2020-105 of February 10, 2020, known as the "Loi Anti-Gaspillage pour une Économie Circulaire" (AGEC), introduced significant measures to promote the circular economy, including the extension of producer responsibility and mandatory eco-design requirements.

regulatory model in which LCA plays an essential role in legitimizing incentives and penalties. However, for effective integration, it is necessary to overcome certain critical issues, such as: data availability and accessibility, methodological transparency, the need to harmonise databases at the European level, and the introduction of third- party verification mechanisms. These conditions are essential to avoid strategic or opportunistic use of LCA, especially in commercial contexts.

In perspective, the coupling between LCA and EPR can help transform environmental responsibility from an external and residual element to an intrinsic factor of industrial design. In this way, coherence between environmental objectives and economic instruments is strengthened, creating a regulatory ecosystem in which market decisions naturally orient towards more sustainable products.

In limine, the EPR does not only operate as a general principle of environmental law, but becomes the concrete channel through which the ESPR's policy objectives are implemented, turning abstract regulatory requirements into measurable incentives and deterrents for producers.

1.7 Standardising LCA for Legal and Regulatory Use: The Role of Iso 14040 and Iso 14044

The International Organization for Standardization (ISO) in the early 1990s began work to define a series of technical standards dedicated to environmental management. Only in 1997 was the technical standardization work completed, and the ISO 14040 standard was published for the first time, followed in 2006 by its revision and the introduction of ISO 14044. These two standards, both part of the ISO 14000 family dedicated to environmental management systems, progressively established themselves as an international reference for conducting LCA studies. The ISO 14040 and ISO 14044 standards, in fact, although both belonging to the same normative family and sharing many fundamental principles, present different roles within the methodological structure of LCA: the ISO 14040 standard focuses mainly on defining the general framework of life cycle analysis, establishing the principles, the reference terminology, and the conceptual structure of LCA, providing a more theoretical orientation. It is in this standard that the four main phases of the study are outlined, in addition to the general criteria of consistency and transparency that must guide every phase of the analysis. On the other hand, ISO 14044 represents an operational extension of the previous one; entering into technical detail, it specifies the requirements necessary to correctly carry out each of the phases provided by the 14040 standards. It deals, for example, with defining how to conduct data collection, which criteria to adopt in the impact assessment, and how to proceed with the interpretation of results. Moreover, ISO 14044 establishes the methods to address complex issues such as the allocation of environmental loads, the management of uncertainties, and the conduct of comparative product analyses.

A substantial difference between the two therefore lies in the area of competence: while ISO 14040 offers general and conceptual guidance, ISO 14044 is configured as a practical manual, indispensable for those who concretely conduct an LCA study. The two standards, however, cannot and must not be seen as autonomous: their strength lies precisely in their complementarity. Their adoption is fundamental not only to ensure the scientific quality of the analyses but also to favor the integration of LCA in regulatory processes, public policies, and market mechanisms. In particular, ISO standards constitute an essential reference for voluntary environmental communication tools, such as ecological labeling (e.g., Ecolabel) or environmental product certifications. Furthermore, thanks to their flexibility, as seen previously, ISO 14040 and 14044 are suitable for use in combination with other methodologies and approaches, allowing for a structured evaluation tailored to the different needs of companies, public entities, and non-governmental organizations. However, there are also critical issues: the integration of LCA into regulatory processes requires a high level of technical expertise and data availability, which is not always guaranteed, especially in small and medium-sized enterprises. Moreover, the risk of selective or instrumental use of LCA results—in the absence of appropriate controls and verifications—remains, especially in areas such as green marketing. Hence the need for a clear regulatory framework and support tools to ensure fair access to LCA: in this way, one can truly speak of an efficient and functional management for authentic sustainability, and not merely for promotional purposes. It is therefore appropriate to recall that the relationship between Life Cycle Assessment and European and international regulations is increasingly close and strategic: LCA is not just a calculation technique but has become, to all effects, a common language for discussing complex issues such as product sustainability, corporate responsibility, consumer protection, and environmental governance. Its inclusion in normative texts, directives, and regulations demonstrates how science and law can collaborate to build an economic model more attentive to the planet's ecological limits. And if it is true that the adoption of LCA involves methodological and operational challenges, it is equally true that without a life-cycle-based approach, many environmental policies risk remaining partial, ineffective, or, in the worst cases, only apparently "green".

In conclusion, the trajectory of Life Cycle Assessment — from its historical emergence and methodological consolidation to its normative codification through ISO standards and its progressive incorporation into the European regulatory framework, including its operationalisation via Extended Producer Responsibility — attests to its transformation from a scientific technique into a legally relevant instrument. LCA today functions as a paradigmatic interface between science and law, capable of conferring normative legitimacy, comparability, and enforceability upon sustainability requirements, thereby laying the doctrinal and methodological foundations for the juridification of environmental responsibility within contemporary regulatory systems.

2 Environmental sustainability as a transversal meta-norm within consumer law

Considering the historic evolution, LCA has progressively moved beyond its original evaluative function to become a strategic reference point in design and innovation processes.

In particular, Life Cycle Thinking finds a natural application in eco-design, where the goal is no longer merely to assess impacts but to anticipate and reduce them from the earliest design stages.

Eco-design is based on a holistic vision of the product, considering its entire life cycle, from material selection to end-of-life management and on the assumption that many environmental performances are determined in the very first phases of development.

In this perspective, LCA is not only a technical support tool but a true cognitive and cultural infrastructure that guides design choices according to principles of sustainability and responsibility.

Amid the profound transformations affecting contemporary economic and social models, environmental sustainability is increasingly emerging as a structural principle of consumer law. Far from remaining confined to a merely programmatic or declaratory function, it permeates legal sources, redefines the role of the stakeholders, and guides the evolution of the discipline toward a systemic dimension, founded upon the integration of environmental protection, consumer safeguarding, and market regulation.

This process is clearly reflected in the policies of the European Union, which has increasingly embraced the goal of the "green transition" as a cornerstone of economic governance. Initiatives such as the Green Deal[19] and the New Consumer Agenda (2020) clearly express the intention to overcome a model of consumption 2030n detached from environmental responsibility, promoting instead a reconfiguration of the relationships among production, exchange, and sustainability. This reconfiguration unfolds not only at the industrial level but also from a legal and cultural perspective, affecting market rules and the behavioural dynamics of economic actors.

Within this new framework, the figure of the consumer—historically protected as the weaker party to the contract under Article 3 of Legislative Decree No. 206/2005 (Consumer Code)[20]—undergoes a significant refunctionalisation: today, the consumer is

[19] European Commission, Nuova Agenda del Consumatore per il periodo 2020–2025, COM(2020) 696 final, Brussels, 13 November 2020. The strategic document identifies five priority areas of action aimed at strengthening consumer protection: green transition, digital transition, protection of vulnerable consumers, effective enforcement of the law, and international cooperation. Notably, the green transition is explicitly aimed at promoting sustainable consumption practices, also through the introduction of regulatory and informational tools intended to empower consumers to choose products based on their environmental impact.

[20] Article 3 of Legislative Decree No. 206 of 6 September 2005 (Consumer Code), which defines the "consumer" as "the natural person who acts for purposes unrelated to any entrepreneurial, commercial, artisanal, or professional activity possibly carried out." Marsico (see infra) observes that such a definition is now inadequate to grasp the new proactive dimension of the consumer in the context of sustainability, proposing a systematic reinterpretation that highlights the consumer's active role in promoting the ecological transition through informed and conscious choices.

assigned an active and co-responsible role in promoting sustainability, through informed purchasing choices oriented toward market ecology. In this perspective, environmental information acquires strategic centrality, becoming a functional right to economic self-determination and a prerequisite for the effectiveness of consumer protections, in accordance with the principles of transparency, truthfulness, and completeness. The growing responsibility attributed to consumers entails, in parallel, a strengthening of the informational duties incumbent upon the professionals, with particular regard to the communication of the environmental qualities of products and services. In this context, the regulation of unfair commercial practices (Articles 20 et seq. of the Consumer Code) constitutes a fundamental legal safeguard, aimed at combating greenwashing phenomena and ensuring the reliability of market information. The data collected by the European Commission in 2020—according to which over 53% of examined environmental claims were found to be misleading or unverifiable[21] — triggered a regulatory impetus culminating in Directive (EU) 2024/825. This legislative act amends Directive 2005/29/EC by introducing specific prohibitions against the use of non-certified environmental labels and vague expressions such as "green" or "eco" when not supported by verifiable evidence[22]. The affirmation of sustainability as a regulatory parameter also has structural implication within consumer law, which is undergoing a process of hybridisation with environmental law and competition law, thus giving rise to an increasingly intersectoral discipline. Precisely within this framework, the figure of the "sustainable consumer" emerges—not merely as a passive beneficiary, but as a conscious and active subject in the transformation of the market. This archetypal figure plays a proactive role, directing demand toward eco-compatible economic models and contributing to the implementation of the principle of sustainability as an ordering criterion within the legal system of consumer law[23].

The evolution outlined above finds further legitimisation at the constitutional level, following the reform of Articles 9 and 41 of the Italian Constitution enacted by Constitutional Law No. 1 of 11 February 2022: the introduction of environmental protection, biodiversity, and ecosystems among the fundamental principles of the legal order entails a redefinition of the axiological balances underpinning the regulation of

[21] Pistilli A, 'Sostenibilità e diritto dei consumi' [2023] Rivista Giuridica dell'Ambiente: the author draws attention to the need for more effective regulatory instruments to ensure the reliability of environmental information and to strengthen the consumer's active role in the green transition.

[22] Directive (EU) 2024/825 of the European Parliament and of the Council of 28 February 2024, amending Directive 2005/29/EC concerning unfair commercial practices. The new directive introduces an express prohibition on the use of generic and unverifiable environmental claims (e.g., "green", "eco-friendly"), as well as environmental labels lacking official certification. The legislative intervention is aimed at countering widespread phenomena of greenwashing and strengthening the transparency of environmental information provided to consumers.

[23] Marsico C, 'La sostenibilità nella disciplina del consumo tra fonti europee e ordinamento nazionale' [2024] Le Nuove Leggi Civili Commentate 302. The author proposes an integrated approach to sustainability, referring both to the Green Deal and to European legislation on the circular economy, arguing that the consumer must be placed at the center of a comprehensive regulatory strategy based on certain, verifiable rules capable of producing educational effects at the social level.

economic freedoms. These freedoms are now legally bound—and no longer merely oriented—toward environmental safeguarding, with significant implications in terms of shaping economic initiative and ensuring compatibility between productive development and ecological principles[24].

In this scenario, the role of enforcement authorities — in particular that of the Italian Competition and Market Authority (AGCM) — becomes increasingly significant; indeed, several sanctioning measures have been adopted against undertakings that employed generic, vague, or unverifiable environmental claims, thereby breaching the obligation of informational transparency towards consumers. Among the most affected sectors are fashion, mobility, packaging[25], and agri-food, areas in which the AGCM has repeatedly found a lack of scientifically substantiated evidence to support environmental claims, thus constituting concrete misleading practices capable of altering the consumer's economic choices.

The link between sustainability and information is particularly evident in the agri-food sector, which represents a paradigmatic field for testing the effectiveness of environmental informational rights. The life cycle of food products significantly impacts the environment, and precisely for this reason, environmental labelling assumes a central role: it must comply with criteria of transparency, accessibility, and verifiability, constituting a tool of legality and protection. Terms such as "organic", "zero-kilometre", or "sustainable" cannot be used arbitrarily but must be backed by objective and widely recognised certification systems, in order to avoid misleading communicative drifts[26].

The most attentive legal doctrine has grasped the systemic scope of this evolution, referring to a consumer law that is "sustainable by default", in which environmental compliance becomes the rule rather than the exception; however, such an approach requires a profound revision of existing legal models, in order to overcome the current regulatory fragmentation and promote effective harmonisation between the various regulatory interests: consumer protection, environmental safeguarding, fair competition, and public health[27]. Within this perspective lies the proposed "Green Claims" Directive

[24] Galli A, 'La tutela dell'ambiente e il diritto dei consumatori nella transizione ecologica' in *Il Diritto dei Consumi* (2024) 7 The author highlights the systemic connection between the constitutional reforms of Articles 9 and 41 of the Italian Constitution (Law No. 1/2022) and consumer law, underlining how environmental sustainability has become a parameter of legitimacy even for private economic activity. In this perspective, consumer law no longer performs solely a protective function, but one proactively oriented toward environmental protection.

[25] DLA Piper, "Sostenibilità e tutela del consumatore: quando i green claims rischiano di integrare pratiche commerciali scorrette" (Legal Update 2024) <https://www.dlapiper.com/it-it/insights/publications/2025/02/environmental-claims-and-consumer-protection> accessed 15 September 2025.

[26] Galli A, in La tutela dell'ambiente e il diritto dei consumatori nella transizione ecologica, underscores how the agri-food sector is emblematic of the connection between environmental sustainability and consumer protection. The author emphasises the importance of clear, verifiable, and normatively harmonised environmental labelling systems capable of ensuring true traceability of the production cycle and preventing unfair practices in the ecological presentation of food products. The need is stressed to overcome the fragmentation of environmental certifications, which are sometimes used in suggestive or misleading ways, and to integrate such tools into a unified discipline of sustainable agri-food law.

[27] Ricci A, "La triade rigenerazione, ambiente e consumo nel modello circolare" (2023) 2 Rivista di Diritto dell'Ambiente 119. The author theorises a model of consumer law structurally grounded in sustainability, wherein

(COM(2023)0166), which mandates the prior verification of explicit environmental claims by third-party and independent bodies, based on reliable scientific evidence[28].

Hence arises the need to ensure environmental information that is clear, comprehensible, and accessible, as an essential condition for the consumer's meaningful role in the ecological transition. Information, once considered a mere accessory element, assumes the status of a legal asset, a fundamental right to be protected through coherent and technically adequate regulatory instruments. The *telos* is not merely to repress unfair practices, but to construct a transparent, trustworthy, and genuinely sustainable market[29].

In this regard, greenwashing does not represent a mere communicative deficit, but rather a legal breach capable of producing distortive effects on competition and undermining consumer trust. The use of environmental claims such as "100% sustainable" or "zero impact" in the absence of scientific foundation or independent certification constitutes a misleading practice, as recognised by the AGCM's case law, and negatively affects both transparency and fair competition.

The challenge is, therefore, twofold: on the one hand, to strengthen the system of control and sanctioning of unlawful conduct; on the other, to promote a reform of the legal sources that may favour systemic harmonisation among the legal fields involved in the regulation of sustainability. Directive (EU) 2024/825 moves in this direction, prohibiting the use of vague claims, non-certified environmental labels, and ecological references not pertinent to the function of the product. The adopted approach reflects a growing application of the precautionary principle, according to which, in the presence of doubts regarding environmental impact, the logic of protection must prevail.

Within this evolution, consumer law takes on a systemic and transformative role, positioning itself as a tool not only for individual protection, but also for the governance of economic structures in accordance with the principles of ecological justice[30]. Environmental sustainability thus becomes not only an object of protection, but also a structural parameter for the assessment of the lawfulness of entrepreneurial conduct and the coherence of normative policies.

environmental compliance constitutes an essential requirement for the lawfulness of commercial offerings. The circular model, understood as a regenerative paradigm, demands a profound reform of the classical categories of consumer law, based on transparency, durability, and reduction of ecological impact.

[28] See also Cecchetti M, "Diritto ambientale e conoscenze scientifiche tra valutazione del rischio e principio di precauzione," (2023) 13 Federalismi 47–76.

[29] Rainone M, Galli A, "Tutela del consumatore e transizione ecologica: diritti informativi e sostenibilità" [2024] Contratto e Impresa 84. The authors analyse the central role of environmental information in shaping consumer economic choices, placing particular emphasis on the need for accessible, complete, and comprehensible information as an essential condition for preventing sustainability from becoming a mere marketing label devoid of verifiable substance.

[30] Imbruglia M, "Consumo, sostenibilità e diritto: un'evoluzione sistemica" [2023] Jus Ambiens 47. The author identifies consumer law as a central tool for market regulation in a sustainable perspective, capable of integrating diverse legal fields (environmental, competition, information) and guiding social transformation towards models of production and purchasing that respect ecological limits. The systemic role of consumer law is emphasised in constructing an economy governed by environmental responsibility.

Finally, and indispensably, a reflection on the educational role of consumer law must be emphasised: accurate environmental information does not merely constitute a right of the individual, but assumes a cultural function of primary importance, fostering the formation of an active and responsible ecological citizenship[31]. The sustainable consumer is not (only) an empirical-sociological phenomenon, but a legal and cultural construct, the development of which depends on the clarity of rules, the transparency of sources, and the credibility of institutions.

It is within this horizon that the law is called to operate, as the normative infrastructure of the ecological transition — not only for professionals, but also for consumers, for citizens.

In other words, eco-design goes beyond its technical dimension to engage directly with legal and social responsibilities[32]: it is not merely a tool to reduce environmental impacts but a core mechanism of accountability for producers throughout the entire life cycle of products.

In the European context, this responsibility is reflected in the principle of Extended Producer Responsibility (EPR), which obliges economic actors to consider not only production but also usage and end-of-life phases.

Simultaneously, the principle of environmental due diligence—now widely acknowledged in legislation and international standards—requires companies to proactively prevent environmental harm. In this sense, eco-design serves as a bridge between innovation, regulatory compliance, and social legitimacy, addressing the increasing demand for transparency and ethical responsibility across production chains.

2.1 The Precautionary Principle and Its Application in Environmental and Consumer Protection Policies

The precautionary principle, already known in common law systems as an axiological precursor to liability for risk, has now become a normative foundation of both environmental law and consumer law, consolidating itself at the supranational and EU level as an instrument for the rationalization of public action in the face of scientific uncertainty. Its codification finds its origin in Article 191(2) TFEU, which states — explicitly

[31] The idea of a pedagogical function of consumer law, conceived not only as a repressive instrument but also as a guiding one, recalls in certain respects the logic of enlightened legal paternalism, which was typical of Habsburg administration, especially in the context of codified legal reforms in the modern era. Just as normative action at that time aimed to guide the behaviour of subjects towards "virtuous" models of conduct, today sustainable consumer law seeks to shape the behaviour of the citizen-consumer according to ecologically responsible standards. Thus is realised a form of legal pedagogy which, while respecting private autonomy, directs economic choices toward collective goals of sustainability and environmental justice. This dynamic underscores the circularity of legal models, whereby the law — from being a mere regulatory tool — reclaims an educational and axiological function, following a paradigm not new to the history of European codifications, but which today acquires renewed force in light of global environmental challenges.

[32] Boschetti L, "Progettazione ecocompatibile e ciclo di vita del prodotto: strumenti normativi e tecnici per la transizione ecologica" (2024) 2 Industria, Diritto, Ambiente 59–80. The author highlights how eco-design, when integrated with LCA mechanisms, can serve as a key legal and industrial driver to anticipate environmental impacts and structure more responsible and traceable production models.

— that "Union policy on the environment shall aim at a high level of protection taking account of the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle." This is a principle that allows — and in certain cases requires — the adoption of restrictive measures on the freedom of economic initiative (enshrined in Article 42 of the Italian Constitution) or containment measures, even in the absence of conclusive scientific evidence, whenever there is a risk, even merely potential, to human health or the environment.

The rationale that led the "continental fathers" to impose such restrictions on the initiatives of the *homines oeconomici* lies in the anticipatory protection of fundamental legal interests such as public health, the environment, and food safety, even when scientific uncertainty precludes the deterministic establishment of a causal link between the activity or product and the feared damage[33].

This postulate, having constitutional value (due to its topographical location within the EU Treaty), is thus situated within a logic of enhanced prevention, which does not require current proof of damage but is activated on the basis of a plausible risk, supported by partial, credible, and consistent evidence. In this sense, it differs from mere technical prudence or procedural caution, acquiring the status of *ius cogens*, as also confirmed by the case law of the Court of Justice of the European Union, particularly in the context of litigation concerning food safety[34] and genetically modified organisms[35].

Assuming a domestic perspective, the precautionary principle is not expressly codified in a single systematic provision but has been progressively incorporated through sector-specific legislative sources and administrative acts (whether general or of guidance nature) with normative value, particularly in the fields of health protection, environmental damage, and product liability. Its operational effectiveness has emerged with particular strength in administrative law, where it has taken on the role of a criterion of legitimacy of public action, justifying even severely restrictive measures on economic freedom or private initiative, provided they are proportionate, time-bound, and specifically balanced.

The precautionary principle — of bifrontal morphology — is articulated in two distinct but interconnected corollaries: on the one hand, it establishes a power-duty on the part of the

[33] Ambra S, "Principio di precauzione e responsabilità civile" [2023] Salvis Juribus. The contribution highlights how the precautionary principle finds concrete application within the discipline of liability for damage caused by unsafe products, governed by Articles 114 et seq. of the Codice del Consumo. From this perspective, the producer is burdened with a continuous obligation of vigilance, information, and timely reaction to potential risks, even in the absence of an already verified damage. Failure to fulfil these duties may give rise to liability by omission, in line with an expanded notion of technical and professional diligence.

[34] Cecchetti (n 29) 152. Within the context of Regulation (EU) 2017/625 on official controls in food law, the precautionary principle imposes on economic operators duties of active monitoring, prior verification, and immediate withdrawal of potentially risky products. This European regulatory framework introduces a control structure oriented toward preventive action, based on traceability and responsiveness, thus configuring precaution as a legal duty with a strong procedural dimension.

[35] Cecchetti A, "Il principio di precauzione nel diritto dell'Unione europea" [2023] Diritti e Politiche Pubbliche 145, where the ruling of the Court of Justice of the European Union in case C-236/01 Monsanto Italia is analysed. The judgment affirms the legitimacy of national restrictions based on the precautionary principle even in the absence of definitive scientific evidence. The case, centred on the withdrawal of GMO products, demonstrates how a plausible risk to health and the environment may justify restrictive measures, thereby consolidating the principle as an autonomous standard of legitimacy, even in relation to the freedom of movement.

administration to act for the protection of the community; on the other, it sets a specific responsibility on economic operators in terms of risk prevention, management, and communication. This results in a redistribution of the burden of proof and a modification of traditional civil liability dynamics, whereby it is no longer necessary to wait for the ascertainment of the causal link in order to act, but it becomes legally permissible to intervene *ex ante*, *in dubio*, in order to prevent even merely potential and irreversible damage[36].

In consumer law, the application of the precautionary principle has found fertile ground particularly in certain sectors more exposed and sensitive to "risk": food products, cosmetics, electronic devices, chemical and pharmaceutical products. In this sense, the logic of precaution intersects, within the framework of legal sources, with the rules on product safety (Articles 102 ff. of the Consumer Code) and with the discipline on liability for damage caused by defective products (Articles 114 ff.); the notion of a "safe product" has thus evolved from mere technical compliance to "anticipatory" compliance — that is, conformity with safety standards that address risks not yet fully known but recognised by empirical science as potentially dangerous.

A clear epiphany of the influence of precaution on the regulation of goods production can be found in the obligation incumbent upon the producer to withdraw or recall the product in the event of supervening factors affecting its safety, regardless of the actual occurrence of damage. This obligation, regulated in general terms by Article 104 of the Consumer Code, constitutes a paradigmatic example of a measure that finds its genetic matrix in the precautionary principle, to the extent that the legislator entrusts the economic operator not only with the control of production but also with responsibility for any evolution of the risk.

In this context, liability assumes a dynamic dimension extending beyond the product's entry into the market and is tied to a duty of constant, potentially infinite, surveillance[37].

The influence of the precautionary principle is not limited to the post-marketing phase, but already significantly affects the stage of product design and market placement. Indeed, the enterprise is called upon to conduct an *ex ante* risk assessment grounded in a prudential — and not merely empirical or statistical — consideration of potential effects. This aspect has repercussions on the configuration of corporate due diligence, which now includes the obligation to equip itself with predictive systems for environmental and health

[36] The dual nature of the precautionary principle: on the one hand, it imposes a duty on public authorities to intervene even under scientific uncertainty; on the other hand, it requires private actors to behave in accordance with informed diligence. It emerges, therefore, as an operative—not merely theoretical—criterion that guides administrative action, entrepreneurial decisions, and the evaluation of liability. See, Ippoliti S, "Precauzione e prevenzione nel diritto contemporaneo" [2024] Giurisprudenza Costituzionale 201.

[37] Longo M, Di Stefano G, "Precauzione e responsabilità nei mercati globali" [2023] Responsabilità e Mercato 89 . The authors introduce the notion of "continuous responsibility", according to which the duty of vigilance imposed by the precautionary principle extends throughout the entire life cycle of the product, not ceasing at the moment of its marketing, but requiring ongoing controls, technical updates, and constant review systems. The failure to implement such measures may give rise to liability for systemic negligence.

risk monitoring, as well as with internal structures dedicated to product safety management.

At the level of civil liability, the precautionary principle has contributed to reshaping the classical categories of harm and causation. Specifically, recent jurisprudence and legal scholarship have identified scientific uncertainty as a legitimate ground for precautionary or injunctive intervention, capable of generating specific obligations even in the absence of a final determination of fault or damage. One need only consider liability for a potentially defective product: actual damage need not be demonstrated; a reasonably foreseeable risk is sufficient to trigger duties of information, withdrawal, and compensation.

It is precisely within the realm of legal theorisation concerning liability for defective products that the precautionary principle has been placed at the centre of an evolutionary interpretation of Article 117 of the Consumer Code, where the liability of the producer is excluded when the defect could not have been known "in light of the state of scientific and technical knowledge at the time the product was put into circulation." However, the reference to the "state of knowledge" cannot be construed as a general exemption but must be integrated with the expert and proactive liability stemming from awareness of indicators, studies, and recommendations originating from institutional or scientific sources.

The precautionary dimension of liability — as previously stated — far from translating into an automatic compression of economic freedom, has unfolded diachronically according to a methodology of proportionality and balancing, a method particularly valued by the Court of Justice of the European Union on multiple occasions. Notably, in Case C-236/01 (Monsanto Italia), the Luxembourg Court affirmed that the application of the precautionary principle cannot result in arbitrary measures but must be based on an objective scientific analysis and a comprehensive risk assessment, which takes into account not only the probability but also the magnitude of potential harm.

The judicial and administrative application of the principle therefore entails a legal obligation of comparative risk assessment, which translates into strict evidentiary requirements for both public authorities and, conversely, also for economic operators. This exegetical vision of the principle under examination has prompted an evolution in product liability and market practices, particularly in sectors where the consumer is structurally placed in an informationally asymmetric position — as in the sale of goods containing chemical or biotechnological substances. In the presence of a potential danger to public health or the environment, public authorities may impose a temporary ban on marketing, even in the absence of definitive proof of harmfulness, provided that such a measure is supported by a scientifically plausible basis and is proportionate to the level of risk.

At the national level, the most recent interpretative practices have confirmed the increasing incidence of the precautionary principle within the domain of civil liability: legal scholarship has observed that, in the face of hypothetical damage that cannot be

demonstrated *ex post*, the judge may nonetheless identify behavioural obligations incumbent upon the producer or distributor, with reference to risk management, preventive communication, and voluntary withdrawal of the good. Thus emerges a model of liability not founded exclusively on the damage actually realised, but rather on the breach of precautionary obligations, which serve as a benchmark for assessing professional diligence; this finds correspondence in Article 117 of the Consumer Code, which, while providing for an exemption based on the "state of knowledge," does not allow for exoneration if the producer has failed to take steps to verify the existence of scientific warnings, technical opinions, or previously reported cases in other jurisdictions[38].

Particularly relevant is also the reference to the REACH Regulation (Regulation (EC) No 1907/2006), expressly mentioned in specialised literature, which imposes on producers of chemical substances the obligation of prior — public — registration, as well as the necessary detailed risk assessment. This system emblematises the substantive import of the precautionary principle, as it places the burden on economic operators to demonstrate product safety prior market placement; the consumer — from this perspective — is thus protected not *a posteriori*, but rather in the preliminary phase prior to market placement, through the normative construction of a preventive framework of shared responsibility.

In the agri-food sector, the articulation of the precautionary principle has assumed increasing importance in light of the complexity of production chains and the potential impact of food on collective health. It is in this context that administrative jurisprudence has assumed a central role in the implementation of the principle. "The existence of a risk, even merely potential, albeit not fully proven, legitimises the adoption of precautionary measures by the competent authorities, provided such measures are proportionate, reasoned, and temporary": thus stated the Council of State in judgment no. 6626/2009, thereby confirming the interpretative orientation subsequently consolidated in other decisions affirming the legitimacy of administrative measures based on scientific plausibility rather than on the certainty of harm[39].

It is evident that in the management of activities presenting a high environmental risk — such as chemical industries, waste disposal plants, energy facilities — precaution becomes the guiding criterion of Environmental Impact Assessment (EIA) and the granting of Integrated Environmental Authorisations (IEA). This entails not only the obligation for public authorities to obtain objective assessment elements, but also the requirement for proponents to submit preventive risk analyses and mitigation plans based on the available

[38] Ambra (n 34), stresses that the precautionary principle entails a growing articulation of producers' duties, which go beyond compliance with minimum safety thresholds. Transparency measures, cooperation with public authorities, and timely information to consumers must be implemented. Inertia in response to even potentially concerning data may result in liability for omission.

[39] Renna G, (see about) 6 ss. The author highlights a significant evolution in the concept of "prejudice eligible for compensation" in the environmental context. Under the precautionary principle, it is no longer necessary to prove certain or irreversible harm: the mere scientific plausibility of a negative impact is sufficient to trigger obligations of prevention and, in certain cases, compensation. This marks a paradigmatic shift, affecting the very structure of civil liability.

scientific data. Should there be omissions, incompleteness, or investigative deficiencies, the authorisation-granting procedure would be vitiated, resulting in unlawfulness[40].

This interpretative model is also reflected in the case law of the Supreme Civil Court, where in some rulings — albeit not always systematically — the omission of precautionary conduct by professionals or businesses has been given prominence. Where such actors, though aware of risk signals, fail to adopt the requisite precautionary measures, this failure to fulfil the duties of updating, monitoring, and informing constitutes *culpa in vigilando* or *in omittendo*, relevant for the purposes of compensatory liability.

The jurisprudential and doctrinal elaboration thus converges toward a model of precaution that is no longer merely declarative or axiological, but effectively operative and juridified. It imposes not only public obligations, but also private duties of responsibility toward collective and intergenerational goods — that is, behavioural duties that extend throughout the entire life cycle of the product or service. This model inevitably shapes the notion of qualified professional diligence, according to which the producer, importer, distributor, and even the certifying body must act as professionals or, at the very least, prudent agents, conscious of the environmental and health impact of their conduct, and bound to reorient their organisational processes according to the highest scientifically justifiable level of caution.

In conclusion, it is possible to assert that the precautionary principle emerges and takes shape as a structural foundation of both environmental law and consumer law, guiding public policies and market practices toward normative models of risk anticipation and the centrality of preventive safety. Its prescriptive, exegetical, and operational efficacy marks the transition from a law of reactive liability to a law of proactive precaution, grounded in the ethics of prevention, the paradigm of holistic sustainability, and a legal culture of limits that places the value of life, health, and the environment at the core of the legitimacy of economic conduct.

2.2 Eco-design and DNSH: A Regulatory Interface for Sustainable Innovation

The integration of the "Do No Significant Harm" (DNSH) principle into the regulatory architecture of the European Green Deal has profound implications for the development of eco-design as both a technical and normative practice.

Established by Regulation (EU) 2020/852 on the EU Taxonomy[41], the DNSH principle requires that any economic activity claiming environmental sustainability must not cause

[40] It is observed that failure to acquire scientific opinions or to adequately assess environmental risks may lead to the annulment of administrative acts due to flawed investigation. Hence, the precautionary principle is strengthened also on a procedural level, becoming not merely a justification for restrictive measures but a criterion for the legitimacy of administrative action itself. Cecchetti (n 29) 157.

[41] The "Do No Significant Harm" (DNSH) principle was introduced by Article 17 of Regulation (EU) 2020/852, known as the EU Taxonomy Regulation, which sets the criteria for determining whether an economic activity qualifies as environmentally sustainable. According to this article, an activity is deemed to cause significant harm if it:
(a) leads to significant greenhouse gas emissions (climate change mitigation);

significant harm to any of six key objectives, including climate change mitigation, circular economy, and pollution prevention. In this framework, eco-design is no longer merely a design methodology aimed at improving product performance; it becomes a concrete and anticipatory instrument for legal compliance and risk prevention.

Unlike traditional environmental measures that operate downstream—such as emission offsetting or end-of-pipe solutions—eco-design intervenes upstream, at the very origin of product development. It enables the producer to address DNSH obligations structurally, through material selection, energy efficiency, modularity, durability, and end-of-life planning. This upstream integration is particularly relevant in light of the proposed Eco-design for Sustainable Products Regulation (ESPR), which explicitly links design obligations with environmental criteria aligned to the Taxonomy Regulation and DNSH. In this perspective, the design phase becomes a legal hinge: the place where sustainability is not merely added, but embedded into the product's identity[42].

Furthermore, the incorporation of DNSH into eco-design processes opens a path toward coherence between environmental innovation and access to finance. With instruments such as the Sustainable Finance Disclosure Regulation (SFDR) and the Corporate Sustainability Reporting Directive (CSRD), both public and private funding increasingly require verifiable alignment with DNSH. Eco-design, therefore, is not only a tool of environmental engineering—it is becoming a condition of legal eligibility and economic competitiveness within a regulated sustainability framework. It transforms the logic of compliance from reactive to proactive, turning regulatory constraints into design-driven opportunities.

2.3 The Impact of the Eco-Design Principle in Consumer Law

The principle of eco-design is currently regarded as one of the regulatory cornerstones through which European Union law and, by extension, national law, are progressively redefining the structural axis between consumption and sustainability. Far from being confined to a strictly technical domain, it entails a profound transformation not only in the logic of industrial design but also in the normative- conceptual framework of contractual obligations. The product is no longer conceived as a static good to be used

(b) increases climate-related risks to people, nature, or assets (climate adaptation);
(c) deteriorates the status of water or marine ecosystems (water and marine resources);
(d) causes inefficient use of natural resources or hinders recycling (circular economy);
(e) contributes to air, water, or soil pollution (pollution prevention);
(f) harms biodiversity or ecosystem condition (biodiversity and ecosystems).
The DNSH principle thus establishes a legally binding environmental safeguard, requiring that no objective be pursued at the expense of another. Its effective application depends on measurable technical screening criteria, reliable environmental data, and early integration into product and process design. In this sense, eco-design serves as a crucial tool to operationalise DNSH, embedding sustainability within the very architecture of goods and services.

[42] Green Finance Institute, *Do No Significant Harm (DNSH) Handbook* (London 2021). The handbook provides practical guidance on how to operationalise the DNSH principle, emphasising the need for early-stage integration in product and infrastructure design to ensure effective environmental safeguards.

and disposed of according to purely mercantile logics, but rather as a dynamic entity embedded in a circular value chain in which design, use, and end-of-life must be considered synoptically and as legally relevant. The adoption of the eco-design principle therefore entails a redefinition of the responsibilities incumbent upon the producer, who can no longer limit themselves to guaranteeing the safety and functionality of the good at the moment of traditio, but must also take responsibility for its sustainability throughout its entire life cycle, including the post-sale phase, by ensuring technical features that favour reuse, reparability, upgradability, and responsible disposal.

This shift in perspective has been enshrined in Regulation (EU) 2024/1781[43], which has superseded the previous framework set forth by Directive 2009/125/EC, extending the scope of application of eco-compatible design measures to almost all product categories and introducing mandatory minimum requirements for durability, spare parts availability, disassemblability, and the percentage of recycled materials. The same rationale inspired the introduction of "harmonised environmental information tools," such as the digital product passport and the repairability index, which must accompany every single product placed on the Union market. In this way, the European legislator has affirmed that product design has legal implications and, as such, must be regulated not only with regard to mercantile-industrial competitiveness and market dynamics, but also in view of environmental sustainability, public health, and corporate social responsibility. This implies that compliance with the eco-design principle does not amount to a voluntary best practice but rather constitutes a legal obligation rooted in public law, whose violation entails consequences also with respect to the contractual conformity of the good and the legitimacy of the economic activity carried out. Within the private law framework, eco-design thus becomes—particularly for the producer—a hermeneutical parameter for assessing compliance with the conformity obligations established by Articles 128 et seq. of the Codice del Consumo[44]: a product that, due to design choice, is not repairable, or whose obsolescence is structurally integrated, may be deemed unlawful under contractual law, even if it functions properly at the time of delivery. In this sense, the concept of defect in the good is broadened, no longer being limited to material flaws or evident discrepancies, but encompassing the absence of expected environmental and performance features according to the nature of the good and the information provided: eco-design

[43] Regulation (EU) 2024/1781 of the European Parliament and of the Council, of 24 April 2024, concerning the eco-design for sustainable products. This regulation replaces Directive 2009/125/EC, significantly broadening its scope: eco-design is extended to almost all product categories, with the imposition of binding requirements regarding durability, reusability, upgradability, reparability, presence of hazardous substances, energy efficiency, and recyclability. Mandatory informational tools (digital product passport) and more stringent market surveillance systems are also provided for.

[44] Pursuant to Articles 128 et seq. of Legislative Decree of 6 September 2005, no. 206 (Codice del Consumo), every consumer good must be in conformity with the contract, including with respect to "usual characteristics of durability and functionality." The most recent interpretation by legal scholarship and practice considers that the absence of reparability, especially if intentionally foreseen by the manufacturer, may constitute a contractual non-conformity even in the absence of immediate malfunctions.

thus entails an elevation of the standard of consumer protection, which is no longer confined, at a merely protective level, to verifying the functional performance of the good, but encompasses the right to demand its real and diachronic sustainability[45].

Eco-design, in its normative projection, also profoundly affects the profile of pre-contractual disclosure and liability[46]. The availability of harmonised and standardised technical data enables the consumer to make informed choices not only regarding the quality of the product but also its alignment with both the individual and collective environmental objectives. Transparency, in this regard, is no longer a mere corollary of the right to information, but rather central to the sustainable regulatory strategy, in which the full accessibility of design features constitutes the prerequisite for valid and truly informed consent: Article 49 of the Codice del Consumo, interpreted in light of the aforementioned European legal sources, therefore imposes the obligation to provide the consumer with clear and complete information also regarding the ecological and structural characteristics of the product. Failure to comply with this obligation may give rise to pre-contractual liability or allow the consumer to bring an action for annulment of the contract or compensation for damages.

Closely connected to the topos of eco-design emerges—by contrast—the issue of planned obsolescence, historically relegated to a technical-economic or industrial discussion, which is now absorbed into the legal sphere, becoming the object of doctrinal and, inevitably, jurisprudential scrutiny. Managerial practices aimed at artificially reducing the useful life of a good—through substandard materials, incompatible software updates, or the unavailability of spare parts—now constitute behaviours likely to infringe the obligations of diligence under Article 1176, para. 2[47], of the Codice Civile, and the provisions concerning conformity set forth in Articles 128 et seq. of the Codice del Consumo. The case law has progressively broadened the scope of contractual liability for defective products: noteworthy in this regard is the judgment of the Corte di Cassazione, Civil Section II, no. 1957 of 2016, which recognised the producer's liability for the lack of functional and environmental conformity of a good, and even more significantly, the judgment of the Tribunale di Milano dated 18 July 2018, which classified as unlawful the

[45] De Cristofaro G, "Sostenibilità e responsabilità del produttore" [2023] Contratti e Consumi, highlights that the design phase is also relevant in terms of pre-contractual and tort liability. The choice of materials, the modularity of the product, and the availability of technical documentation for repair translate into legal criteria that integrate or aggravate the obligation of professional diligence, within a perspective that links consumer law to the precautionary principle.

[46] Article 49 of the Codice del Consumo provides for pre-contractual information obligations on the part of the professional. In this context, the omission of the expected lifespan of the good or the availability of spare parts constitutes a relevant missing piece of information, with possible violation of Articles 20–23 concerning the prohibition of unfair commercial practices.

[47] Article 1176, paragraph 2, c.c., imposes on the debtor a qualified diligence if they engage in a professional activity. According to legal doctrine (De Cristofaro, op.cit.), such diligence extends to the design phase, implying the necessity of complying with sustainability and durability criteria, which are today considered structural components of the quality of the good, also with regard to the safety and transparency of the entire supply chain.

deliberate design of a product with a planned lifespan of no more than two years of standard use[48].

Within the same political-cultural milieu, one may find the rationale behind the right to repair, codified in the recent Directive (EU) 2024/1799[49], which obliges producers not only to refrain from obstructing repairability but to actively ensure it, through the availability of spare parts for a minimum period, access to the technical documentation necessary for repair, and enabling access for independent repairers. The legally binding dimension of repairability is thus fully integrated with the voluntary-contractual one, expanding the content of the conformity obligation beyond the initial moment of delivery: the good (subjected to traditio) is no longer deemed conforming solely because it functions upon purchase, but rather if it is structurally suitable for log-term use, and such capacity must be rendered effective for the consumer through concrete and documentary means[50].

These protective aspects, although rooted in the private law sphere, intersect and inevitably find their axiological foundation in the constitutional principles recently reformed—in 2022—and inserted into the wording of Article 9 of the Italian Constitution[51] (new formulation), which mandates the protection of the environment, biodiversity, and ecosystems also in the interest of future generations; and in the wording of Article 41 of the Constitution[52] which traditionally limits private economic initiative when it conflicts with human dignity, health, or the environment. Given these premises, it is manifest that the production of a good deliberately designed to be short- lived, non-repairable, or disposable is now not only at odds with the economic logic of sustainability but also with the supreme values of the constitutional order: the principle of eco-design thus becomes

[48] Tribunale di Milano, Sez. XI, 18 July 2018, recognised the liability of a manufacturer who had deliberately designed an electronic device with software updates that accelerated its functional obsolescence. The conduct was deemed in violation of Article 1176, paragraph 2, c.c., and of the consumer's legitimate expectations regarding the durability of the good.

[49] Directive (EU) 2024/1799, approved by the European Parliament on 23 April 2024, establishes the "right to repair," imposing precise obligations on manufacturers: ensuring the availability of spare parts for at least 5 years, making repair manuals accessible, and not obstructing access to repair by independent operators. Non-compliance with these obligations may constitute contractual violation or unfair commercial practice, according to the national implementing legislation.

[50] Manstretta A, "Diritto dei consumi e progettazione sostenibile: verso un obbligo di durabilità?" [2023] Rivista di diritto dell'ambiente 118. The author analyses the principle of durability as an implicit clause in consumer contracts. Starting from the combined reading of Articles 132 and 134 Cod. Cons., he argues that the absence of information on the useful life of the good and the intentional design of obsolescence represent determining factors in the assessment of contractual liability.

[51] Article 9 of the Costituzione, amended by Constitutional Law no. 1/2022, now includes among the fundamental principles the protection of the environment, biodiversity, and ecosystems. This provision is also relevant in consumer law, as it imposes on the legislator and sector operators an obligation to comply with environmental needs, translating into interpretative criteria for the entire contractual system.

[52] Article 41 Cost., also reformed in 2022, provides that private economic initiative may not take place in contrast with the environment. The constitutional principle acts as an external limit to contractual autonomy, preventing production practices that, although economically efficient, are structurally harmful to the environment and to consumer rights. The combined reading of Articles 9 and 41 Cost therefore requires a sustainable reinterpretation of entrepreneurial freedom and contractual liability.

a benchmark for assessing the legitimacy of production practices and a hermeneutic parameter for the judge, also in view of constitutionally oriented interpretation.

The benefits of this innovative regulatory framework for consumers are both manifold and tangible: firstly, on the economic level, the increased durability of goods leads to a significant reduction in replacement and maintenance costs, fostering overall savings that are not only individual but systemic, as it entails reduced pressure on production chains and natural resources. Secondly, on the informational-gnoseological level, the consumer acquires decisive tools to make informed choices, thanks to harmonised labels, digital passports, technical data sheets, and repairability indices: transparency becomes a legally protected interest even in the contractual domain, and the ecological quality of the product acquires legal significance equal to its material conformity. Eco-design, as a parameter for assessing the validity of the contractual scheme, implies that any product which lasts longer can be repaired rather than discarded, contains recycled materials or is designed for reuse, constitutes a concrete step towards realising a regenerative economy model, in compliance with the objectives of the European Green Deal and the principles of the circular economy.

2.4 Critical perspectives and regulatory implications

Despite its relevance, the Life Cycle Assessment (LCA) approach also presents a number of limitations that risk undermining its potential if not adequately addressed. One of the main issues lies in the complexity of data collection, especially when it comes to upstream supply chains, which are often opaque, fragmented, or located in jurisdictions with low reporting standards. Furthermore, the lack of harmonised methodologies and reference parameters frequently results in inconsistencies that weaken the comparability of results across sectors and regions. Another critical aspect concerns the use of LCA as a communication tool: while it can support informed decision-making and transparency, it is also susceptible to manipulation, especially when selectively employed to legitimise green claims that are not supported by a systemic improvement of processes—a phenomenon commonly referred as greenwashing.

A further obstacle, often underestimated, concerns the accessibility and usability of environmental data, particularly for small and medium-sized enterprises. Unlike large corporations, SMEs frequently lack the internal expertise, digital infrastructure, or financial capacity to carry out rigorous LCA studies or to comply with increasingly complex reporting frameworks. This structural gap risks excluding a substantial portion of the production fabric from the transition towards verifiable and traceable sustainability[53].

[53] Gómez Garza R, Güereca LP, Padilla Rivera A, Aguilar Ibarra A, 'Barriers and Enablers of Life Cycle Assessment in Small and Medium Enterprises: A Systematic Review' in *Environment, Development and Sustainability* (2024). The authors provide a comprehensive overview of the structural and operational barriers that hinder the adoption of LCA among SMEs, highlighting issues such as limited access to high-quality environmental data, lack of trained workers and

Recognising these difficulties, the European Union is promoting tools such as the Digital Product Passport (DPP) and the Product Environmental Footprint (PEF), with the aim of simplifying data collection, ensuring greater transparency, and facilitating access to reliable and comparable environmental information, especially for less structured operators.

Today, eco-design goes beyond its technical dimension to engage directly with legal and social responsibilities. It is not merely a tool to reduce environmental impacts but a core mechanism of accountability for producers throughout the entire life cycle of products. In the European context, this responsibility is reflected in the principle of Extended Producer Responsibility (EPR), which obliges economic actors to consider not only production but also usage and end-of-life phases. Simultaneously, the environmental due diligence principle requires proactive risk management. The proposed Eco-design for Sustainable Products Regulation (ESPR) and the 'do no significant harm' (DNSH) criterion further reinforce the alignment of design processes with long-term sustainability goals.

A clear example of practical LCA application is the comparison between beverage bottles made of glass and those made of recycled PET. Intuitively, glass might appear to be the more sustainable option due to its reusability and 'natural' image. However, LCA demonstrates that in well-structured recycling systems, recycled PET can have a lower environmental impact. This is due to its lighter weight, reduced transportation emissions, and lower energy requirements for recycling compared to glass. This case highlights how LCA enables us to move beyond intuitive perceptions and rely instead on objective data to inform more sustainable design and policy decisions[54].

2.5 Conclusion

In conclusion, this paper aimed to highlight how life cycle assessment and eco-design, far from being mere technical tools, stand at the heart of a broader cultural and regulatory transformation calling economic actors to greater responsibility.

LCA and eco-design are not only methodologies but also cultural and legal frameworks that embed sustainability into production logic, addressing growing demands for transparency, ethics, and environmental resilience. Through policies like the Green Deal, the green transition, and sustainable product regulation, the European Union is shaping a landscape in which these tools are becoming mandatory rather than optional. The emerging challenge is thus to achieve structural and interdisciplinary integration—shifting from fragmented approaches to a genuine model of sustainable and regenerative governance. Only in this way can we truly reconcile innovation with responsibility, and

prohibitive costs. The study reinforces the need for policy frameworks and technical infrastructures that democratise LCA tools and make them accessible to less resourced enterprises.

[54] Ferrara (n 10) 50.

efficiency with ecological justice, within an economy oriented not solely toward profit, but toward the common good.

In light of this evolution, LCA has progressively moved beyond its original evaluative function to become a strategic reference point in design and innovation processes. In particular, Life Cycle Thinking finds a natural application in eco-design, where the goal is no longer merely to assess impacts but to anticipate and reduce them from the earliest design stages. Eco-design is based on a holistic vision of the product, taking into account its entire life cycle—from material selection to end-of-life management—and on the assumption that many environmental performances are determined in the very first phases of development. In this perspective, LCA is not only a technical support tool but a true cognitive and cultural infrastructure that guides design choices according to principles of sustainability and responsibility.

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SPECIAL ISSUE

THE IMPACT OF INTELLECTUAL PROPERTY PROTECTION ON THE EU'S RIGHT TO REPAIR[1]

Abstract

The shift from a linear (take-make-consume-dispose) to the of the circular economy (CE) has been widely recognised as a key driver ecological sustainability. Contrary to linear business models, the CE aims to restore and regenerate resources and is characterised by a certain number of 'circular operations'; incl. repair and maintenance. As a circular operation, repair and maintenance play an important role as it aims to extend a product's lifespan, resulting in less waste. However, repair can be obstructed by a number of material and legal barriers, which become more and more pronounced with the computerisation of products. For this reason, the so-called 'Right to Repair' movement has become increasingly popular in recent years. Intellectual Property (IP) rights and trade secrets are among the barriers identified to repair and to circularity in general. With the exception of a specific intervention in design law, no changes to European Union (EU) IP legislation have been proposed to support (independent) repair services. Instead, the EU is facilitating the transition from a linear to a circular economy through other initiatives in EU consumer, product design, competition and data governance legislation. Rights and obligations under these instruments create together a right to repair *sensu lato*. The contribution investigates the relationship between selected instruments expressing a right to repair *sensu lato* and EU IP rights.

To do this, the contribution first summarises how IP rights can serve as barriers to material and legal access to essential repair commodities. Essential repair commodities are defined as hardware (affordable spare parts and repair and maintenance tools), software and repair information. It then continues to describe provisions materialising the right to repair *sensu lato*. The selected instruments are Directive (EU) 2024/1799 on common rules on the repair of goods, Regulation (EU) 2024/1781 establishing a framework for the setting of ecodesign requirements for sustainable products, and Regulation (EU) 2023/2854 on harmonised rules on fair access to and use of data. For each instrument, the contribution scrutinises the scope of provisions that facilitate repair and their limitation. I further address the interaction between (*i.*) the instruments in themselves; and (*ii.*) EU IP rights. The contribution summarises its research results in a final, conclusionary chapter.

JEL CLASSIFICATION: K12, K10

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[1] This article translates and builds upon the research results in 'Friends or Foes – Het Recht op Reparatie sensu lato en de Interactie met Intellectuele Eigendomsrechten in de Europese Unie' (2025) DCCR 3-34 (only available in Dutch).

10.13135/2785-7867/12835

SUMMARY

1 Introduction

Contemporary products are becoming increasingly complex. While a vacuum cleaner in previous decades consisted mainly of physical components or hardware, modern models are now frequently operated via software 'embedded' or integrated directly into the product. At times, they are even 'smart', equipped with sensors and integrated software that allow them to collect and process information. This data can then be transmitted via an internet connection to other devices—an interconnected system commonly referred to as the 'Internet of Things'. One example of this is a link to a mobile application that notifies you when it's time to replace or service specific components.

The increasing technological complexity of products poses significant challenges for maintenance and repair operations, aimed at maximising their lifespan. In practice, however, a variety of legal and material obstacles continue to hinder a meaningful shift from product replacement towards repair. These obstacles have fuelled the emergence of a socio-legal movement referred to as the 'right to the repair' movement.[2] The conceptual scope of this 'right to repair' differs in literature.[3] This contribution interprets the right to repair according to the majority opinion, which argues that an effective right to repair must allow for competition in the repair and maintenance market.[4] Using this definition, an effective right to repair requires (independent) repairers to have access to a number of 'commodities'. These 'essential repair commodities' are set out in Section 1 below.

Obstacles to repair also impede an effective shift to a Circular Economy (CE), in which repair and maintenance are key operations.[5] This CE-transition is clearly supported by EU

[2] Aaron Perzanowski, The Right to Repair: Reclaiming the Things We Own (1st edn, Cambridge University Press 2022).
[3] For an overview, see Elias Van Gool, 'Product Liability in a More Circular Economy' (doctoral dissertation, KU Leuven and Université de Lille 2024) para 87.
[4] See for example Evelyne Terryn, 'A Right to Repair? Towards Sustainable Remedies in Consumer Law' (2019) 27 European Review of Private Law 851; 'A European "Right to Repair": Yes! But How (Far)?' (Faculteit Rechtsgeleerdheid en Criminologische Wetenschappen) < https://shorturl.at/w0DaB > accessed 11 July 2025; Aaron Perzanowski, The Right to Repair: Reclaiming the Things We Own (1st edn, Cambridge University Press 2022).
[5] ibid, 8. See also European Commission, 'Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on A New Circular Economy Action Plan For a Cleaner and More Competitive Europe' (2020) COM(2020) 98 final 6, 7 and 10; Ellen MacArthur Foundation, 'The Technical Cycle of the Butterfly Diagram' (23 May 2022) <https://www.ellenmacarthurfoundation.org/articles/the-technical-cycle-of-the-butterfly-diagram> accessed 7 May 2025.

policy, most prominently in the European Green Deal.[6] Accordingly, the EU is seeking to address shortcomings in the current repair and maintenance market which fail to sufficiently incentivise consumers to opt for repair over replacement.[7] The European Commission's (Commission) Impact Assessment accompanying the proposal for Directive (EU) 2024/1799[8] identifies the various factors that influence such consumer decisions. Within the legal guarantee period, the previous version of the Sale of Goods Directive[9] placed repair and replacement on an equal footing.[10] This resulted in 65% of consumers choosing replacement over repair in case of a lack of conformity.[11] Outside the legal guarantee period, factors such as the cost of repair[12], specific burdens[13], supply-related problems and technical limitations[14] discourage consumers from choosing repair. Intellectual Property (IP) rights influence many of these factors, as well as the general availability[15] of 'essential repair commodities'[16], in particular for independent aftermarket players.[17] However, there are no changes to EU IP law aimed at supporting the repair market except for the design clause in EU design law.

[6] European Commission, 'Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on the European Green Deal' (2019) COM(2019) 640 final 7-10.

[7] This prevailing trend of *replacing* (complex) products aligns more with a linear economic model that encourages the premature disposal of otherwise functional goods.

[8] European Commission, SWD Impact Assessment Accompanying the document Proposal for a Directive of the European Parliament and of the Council on common rules promoting the repair of goods and amending Regulation (EU) 2017/2394, Directives (EU) 2019/771 and (EU) 2020/1828 2023 [SWD(2023) 59 final].

[9] Directive (EU) No 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC (2019) OJ L136/43 (Sale of Goods Directive).

[10] Recital 48 and Art 13 Sale of Goods Directive.

[11] European Commission, SWD Impact Assessment Accompanying the document Proposal for a Directive of the European Parliament and of the Council on common rules promoting the repair of goods and amending Regulation (EU) 2017/2394, Directives (EU) 2019/771 and (EU) 2020/1828 2023 [SWD(2023) 59 final] 196 14.

[12] The price of repair if often relatively higher than that of replacement, a disparity shaped by multiple interrelated factors. These factors include: the availability and accessibility of repair and maintenance services and therefore the degree of competition within the repair market; the price and availability of spare parts (particularly in the context of complex products); the increased technical complexity of products, largely driven by evolving design practices. An enhanced competition in complex products' aftermarkets can pressure repair prices downwards however, such competition can be restrained or restricted by manufacturers, *inter alia* based on their IP Rights and TSs.

[13] Including the labour-intensive nature of repair processes, the inconvenience for the consumer of losing material ownership of the product for an extended period, and the transport or logistical costs associated with repair and maintenance activities.

[14] These may include product design by the manufacturer that prevents or makes repair more difficult such as: the difficulty or denial of access to information necessary for repair on the one hand, and the lack of access to necessary data and e.g. software updates on the other hand (see SWD Impact Assessment Accompanying the document Proposal for a Directive of the European Parliament and of the Council on common rules promoting the repair of goods and amending Regulation (EU) 2017/2394, Directives (EU) 2019/771 and (EU) 2020/1828, EUROPEAN COMMISSION, 22 March 2023, SWD(2023) 59 final, 17).

[15] Availability is defined in a broad way for the purposes of this contribution, including effective, 'material' access to the commodities in question, but also mor generally 'legal' access (i.e., the ability to use the commodities without infringing upon someone's third party rights).

[16] 'Essential repair commodities' are understood as hardware (such as spare parts and repair tools), software and repair information.

[17] See, among others, Shahrzad Manoochehri and others, 'An Overview of Europe's Repair Sector' (2022) 17; Aaron Perzanowski, *The Right to Repair: Reclaiming the Things We Own* (1st edn, Cambridge University Press 2022); Taina Pihlajarinne, 'Repairing and Re-Using from an Exclusive Rights Perspective: Towards Sustainable Lifespan as Part of a

Instead, the EU legislator has adopted a consumer- and product-design-oriented approach. The most prominent of these initiatives is the recently adopted Directive (EU) 2024/1799[18] on common rules for the promotion of the repair of goods (Right to Repair Directive or R2RD), which formally introduces the notion of a consumer 'right to repair' in EU law. That said, other EU legislation also influences access to (independent) repairers. The contribution therefore speaks of a 'right to repair *sensu lato*', which will be further conceptualised in section 3.

This observation underwrites the relevance of the main research question: How do European intellectual property rights interact with the right to repair *sensu lato* as expressed in Directive 2024/1799, Regulation 2024/1781 and chapter II Regulation 2023/2854? To answer this question, the contribution is sub-divided into two sections. Section 2 highlights how IP rights can intervene with (independent) repair and maintenance market. It focusses on four types of IP protection: copyright, design, patent and trade mark law.

Section 3 scrutinises a selection of EU laws aimed at materialising a 'right to repair' *sensu lato*[19], in particular: the aforementioned R2RD, Regulation (EU) 2024/1781[20] (ESPR) and Chapter II of Regulation (EU) 2023/2854[21] (Data Act). The analysis focusses on their scope and their interplay with IP rights. The contribution only discusses those provisions that further impact material and legal access to affordable repair and maintenance services.[22]

New Normal?' in Ole-Andreas Rognstad and Inger BØrstavik (eds), *Intellectual Property and Sustainable Markets* (Edward Elgar Publishing 2021); European Commission. Directorate General for Communications Networks, Content and Technology. and others, 'Study to Support an Impact Assessment on Enhancing the Use of Data in Europe.' (Publications Office 2022) 270-271.

[18] Directive (EU) No 2024/1799 of the European Parliament and of the Council of 13 June 2024 on common rules promoting the repair of goods and amending Regulation (EU) 2017/2394 and Directives (EU) 2019/771 and (EU) 2020/1828, *OJ L* 10 July 2024.

[19] See *infra* sub-section 3 for an introduction to this concept.

[20] Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (2024) OJ L (Ecodesign for Sustainable Products Regulation or ESPR).

[21] Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (2023) OJ L (Data Act).

[22] Other EU legislation such as Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure and other consumer law is not addressed. See, in particular: European Commission Proposal for a Directive on the substantiation and communication of explicit environmental claims (2023) [COM(2023) 166 final] (Green Claims Directive), for which the Council voted its position for its negotiating mandate on 17 June 2024; Directive (EU) No 2024/825 of the European Parliament and of the Council of 28 February 2024 amending Directives 2005/29/EC and 2011/83/EU as regards empowering consumers for the green transition through better information and through protection against unfair practices (2024) OJ L; Directive (EU) No 2011/83 of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council (2011) OJ L304/64.

2 An overview of Intellectual Property limitations on the repair and maintenance market

IP rights are exclusive rights[23], empowering their holders to restrict certain acts on or with the protected subject matter. This exclusivity necessarily impacts independent players, hindering their access to certain essential commodities for repair and maintenance. As discussed in footnote 16, these commodities include material and legal access to technical repair information, affordable spare parts, integrated software and on-board systems, as well as product-generated data. The impact of the selected IP rights on these commodities is outlined in sub-sections 2.1 to 2.3. The contribution distinguishes between three different kinds of repair commodities: hardware, software and repair information.[24]

2.1 Intellectual Property Protection and Hardware

The Commission has identified the price and availability of spare parts as an important barrier for effective repair and maintenance.[25] This can be influenced by IP protection on (aspects of) the products and/or the part in question, among other factors.[26]

The design of spare parts may be protected under national or EU[27] design law. Design law historically recognised the impact of design rights on the availability and price of spare parts within the repair and maintenance market. In an attempt to limit anticompetitive effects, the Community Design Regulation[28] (CDR) introduced a limitation to design rights on components of complex products used solely for repair purposes. Following a turbulent legislative process[29], the recently published Design Directive

[23] Protected under Art 17.2 of EU Charter of Fundamental Rights.
[24] Note that the overview below represents a high-level overview. For a more extensive, all-encompassing discussion, see Aaron Perzanowski, 'Repair and Intellectual Property', *The Right to Repair: Reclaiming the Things We Own* (1st edn, Cambridge University Press 2022); Manon Vanderhaeghe and Jozefien Vanherpe 'The "right to repair" in the European Union: considerations from an EU intellectual property perspective' in Dorothy Gruyaert (ed), *Sustainability, law and criminology – provoking a sustainability reflex in (future) lawyers and criminologists* (Intersentia 2025) 475-503.
[25] M Shahrzad Manoochehri and others, 'An Overview of Europe's Repair Sector' (2022) 17.
[26] Dana Beldiman and Constantin Blanke-Roeser, 'European Design Law: Considerations Relating to Protection of Spare Parts for Restoring a Complex Product's Original Appearance' (2015) 46 IIC 915-919.
[27] Up until 1 May 2025, this was referred to as 'Community' protection under the previous version of Council Regulation (EC) No 6/2002 on Community Designs (2002) OJ L3/1 (Community Design Regulation or CDR).
[28] CDR, Art 110. Aimed at the harmonisation of national design laws, Directive (EC) 98/71 of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs (1998) OJ L289/28, Art 14 (Design Directive or DD) did not contain a similar provision, but adopted a compromise in which members states were not required to amend their national design laws to include a similar 'repair clause' as under the Community Design Regulation but when it would change their corresponding national provisions, it could only have the effect of favouring the liberalisation of the spare part market.
[29] Which is does not fall under the scope of the article. For an overview of the legislative history of the repair clause, see *inter alia* Joseph Drexl, Reto M Hilty and Annette Kur, 'Design Protection for Spare Parts and the Commission's Proposal for a Repairs Clause' (2015) 46 IIC 915-919; David Stone, *European Union Design Law: A Practitioners' Guide* (2nd edition, Oxford University Press 2016) 481-468.

(recast)[30] and the amended EU Design Regulation[31] now introduce such a (permanent) limitation for users[32] of form-dependent components of complex products.[33] As noted in the impact assessment accompanying the R2RD, this legislative change is considered a key driver of product repairability in the EU from a supply-side perspective, alongside measures introduced under the ESPR.[34]

That said, its conceptual scope is narrow. First, the limitation only applies to *form-dependent* components of complex products. This requirement deviates from the accepted standard established by the Court of Justice of the European Union (CJEU), which clarified that 'the protected design's dependence upon the appearance of the complex product' is not one of the conditions of the old repair clause in the CDR.[35] An explicit reference to form-dependency would prevent manufacturers of items such as wheel trims[36] to rely on the repair clause as a defence for infringement. Second, the use of the component must be *necessary* for repairing the complex product.[37] Third, the alleged infringer invoking the defence must comply with two obligations with regard to downstream users. Specifically, the repairer must (*i.*) inform users of the origin of the spare part, i.e. the identity of the manufacturer[38] and (*ii.*) respect the duty of care, ensuring through appropriate measures that users will only use the spare part for repair

[30] Directive (EU) No 2024/2824 of the European Parliament and of the Council of 23 October 2024 on the legal protection of designs (recast) (2024) OJ L (DD recast).

[31] The CDR, amended by Regulation (EU) No 2024/2822 of the European Parliament and of the Council of 23 October 2024 amending Council Regulation (EC) No 6/2002 on Community designs and repealing Commission Regulation (EC) No 2246/2002 (2024) OJ L (Amending Regulation).

[32] Note that the term 'use' is interpreted broadly. Under the DD recast, Art 12(1) and the CDR, Art 19(1), it was defined as "the making, offering, putting on the market, importing, exporting or using of a product in which the design is incorporated or to which it is applied, or stocking such a product for those purposes" (see also joined cases C-397/16 and C-435/16 *Acacia srl v Pneusgarda Srl/Audi AG* and *Acacia Srl/Rolando D'Amato v Dr. Ing. h.c. F. Porsche AG* (2017) ECLI:EU:C:2017:992 para 68. Under the DD recast and the EUDR, 'use' further also explicitly includes the (*i.*) stocking of a product for such purposes and (*ii.*) creation, download, copying and sharing or distribution of a medium or software which records the design for the purpose of enabling a protected product to be made (for 3D printing purposes) (DD recast, Art 16(1)(c) and (d) and Amending Regulation, Art 1(17)).

[33] Art 19 DD recast and Art 20a EUDR (inserted by Art 1(18) Amending Regulation).

[34] SWD Impact Assessment Accompanying the document Proposal for a Directive of the European Parliament and of the Council on common rules promoting the repair of goods and amending Regulation (EU) 2017/2394, Directives (EU) 2019/771 and (EU) 2020/1828, EUROPEAN COMMISSION, 22 March 2023, SWD(2023) 59 final, 4.European Commission SWD Impact Assessment Accompanying the document Proposal for a Directive of the European Parliament and of the Council on common rules promoting the repair of goods and amending Regulation (EU) 2017/2394, Directives (EU) 2019/771 and (EU) 2020/1828 (n 15) 4.

[35] Joined cases C-397/16 and C-435/16 *Acacia srl v Pneusgarda Srl/Audi AG* and *Acacia Srl/Rolando D'Amato v Dr. Ing. h.c. F. Porsche AG* (2017) ECLI:EU:C:2017:992 para 34.

[36] Which was the protected subject-matter in the *Acacia* case law (ibid).

[37] In other words: without the component part, normal use of the complex product would not be possible. For an extended analysis of the conceptual scope of 'normal use', see Hendrik Vanhees, 'Wanneer is er nu juist sprake van een onderdeel in het modellenrecht, wanneer zijn de kenmerken van een onderdeel zichtbaar en wanneer is er sprake van normaal gebruik van het samengestelde voortbrengsel?' (2024) 28 17-30 (only available in Dutch).

[38] European Parliament 'European Parliament legislative resolution of 14 March 2024 on the proposal for a regulation of the European Parliament and of the Council amending Council Regulation (EC) No 6/2002 on Community designs and repealing Commission Regulation (EC) No 2246/2002' (2024) P9_TA(2024)0164 Art 1(16) (EP Resolution Amending Regulation); European Parliament 'European Parliament legislative resolution of 14 March 2024 on the proposal for a directive of the European Parliament and of the Council on the legal protection of designs (recast)' (2024) P9_TA(2024)0165 Art 16(2) (EP Resolution DD recast).

purposes.[39] Lastly, the repaired product must have an identical visual appearance to the original complex product. In other words, the allegedly infringing part and the original part must be identical.

The application of this last requirement may be challenged if the part in question incorporates a trade mark. In that scenario, an independent actor (e.g. a spare part manufacturer) is 'stuck' between trademark and design protection. On the one hand, it cannot incorporate a sign confusingly similar or identical to the trade mark without committing a trade mark infringement.[40] On the other hand, failing to include the trade mark may undermine the requirement of visual identity of the repair limitation.

(Parts of) spare parts can also fall under patent protection[41] if they are new, inventive and industrially applicable.[42] In such cases, independent manufacturers and suppliers of non-original spare parts commit a patent infringement when they make or import spare parts without obtaining an authorisation from the patent holders. In the case of original second-hand parts, the principle of exhaustion applies, unless a further modification takes place. If such a modification is applied, patent infringement could still occur whenever it can be qualified as 'remanufacturing'.[43]

The previous considerations regarding spare parts also apply to the protection of the product to be repaired in itself. Repairing a patented product as such may pose a risk of patent infringement. The risk not only affects independent repairers, but also to the manufacturers and suppliers of non-patented spare parts or repair tools. The former may infringe a product patent if the repair amounts to remanufacturing. If not, EU patent law accepts that patent rights on that specific product are exhausted, thereby allowing independent repair and maintenance.[44] However, the point at which legitimate repair becomes illegitimate remanufacturing is not clearly or uniformly defined.[45] While both concepts are now clearly defined within the ESPR[46], European patent courts apply different criteria.[47]

[39] This requirement however does not amount to warranty from the part of the alleged infringer. See EP Resolution Amending Regulation, Art 1(17) and EP Resolution DD recast, rec 35 *juncto* Art 19(2).
[40] There is no similar 'repair' defense in EU trade mark law. This has been further confirmed in case C-334/22 *Audi AG v CQ* (2024) ECLI:EU:C:2024:76.
[41] Within the EU, this can be either national or, since 1 June 2023, unitary patent protection.
[42] European Patent Convention (EPC), Art 52(1).
[43] See below for a more detailed analysis.
[44] See, *inter alia*, Niels Hölder, 'Contributory Patent Infringement and Exhaustion in Case of Replacement Parts - Comment on a Recent Supreme Court Decision in Germany' (2005) IIC 889; Christopher Heath, 'A Three-Step Test for Determining Patent Infringement Related to Repair' (2024) 55 IIC 762, B Whitehead and R Kempner, 'Manufacture or Repair?' (2011) 6 Journal of Intellectual Property Law & Practice 9; Klaus Haft and others, 'Die Erschöpfung von Rechten des Geistigen Eigentums in Fällen des Recyclings oder der Reparatur von Waren (Q 205)' GRUR International (2008) 944.
[45] ibid.
[46] ESPR, Art 2(16) and (20). See below for the description of the scope of repair provisions within the ESPR.
[47] In their analysis of relevant European jurisprudence, R.M. Ballardini, I. Flores Ituarte and E. Pei distinguish four criteria that are usually taken into account when analysing repair *versus* remanufacturing: (1) the extent to which the technical effects of the invention are embodied by the component to be replaced; (2) the need to repair the product; (3) the extent of the repair compared to the manufacturing process of the original product; and (4) the extent to which the repaired part competes with the original parts (Rosa Maria Ballardini, Iñigo Flores Ituarte and Eujin Pei, 'Printing

Furthermore, manufacturers of non-patented spare parts or repair tools can be prosecuted for indirect patent infringement. Such infringement exists where an entity (*i.*) offers means relating to an essential element of the invention *and* (*ii.*) where it should have known that these means are suitable and intended for putting that invention into effect.[48]

In addition to patent and design rights, (parts of) complex products and spare parts can further be protected by copyright if the shape of a utilitarian product is not solely defined by its technical function and is original.[49] Reproducing and commercialising original elements of that shape would then constitute a copyright infringement. Trademark law can further also affect the trade of repaired products.[50]

2.2 Intellectual Property Protection and Software

In recent years, the hardware of complex products is often equipped with and/or driven by 'on-board computer systems' and 'embedded software'. Access to such software is often required for an (independent) repairer to perform repair and maintenance tasks.[51] However, software is eligible for copyright protection within the EU. This enables the copyright holder[52] to prevent third parties from reproducing, altering (including translation or adaptation) or distributing the software.[53] For historical reasons[54], the Software Directive[55] and EU copyright law *sensu stricto*[56] allow the introduction of Technological Protection Mechanisms (TPMs) to prevent third parties from accessing protected works.[57] Circumventing such TPMs or circulating means for circumventing them

Spare Parts through Additive Manufacturing: Legal and Digital Business Challenges' (2018) 29 Journal of Manufacturing Technology Management 958).

[48] Agreement on the Unified Patent Court (2013) OJ C175/1 Art 16 (UPCA).

[49] Case C-833/18 *SI/Brompton Bicycle Ltd v Chedech/Get2Get* ECLI:EU:C:2020:461 paras 33 and 35.

[50] For an overview of the problematic interaction between the resale of repaired products bearing a trade mark, see Annette Kur, '"As Good as New" – Sale of Repaired or Refurbished Goods: Commendable Practice or Trade Mark Infringement?' (2021) 70 GRUR International 228; Simon Geiregat, 'Trading Repaired and Refurbished Goods How Sustainable Is EU Exhaustion of Trade Marks?' (2023) 73 GRUR International 287.

[51] Sarah Kessler, 'The Connected Car of the Future Could Kill off the Local Auto Repair Shop' (*Quartz*, 5 September 2017) <https://qz.com/1054261/the-connected-car-of-the-future-could-kill-off-the-local-auto-repair-shop> accessed 7 February 2024.

[52] Usually, the original manufacturer of the complex product, as economic rights will oftentimes be transferred to the company in the case of an employer-employee relationship.

[53] Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (2009) OJ L111/16, Art 4(1). The Software Directive refers to 'computer programs' instead of 'software'.

[54] For an overview of the legislative history and *ratio legis* for the protection of TPMs, see Anthony D Rosborough, 'Unscrewing the Future: The Right to Repair and the Circumvention of Software TPMs in the EU' (2020) 26 JIPITEC 26 paras 32-52.

[55] Directive (EC) 2009/24 of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (2009) OJ L111/1 (Software Directive).

[56] Directive (EC) No 2001/29 of the European Parliament and of the Council of 22 May 2001 (2001) OJ L167/10 (InfoSoc Directive).

[57] Software Directive, Art 7(1)(c) and InfoSoc Directive, Art 6(1).

is also illegitimate under these provisions.[58] The rightsholder can prevent such circulation as well, irrespective of a subsequent illegitimate use of the protected work.

European patent law excludes patent protection for computer programs *per se*.[59] However, software can be considered a patentable invention if the applicant can demonstrate a further technical effect.[60] Specifically, the grant of method patents that can be executed on a computer will not be refused based on a lack of technical character.[61]

2.3 Intellectual Property Protection and Repair Information

Information in the of form of raw, unstructured data does not qualify for IP protection in itself.[62] There is some debate as to the scope of process patents protection and whether it extents to information directly resulting from the process covered by the patent.[63] The restrictive interpretation prevailing in national patent courts seems to suggest that it does not.[64] However, as previously stated, patent law can protect data structures and data formats to the extent that they are technical in nature.

In addition to patent protection, the specific formulation and representation of repair and maintenance information may be covered by other IP regimes. For example, a manual may consider a 'work' under copyright *sensu stricto*.[65] This restricts the reproduction and distribution of physical or digital copies, as these acts may amount to a copyright infringement if they are undertaken outside the mere private and non-commercial sphere. The reproduction of information may also fall within the scope of a *sui generis* database right.[66]

[58] Anthony D Rosborough, 'Unscrewing the Future: The Right to Repair and the Circumvention of Software TPMs in the EU' (2020) 26 JIPITEC 26.
[59] Art 52(2) European Patent Convention.
[60] This is also referred to as the requirement of a 'technical character', which is necessary for subject-matter to fall under the scope of an 'invention' thus not qualifying as excluded subject-matter. See European Patent Office 'Guidelines for Examination Part G-Chapter II-3.6 Programs for computers'.
[61] ibid.
[62] Note that these may fall under TS protection however, this is beyond the scope of the contribution.
[63] UPCA, Art 25(c).
[64] Josef Drexl and others, 'Position Statement of the Max Planck Institute for Innovation and Competition of 25 May 2022 on the Commission's Proposal of 23 February 2022 for a Regulation on Harmonised Rules on Fair Access to and Use of Data (Data Act)' [2022] SSRN Electronic Journal para 9, referring to Case X ZR 33/10 *MPEG-2-Videosignalkodierung* [2012] BGH and Case X ZR 124/15, *Receptor Tyrosine Kinase II* [2019] BGH para 21; Josef Drexl, 'Data Access and Control in the Era of Connected Devices' (BEUC 2018) 87.
[65] For example, the authors of the manual can make free and creative (and thus original) choices by the structuring of information and/or by including photos, diagrams, illustrations, etc. For a detailed overview, see Aaron Perzanowski, *The Right to Repair: Reclaiming the Things We Own* (1st edn, Cambridge University Press 2022); Anthony D Rosborough, 'Zen and the Art of Repair Manuals: Enabling a Participatory Right to Repair through an Autonomous Concept of EU Copyright Law' (2022) 13 JIPITEC 113.
[66] See below, section 3.4.

3 The right to repair *sensu lato* and its interaction with Intellectual Property Rights

3.1 Introduction

The EU's legislative intervention to stimulate the repair and maintenance aftermarket is designed in different ways and across different legal disciplines. The legislation discussed below either explicitly focusses on repair for environmental sustainability reasons, or envisions more general objectives tat encompass repair. In the context of the R2RD, the Commission presented the various legislative interventions in favour of repair and the CE more generally by referring to the stages of a standard product manufacturing and sale process: the production stage (e.g., product design regulation[67]); the purchase and sale stage[68]; and the post-sale stage.[69] In that sense, the contribution applies the concept of a right to repair *sensu lato*, which is further materialised through various statutory rights and obligations that impact affordable services within the repair and maintenance aftermarket, such as the right to repair *sensu stricto* for consumers under the R2RD.[70]

As mentioned, this contribution focusses on three legislative initiatives[71] that affect the repair and maintenance market: the R2R Directive, the ESPR and the Data Act.[72] For each instrument, it first analyses the scope of provisions affecting (independent) players in the repair aftermarket. Then, it will consider how these initiatives interact with and/or accommodate for IP protection.

3.2 The Right to Repair Directive

The recently published R2RD was adopted in the context of the EU's green ambitions.[73] It promotes repair and reuse of products in two situations. First, *within* the legal warranty period by introducing an amendment to the SGD[74], extending the legal warranty period

[67] Incl. the ESPR.
[68] With f.e. Directive (EU) No 2011/83 of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council (2011) OJ L304/64.
[69] With f.e. the R2R Directive.
[70] In its new CEAP, the Commission refers to the concept 'right to repair' as horizontal material rights for consumers. Despite proposed amendments by the European Parliament, the term is not featured within the final text of the R2RD.
[71] The contribution does not represent an all-encompassing study of all relevant provisions to that may influence the right to repair *sensu lato* in the EU. Instead, it takes focussed approach, limited to the three selected instruments on the one hand, and, within those instruments, to specific provisions affecting independent players on the other hand.
[72] See footnote 21 before.
[73] Recital 5 R2RD states that it pursues the objective of more sustainable product design at the production phase.
[74] Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC (2019) OJ L136/28 (Sale of Goods Directive or SGD).

for repair compared to replacement. Second, *outside* the legal warranty period with the creation of an obligation to repair on the part of the manufacturer.

The R2RD also introduces information requirements. It establishes a standardised European Repair Information Form (ERIF) that is accessible to consumers via a European online repair platform. Use of the ERIF and the access to the platform are voluntary.[75] Manufacturers must be transparent about the extended warranty period for repair as a remedy under the SGD and on their obligation to repair beyond the legal warranty period. Given its scope, this contribution focuses on the newly introduced repair obligation for manufacturers.

In terms of its personal scope, the repair obligation only applies to the manufacturer of the products.[76] Art 2(5) R2RD[77] defines a 'manufacturer' as a natural person or legal entity that 'manufactures a product or that has a product designed or manufactured, and markets that product under their name or trademark'. For non-EU manufacturers, the obligation falls upon one of the economic operators described in the form of a cascade structure: the authorised representative, the importer, the distributor.[78] While Art 5(1) R2RD accepts that the obligation is outsourced, the manufacturer is still responsible for complying with the associated duty to inform. Member states must transpose the R2RD by 31 July 2026.[79]

There are a number of ways in which the repair obligation in the R2RD is further limited. Art 1(2) R2RD stipulates a first material limitation in that the provisions of the R2RD only apply to consumer goods.[80] In addition, Art 5(1) and recital 21 R2RD further specify that the repair obligation *only* applies to goods that are subject to repairability requirements under specific EU legislation.[81] This is an important practical limitation with regard to its effective application. Of course, this also means that the material scope is bound to evolve in a significant manner over time, when more and more products will be dictated by ecodesign requirements. The appropriateness of such a rule lies within the acceptance

[75] The communication of the ERIF was initially drafted as an obligation for the manufacturer upon request by a consumer. The European Parliament introduced the optional nature in European Parliament, 'Amendments adopted on 21 November 2023 to the proposal for a directive of the European Parliament and of the Council on common rules for facilitating the repair of goods and amending Regulation (EU) 2017/2394 and Directives (EU) 2019/771 and (EU) 2020/1828' (2024) C/2024/4233 OJ C Amendments 6 and 34.
[76] It also applies to micro, small and medium-sized enterprises, see R2RD, Art 10.
[77] *Juncto* ESPR, Art 2(42).
[78] R2RD, Art 5(3).
[79] R2RD, Art 21 and 22.
[80] R2RD, Art 1(2).
[81] Included in Annex II R2RD. R2RD, recital 8. For example, requirements included in the ESPR discussed below; requirements included in Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (recast) (2009) OJ L 285/10; Regulation 2009/125/EC of the European Parliament and of the Council of 12 July 2023 on batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (2023) OJ L 191/1.

that these products are already repairable *by design*, in application of EU or national requirements.[82]

This obligation is intended to complement the limited scope of the SDG.[83] The revised SDG also includes a repair obligation as a remedy of choice for the consumer. However, the choice only applies with regard to the seller to mediate a lack of conformity becoming apparent within three years.[84] The separate repair obligation therefore encourages consumers to get their defective products repaired, even *after* the liability period and for defects that do not constitute a 'lack of conformity'.[85] It operates outside the legal framework set up by the SGD, and only shifts to an obligation to offer a refurbished good when repair is impossible.[86]

The interaction between the R2RD and the ESPR extends beyond the material scope of the repair obligation. Indeed, the provisions of the ESPR[87] also affect the repair and maintenance aftermarket, complementing provisions in the R2RD to a certain extent. For example, the ESPR obliges manufacturers to provide access to spare parts and repair-related information and/or tools, also to what recital 18 R2RD refers to as 'other' repairers.[88] While the initial amendment in the IMCO report spoke of 'independent repairers', we no longer see this term in the final, published R2RD.[89] However, we can infer that this alludes to independent repairers as recital 18 refers to ecodesign obligations under the ESPR, that *are* aimed at enhancing access for independent repairers.

Art 5(4) R2RD, in addition, requires that spare parts and repair-related information and/or tools are offered at a reasonable price. It further prohibits the manufacturer to prevent independent repairers from supplying original, second-hand, compatible or 3D-printed spare parts.[90] Art 5(6)-(7) also prevents the manufacturer from using contractual provisions, hardware or software techniques that impede upon repair, and from refusing repair because of an intervention by an independent repairer.

Importantly, recital 18 *juncto* Art 5(6) present IP rights as legitimate and objective justifications to discard the prohibitions imposed by the R2RD and referred to in the paragraph above.[91] Consequently, rightsholders are still entitled to use TPMs[92] to shield

[82] European Commission, SWD Impact Assessment Accompanying the document Proposal for a Directive of the European Parliament and of the Council on common rules promoting the repair of goods and amending Regulation (EU) 2017/2394, Directives (EU) 2019/771 and (EU) 2020/1828 2023 [SWD(2023) 59 final] 34.
[83] In its version amended by the R2RD.
[84] Taking account of the extended liability period for the seller under R2RD, Art 16(2). The lack of conformity must exist at the time of delivery, see SGD, Art 10(2).
[85] R2RD, recital 15.
[86] R2RD, Art 5(2)(d).
[87] Drafted to intervene of the product design stage.
[88] See also R2RD, recital 18.
[89] European Parliament 'Amendments adopted by the European Parliament on 21 November 2023 on the proposal for a directive of the European Parliament and of the Council on common rules promoting the repair of goods and amending Regulation (EU) 2017/2394, Directives (EU) 2019/771 and (EU) 2020/1828 (COM(2023)0155 – C9-0117/2023 2023/0083(COD)' (2023) P9_TA(2023)0400, Amendment 11.
[90] Note that this does not apply to repair-related tools or instruments.
[91] R2RD, recital 18 and Art 5(6).
[92] As discussed before.

copyright-protected software. Despite their obligation to foresee in the availability of repair information and hardware, they can charge higher prices whenever IP protection would be involved. This hurts the effectiveness of a right to repair, as the price of spare parts is identified as one of the main barriers for repair. In addition, it is possible that only a small part of a spare part or tool is covered by IP rights. The carve-out represents an important limitation, as manufacturers generally use the protection of *quasi*-IP[93] and safety concerns to justify denying access to spare parts or repair information.[94]

3.3 The Ecodesign for sustainable products Regulation

As previously mentioned, the ESPR is designed to be implemented at the production stage. The objective of the ESPR is to enhance certain product aspects, including repairability[95], with the aim reducing premature obsolescence. The ESPR replaces the Ecodesign Directive.[96] It operates as a horizontal framework, based on which secondary legislation can formulate specific requirements for certain product categories.[97]

Due to its horizontal character, the ESPR applies to all products – with the exclusion of some specific product categories. This is in contrast with its predecessor, the Ecodesign Directive, which only applied to energy-related products.[98] More specifically, the ESPR covers "any physical goods that are placed on the market or put into service, including components and intermediate products".[99] This allows the Commission to take measures with regard to a wide range of products.[100] Recital 13 clarifies that the ESPR also covers digital content that is an integral part of a physical product.[101] Specific product groups are excluded from the outset. This is due to the fact that ecodesign requirements are already set by different legislative frameworks or because they are subject to specific market approval requirements.[102] Excluded product groups include *inter alia* food and feed products, (veterinary) medicinal products, and vehicles to the extent that product aspects are not already covered by existing legislative acts.

[93] Including IP and TS protection.
[94] Aaron Perzanowski, *The Right to Repair: Reclaiming the Things We Own* (1st edn, Cambridge University Press 2022) 110-166.
[95] Other product characteristics are: durability, reliability, repairability, upgradability, reusability and recyclability. See ESPR, recitals 6, 16, 23 and Art 5(1).
[96] Directive No 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (recast) (2009) OJ L285/10 (Ecodesign Directive).
[97] The Commission further explicitly recognises that the development of ecodesign requirements on the repairability of consumer products serves to extent the 'right to repair' under the R2RD, see Communication from the Commission - Ecodesign for Sustainable Products and Energy Labelling Working Plan 2025-2030 2025 (2025) COM(2025) 187 final 1.
[98] ESPR, Art 79 and Ecodesign Directive, Art 1(1).
[99] ESPR, Art 1(2). There are some exclusions for *inter alia*, food, plants, etc. under ESPR, Art 1(2)(a)-(h).
[100] ESPR, recital 13.
[101] There no further referral to digital content in the definition of a product in ESPR, Art 2(1), which only refers to physical goods. As Christopher and others point out, it may have been more desirable for legal certainty to further include this reference in the articles of the ESPR themselves, certainly because of the role that software plays with regard to the various product parameters envisioned by the ESPR (Christopher Borucki and others, 'Lifespan Extension of Products - European & National Initiatives' (2024) 31 CE Center publication 20).
[102] ESPR, recital 13.

Second-hand products are excluded from the scope of the ESPR as long as they cannot qualify as 'remanufactured' products.[103] As Christopher Borucki and others have observed, Art. 2(1)(38)-(39) ESPR refer only to products being 'placed on the market'[104] or 'put into service'[105],[106]. Second-hand products imported in the EU are placed on the market outside the EU and thus excluded. A similar consideration applies for products manufactured in the EU but intended for export.[107]

The ESPR further expands the list of product aspects for which the Commission can set requirements, no longer being limited to the improvement of energy efficiency as was the case under the Ecodesign Directive.[108] Repairability is included within this aforementioned list of product aspects.

The ESPR also has a broad personal scope, determining obligations[109] for all economic operators in a product's supply chain.[110] The role of online marketplaces and online search engines is also envisioned, as they are required to cooperate with market surveillance authorities to facilitate the removal of non-compliant products from their platforms.[111] In contrast to the R2RD, the ESPR's personal scope extends beyond the B2C sphere, with the exception of the requirements on product destruction, which only target consumer goods.[112] The inclusion of B2B interactions is also evident from the terminology, which refers to 'customers'[113] and 'end-users'[114] as opposed to 'consumers'. The introduction of Digital Products Passports (DPPs) is further intended to benefit multiple, targeted market

[103] ESPR, recital 17.
[104] Defined as 'any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge'.
[105] Defined as a product's 'first use, for its intended purpose, in the Union'. See ESPR, Art 2(1)(41).
[106] ESPR, Art 1(2).
[107] For a more extensive discussion on the exclusion of second-hand products and whether or not this is desirable, see Christopher Borucki and others, 'Lifespan Extension of Products - European & National Initiatives' (2024) 31 CE Center publication 25-28.
[108] See footnote 96 above.
[109] For example but not limited to: ecodesign requirements set by delegated acts (Art 4), obligations and restrictions regarding the destruction of unsold consumer goods (Chapter VI), other obligations under Chapter VII including for example, the prohibition to engage in behaviour that undermines the compliance of products the ESPR (Art 40), monitoring and recording obligations (Art 37), information obligations (Art 36) and labelling obligations (Art 32).
[110] Requirements can apply to manufacturers (or its authorised representative), importers, distributors, traders or service providers. For the definition of these concepts, see ESPR Art 2(1).
[111] ESPR, recital 70-72 and Art 35(2). These apply without prejudice to existing obligations under the Digital Services Act, see ESPR, Art 35(1).
[112] Included in Annex VII (which at the time of writing only mentions clothing and footwear).
[113] Defined as 'a natural or legal person that purchases, hires or receives a product for their own use whether or not acting for purposes which are outside their trade, business, craft or profession' (emphasis added) (ESPR, Art 2(1)(35)).
[114] Defined as 'any natural or legal person residing or established in the Union, to whom a product has been made available either as a consumer outside of any trade, business, craft or profession or as a professional end user in the course of its industrial or professional activities' (emphasis added) (ESPR, Art 2(10), read in conjunction with Art 3(21) Regulation (EU) 2019/1020).

participants in the broad sense, including independent operators.[115] The definition of independent operators is broader than that of an 'ordinary' economic operator.[116]

Art 1(1) ESPR identifies four subject-matters, including (1) the establishment of a framework for the setting of ecodesign requirements and the creation of obligations for market participants; (2) the creation of DPPs; (3) the setting of mandatory green public procurement requirements and (4) the creation of a framework to prevent the destruction of unsold consumer goods. Because of its focus on the right to repair, the present contribution mainly focusses on the first two points.[117]

As previously mentioned, the ESPR establishes the horizontal framework within which the Commission is allowed to set Ecodesign requirements in delegated acts. Ecodesign requirements must aim to improve certain product aspects, including repairability. To that end, the Commission is obliged to take product parameters established in Annex I as a basis. Ecodesign requirements can either take the form of specific performance requirements, or information requirements on specific product aspects. The product parameters for repair and maintenance include aspects on which IP rights can have an important impact. These comprise, for example, the conditions for access to product data[118] and the conditions for access to or use of the necessary hardware and software.[119] In accordance with the 2025-2030 working plan of the Commission, the establishment of horizontal repairability requirements is scheduled prior to 2027.[120] Horizontal ecodesign requirements apply to a wider range of product groups with technical similarities. They can be further supplemented by specific ecodesign requirements on specific product groups.[121]

The Commission can set minimum or maximum standards for performance requirements relevant to repairability[122] or recourse to non-quantitative performance requirements.[123] These can include the obligation for the manufacturer to ensure the availability of a

[115] ESPR, Art 11. These include *independent* operators, defined in the broad sense as 'a natural or legal person that is independent of the manufacturer and is directly or indirectly involved in the refurbishment, repair, maintenance or repurposing of a product, and includes waste management operators, refurbishers, repairers, manufacturers or distributors of repair equipment, tools or spare parts, as well as publishers of technical information, operators offering inspection and testing services and operators offering training for installers, manufacturers and repairers of equipment' (ESPR, Art 2(1)(47)).
[116] Defined in the ESPR as 'manufacturer, the authorised representative, the importer, the distributor, the dealer and the fulfilment service provider' (ESPR, Art 2(1)(46)).
[117] Point (4) will be touched upon as well, because of the provision's explicit reference to IP rights.
[118] Access to data is discussed within the section on the Data Act, see section 3.4 below.
[119] ESPR, Annex I (b).
[120] Communication from the Commission - Ecodesign for Sustainable Products and Energy Labelling Working Plan 2025-2030 2025 (2025) COM(2025) 187 final 6.
[121] ESPR, recital 15 and Art 5(7).
[122] For example, the limitation of a certain material incorporated in the products.
[123] ESPR, Art 6(2).

certain quantity of spare parts to independent repairers[124] or the prohibition of a specific technical solution that is detrimental to product repairability.[125]

Information requirements may encompass repair and maintenance information, in addition to information on the price and availability of spare parts.[126] It can also relate to information on 'how to install, use, maintain and repair the product, in order to minimise its impact on the environment and to ensure optimum durability, on how to install third-party operating systems where relevant, as well as on collection for refurbishment or remanufacture'.[127]

The newly introduced DPP is also intended to encourage competition within the repair and maintenance market. The ESPR presents a DPP as one of the information requirements that can be imposed by the Commission on manufacturers, to be made available to independent operators[128] as well. Art 9(1) ESPR appears to suggest that the provision of a DPP should be *mandatory* within delegated acts.[129] In practice, the DPP is thus a prerequisite for market entry under future delegated acts[130], with the aim of collecting and facilitating access to relevant information for different players.[131] It is further intended to feature as an important governance tool for competent authorities.[132]

The objective of the ESPR is to advance the availability of spare parts and other repair information, also for independent repairers. As IP rights further influence this availability, the question of interaction between the access provisions of the ESPR and the EU's IP framework bear a particular importance. The ESPR does refer to IP rights however only to a limited extent. These references include (*I.*) the differentiated 'access' regime to information requirements, (*II.*) the proliferation of IP rights as an exception to the prohibition of unsold consumer goods; and (*III.*) the referral to conditions for access to or use of technologies protected by IP rights as a factor influencing the product parameter

[124] *See f.e.* Ecodesign requirements of refrigerator appliances under Commission Regulation (EU) 2019/2019 of 1 October 2019 laying down ecodesign requirements for refrigerating appliances pursuant to Directive 2009/125/EC of the European Parliament and of the Council and repealing Commission Regulation (EC) No 643/2009 (2019) OJ L315/187.
[125] ESPR, recital 24 and Art 5(7).
[126] ESPR, recital 30 and Art 7(2)(i).
[127] ESPR, Art 7(2)(ii).
[128] For the definition of independent operators, see footnote 116.
[129] ESPR, Art 9(1) states the following: "The information requirements shall provide that products can only be placed on the market or put into service if a digital product passport is available in accordance with the applicable delegated acts adopted pursuant to Article 4 and with Articles 10 and 11. The data in the digital product passport shall be accurate, complete and up to date." (emphasis added) Note that the Commission may also exempt certain product groups from the requirement to have a DPP when (1) technical specifications of the digital product passport are not available in relation to the essential requirements included in Articles 10 and 11 or (2) other Union law includes a system for the digital provision of information related to a product group which the Commission considers achieves the objectives (…) [of access to product information that is relevant for them and of facilitating the verification of product compliance by national authorities]" (ESPR, Art 9(4)). See also Christopher Borucki and others, 'Lifespan Extension of Products - European & National Initiatives' (2024) 31 CE Center publication 42-43.
[130] Note however that a DPP can also be installed as a measure of self-regulation.
[131] ESPR, recital 26 *juncto* Art 7(1) and Art 8(1).
[132] ESPR, recitals 32 and 74 and European Commission, 'Part 4/4 - Commission Staff Working Document (Impact Assessment) Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council Establishing a Framework for Setting Ecodesign Requirements for Sustainable Products and Repealing Directive 2009/125/EC' (Hart Publishing Ltd 2022) 616.

for 'ease of upgrading, reuse, remanufacturing and refurbishment'.[133] Furthermore, it is clear that certain statutory obligations requiring access towards market participants may conflict with IP rights, even when this is not specifically addressed within the ESPR in itself (*IV.*).

I. The ESPR introduces the concept of a differentiated access to the DPP as opposed to an 'open access' approach, which was also considered by the Commission.[134] Consequently, delegated acts will define access rights in relation to specific independent market participants, users, and authorities. Each of these participants will only be granted access to certain parts of the DPP, in accordance with their rights. IP rights are presented as at least one of the reasons for introducing such access limitation.[135] While recital 33 ESPR focusses on IP rights, preparatory documents refer to the 'confidentiality' of such information as the main reason for access on a need-to-know basis.[136] Confidentiality however typically refers to TS rather than IP rights. From a theoretical perspective, TSs are more relevant obstacles in the context of DPPs as IP rights generally already require some kind of publicity.[137] From a practical viewpoint, for DPPs, one can take inspiration from the EU Battery Regulation[138] that entered into force in August 2023. The EU Battery Regulation requires batteries to have a DPP by February 2027. Within the context of the DigitalEU funded CIRPASS project in 2021, the loss of confidentiality was identified as one of the main barriers (risks) of the DPP.[139] Again, at one instance, the report

[133] ESPR, Annex I(c).
[134] European Commission, 'Part 4/4 - Commission Staff Working Document (Impact Assessment) Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council Establishing a Framework for Setting Ecodesign Requirements for Sustainable Products and Repealing Directive 2009/125/EC' 616-619.
[135] ESPR, recital 33 states the following "(…) To optimise access to the resulting data while also protecting intellectual property rights, the digital product passport needs to be designed and implemented in a manner that allows differentiated access to the data in the digital product passport depending on the type of data and the typology of stakeholders." It is notable that the ESPR makes no mention of trade secrets in this context, as IP rights do not in principle apply to *information*, only to the concrete representation of such information (see section 2.3 above). Confusingly, the SWD supporting the proposal does not make any mention to IP rights in the context of the discussion of the different types of access regimes for DPPs, but does refer to 'confidentiality'.
[136] EUROPEAN COMMISSION, 'Part 4/4 - Commission Staff Working Document (Impact Assessment) Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council Establishing a Framework for Setting Ecodesign Requirements for Sustainable Products and Repealing Directive 2009/125/EC' (Hart Publishing Ltd 2022) 602–603. The SWD states the following: "The information contained in an EU DPP could be potentially very comprehensive for the sake of maintenance, repair or re-manufacturing – but also therefore confidential, at least during the period of time when the company is actively supporting the product. For this reason, the European digital product passport should enable access to information on a "need-to-know" basis (…)" (emphasis added).
[137] For registered rights, this is done with the requirement of registration. For certain types of IPRs, this is further underwritten within validity conditions such as the disclosure requirement in patent law. For non-registered rights, such as copyright protection in the EU, the requirement of publicity can be derived from the condition of concrete form and the fact that protection only adheres to that specific expression of an idea to the general public. For copyright, this statement must, however be nuanced as the author has a moral right to decide when to release its work to the general public (the moral right of 'disclosure').
[138] Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC OJ L191/1 ("EU Battery Regulation").
[139] Thibaut Wautelet and Anne-Christine Ayed, 'Exploring Possible Digital Product Passport (DPP) Use Cases in Battery, Electronics and Textile Value Chains' 35–36 <https://zenodo.org/doi/10.5281/zenodo.10974901> accessed 27 May 2025.

referred to 'confidential information'[140] while at other instances it refers to the 'risk of intellectual property loss'.[141]

II. The ESPR further *allows* the Commission to make derogations to the prohibition of the destruction of unsold consumer goods where these products have become 'unsaleable' due to an infringement of IP rights. The exception refers to statutory penalties provided in IP legislation, which allow destruction of infringing goods as a corrective measure, available for the rightsholder next to the standard remedy of obtaining an injunction against illegitimate acts. Further supported by Art 46 of the World Trade Organisation agreement on Trade-Related aspects of Intellectual Property Rights, corrective measures include a possibility for rightsholders to request a recall and/or permanent removal from the market and/or the destruction of infringing products.[142] In appropriate cases, this sanction may even extend to the 'materials and implements principally used in the creation or manufacture of these goods'.[143] The possibility to claim destruction of infringing products as a corrective measure has been criticised in legal doctrine for its negative impact on environmental sustainability, and several authors argue that the enforcement of IP rights should become more sustainable.[144] The inclusion however supports legal certainty, as judges would still have the possibility to order the sanction of destruction when claimed by an IP rightsholder, for infringing products that would also be covered by the scope of a delegated act under Art 25 ESPR. However, the optional nature of the limitation may still allow judges to use their discretionary power to further refuse a claim for destruction by the rightsholder.[145]

III. Annex I, point C refers to 'conditions for access to or use of technologies protected by intellectual property rights' as a product parameter that influences the 'ease of upgrading, reuse, remanufacturing and refurbishment'. IP rights are not explicitly referred to in relation to the product aspect 'ease of repair'. However, a number of product parameters relating to the ease of repair are further also affected by IP rights. This will be discussed further in point IV. below.

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[140] ibid 36.
[141] ibid 82.
[142] Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (2004) OJ L157/45 (Enforcement Directive), recital 24 and Art 10.
[143] ibid.
[144] See Charlotte JS Vrendenbarg, 'Towards a Judicial Sustainability Test in Cases Concerning the Enforcement of Intellectual Property Rights' (2023) 72 GRUR International 1125; Jozefien Vanherpe and Manon Vanderhaeghe, 'Ecologisch verantwoorde handhaving in de Belgische IE-praktijk: nog groen achter de oren?' (LeA uitgevers) (forthcoming).
[145] Enforcement Directive, Art 10(1)(3) stipulates that corrective measures are optional in nature (the court must take 'appropriate measures'). It requires courts to consider the proportionality between the 'seriousness of the infringement and the remedies ordered as well as the interests of third parties (…)' (emphasis added). For a more extensive discussion on the extent of the discretionary power given to judges, see Charlotte JS Vrendenbarg, 'Towards a Judicial Sustainability Test in Cases Concerning the Enforcement of Intellectual Property Rights' (2023) 72 GRUR International 1125; Jozefien Vanherpe en Manon Vanderhaeghe, 'Ecologisch verantwoorde handhaving in de Belgische IE-praktijk: nog groen achter de oren?' (LeA uitgevers) (forthcoming).

IV. This contribution already demonstrated that the IP rightsholder can influence legal and material access to repair commodities for independent repairers. Such restrictions are also included in certain product parameters for repairability under Annex I ESPR.[146] We have to await specific delegated acts to further assess the interaction between ecodesign requirements on repairability parameters to be able to see how IP rights would be addressed. That said, it seems possible - at least in theory - that repair requirements in delegated acts can lead to a friction between *on the one hand* an obligation for the manufacturer[147] to provide access to essential repair commodities[148] and on *the other hand* its IP right to decide to whom and under what conditions it grants an authorisation to 'use'[149] that commodity. For information requirements, it remains to been seen how the Commission will elaborate the requirement of 'differentiated access' in its delegated acts.

3.4 The Data Act

Today, a significant proportion of products are equipped with devices capable of measuring and generating data. Combined with specific (analytical) tools such as software, that data can give information on the performance and use of the product or its environment. This, in turn, facilitates repair and maintenance. In addition, access to certain types of data such as real-time data, data on performance monitoring, self-diagnosis, etc. is often necessary or at least valuable for repair purposes. In the absence of legislative intervention, manufacturers have a *de facto* control over such information, as they have the final say in deciding whether or not to allow the user and/or third parties access to such data. Importantly, this *de facto* control over the data must be distinguished from a form of *de jure* control on the data's availability[150] or accessibility.[151] Specifically for the repair and maintenance market, shielding such information from independent players may be appealing, as manufacturers often operate on that market as well. After all, the repair and maintenance market is valuable, certainly for complex products.[152] In

[146] For example, ESPR Annex I (b). While IP rights influence the characteristics of this product parameter, and therefore the 'ease of repair' as a parameter in itself, IP rights are not explicitly referred to within the provision itself. That said, 'conditions for access to or use of technologies protected by intellectual property rights' do feature as an influencing factor for the product parameter 'ease of upgrading, reuse remanufacturing and refurbishment' under ESPR, Annex I (c).
[147] Often the IP rightsholder.
[148] Whether or not under certain conditions.
[149] In the IP sense of the word, including infringing acts covered by the IP right only, see section 2.
[150] Which is also influenced by TS protection however, this is out of scope.
[151] Interpreted by this contribution in the sense of 'usability', covering all the acts that are reserved to the IP holder.
[152] See f.e. for automotive aftermarket: Friso Bostoen, Liesbet Van Acker and Wouter Devroe, 'Servitization and Competition Law' in Bert Keirsbilck and others (eds), *Servitization and Circular Economy: Economic and Legal Challenges* (Intersentia 2023) 69-92; European Commission. DG for Communications Networks, Content and Technology, 'Study to Support an Impact Assessment on Enhancing the Use of Data in Europe.' (Publications Office 2022) <https://digital-strategy.ec.europa.eu/en/library/impact-assessment-report-and-support-studies-accompanying-proposal-data-act> accessed 27 May 2025 181, stating that f.e. automotive aftermarkets represent an important business impact as aftersales generate 20% of revenue and approx. 50% of profits for manufacturers.

addition, repair diminishes the need for consumption, which can be detrimental for manufacturers' revenue.[153]

The present contribution focuses of the Data Act as the instrument within this horizontal data sharing framework that is most relevant to the repair and maintenance aftermarket. It concentrates on one aspect of the Data Act, namely the creation of a right to access and corresponding obligation to share data from connected products. The statutory rights under Chapter II Data Act benefit to the user and independent repairers of their choice. They can thus be qualified as components of the right to repair *sensu lato* applying to connected products specifically.[154]

This link with the repair and maintenance market is recognised in the Data Act itself. Chapter II of the Data Act lists as one of its objectives to enable users of connected products to gain access to specific after-market services such as maintenance and repair. These services are often dependent upon access to data from connected products.[155] The objective is closely linked with the Data Act's broader aim of giving users of connected products a renewed *control* over the data generated by such products.[156] This control encompasses not only effective *access* to the data[157], but also the ability to *transfer* it to third parties of their choice.[158] This is based on the idea that both the manufacturer[159] of the connected product and the user are co-generators of data from connected products.[160]

Broadly speaking, Chapter II sets out three steps as to determine the scope of the rights on data from connected products. First, Art 3 creates a *statutory obligation* for manufacturers of connected products and providers of related services to make 'product data and related service data' accessible to users.[161] Products and services must be designed in such a way as to allow this access. This requirement therefore serves as a horizontal product design requirement aimed at data generation. Specific, sectoral

[153] Francisco López Bermúdez and Xavier Vence, 'The European Directive on Common Rules Promoting the Repair of Goods. A Critical Assessment of Its Drafting Process' [2024] Revista Galega de Economía 1, 3.
[154] The other chapters of the Data Act, which set out the rules for Business to Government (B2G) data sharing, and create obligations for providers in respect of Cloud and Edge services, are beyond the scope of this contribution. The provisions of Chapters III (creating obligations for data holders obliged to make data available under Union law) and IV (defining unfair contractual terms in relation to access and use of data in a B2B context) of the Data Act are also relevant to the right to repair *sensu lato*, but will not be further addressed.
[155] Data Act, recital 6.
[156] Charlotte Ducuing, 'Data Governance for the Ecological Transition: An Infrastructure Perspective' [2024] Review of European, Comparative & International Environmental Law 5. Josef Drexl and others, 'Position Statement of the Max Planck Institute for Innovation and Competition of 25 May 2022 on the Commission's Proposal of 23 February 2022 for a Regulation on Harmonised Rules on Fair Access to and Use of Data (Data Act)' [2022] SSRN Electronic Journal para 24.
[157] Data Act, Art 3 and 4.
[158] Data Act, Art 5.
[159] Identified as the 'data holder' under the Data Act.
[160] Data Act, recital 6. EUROPEAN COMMISSION, 'Commission Staff Working Document - Impact Assessment Report: Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on Harmonised Rules on Fair Access to and Use of Data (Data Act)' (Hart Publishing Ltd 2022) SWD(2022) 34 final 29; European Commission. Directorate General for Communications Networks, Content and Technology. and others, 'Study to Support an Impact Assessment on Enhancing the Use of Data in Europe.' (Publications Office 2022) <https://digital-strategy.ec.europa.eu/en/library/impact-assessment-report-and-support-studies-accompanying-proposal-data-act> accessed 27 May 2025 176-196.
[161] Data Act, Art 3.

product design requirements can be added.[162] Second, where such data access is not guaranteed, Art 4 establishes a second *statutory obligation* for data holders[163] to make 'readily available' data[164] available. This corresponds to a *right* for users to request and obtain *access* to such data. Third, Art 5 establishes the *right* of users to *share* IoT data with third parties of their choice. The request can be addressed to the data holder by the user or by another party acting on their behalf, such as a data intermediation service under the DGA.[165]

The aforementioned rights and obligations are subject to legal restrictions regarding the use of the IoT by data holders and/or data recipients.[166] For example, third party recipients are prohibited from developing a product that competes with the connected product generating the connected product data.[167] They are also not permitted to share connected product data with other parties.[168] The data holder has a right to request corrective action, including a claim for the destruction of competing products.[169]

The Data Act has a broad personal scope. The provisions of Chapter II of the Data Act benefit users of connected products placed on the EU market.[170] 'Users of connected products' are broadly defined and include the owner of the connected product or anyone with temporary rights on its use.[171] The scope exceeds the personal scope of the repair obligation under the R2RD, as it also addresses professional users.[172] Obligations fall upon both manufacturers of connected products[173] and holders of connected product data.[174] In practice, these two categories often overlap, as they are often also the holders of IP rights and trade secrets on the products or connected product data.[175] Connected product data from micro or small enterprises are excluded from Chapter II obligations.[176] Although such formulation focusses on the data rather than the enterprises, it is a limitation of the personal rather than the material scope. Indeed, it is solely because of the involvement of micro and small enterprises that the limitation applies.[177]

In terms of its material scope, Chapter II applies to 'data, with the exception of content, concerning the performance, use and environment of connected products and

[162] Such as Ecodesign requirements under the ESPR, see section 3.3 above.
[163] In practice however, data holders are often also the manufacturers of connected products.
[164] Along with the metadata necessary to interpret this data. See Data Act, Art 4 and the discussion below.
[165] Data Act, recital 26; DGA, Art 2(11).
[166] I.e. Data user of third parties receiving the IoT data as a result of a data sharing request by the user.
[167] Data Act, Art 6(2)(c).
[168] Data Act, Art 6(2)(d).
[169] Data Act, recital 57 and Art 11(2)(b).
[170] Data Act, Art 1(3)(a) and Art 1(3)(b).
[171] F.e. in application of a leasing or rental agreement. Data Act, Art 2(12).
[172] Note that data sharing and access rules also apply when there are multiple users.
[173] For the statutory obligations under Article 3 Data Act.
[174] For the statutory obligations under Article 4 and 5 Data Act.
[175] Charlotte Ducuing and others, 'White Paper on the Data Act Proposal' [2022] SSRN Electronic Journal 95.
[176] Data Act, Art 7.
[177] This limitation however does not apply when the micro or small enterprise has a non-micro or small partner or linked enterprise and the when the micro- small enterprise is subcontracted to manufacture of design a connected product or to provide a related service. See Data Act, Art 7(1).

related services'.[178] This material scope is again important for the repair and maintenance market, as a limited scope may result in lesser opportunities for (independent) repair and thus for a weaker component of the right to repair *sensu lato*. In order to understand this effective scope, one needs to consider first what is meant by 'product data' of a 'connected product' and 'data relating to a 'related service'.[179] Art 2(15) Data Act defines product data 'data generated by the use of a connected product that the manufacturer designed to be retrievable, via an electronic communications service, physical connection or on-device access, by a user, data holder or a third party, including, where relevant, the manufacturer'. The term covers both data 'recorded intentionally' and 'data which result indirectly from the user's action'.[180] The focus explicitly lies on data *generated* by the product.[181]

However, Recital 15[182] specifies that 'inferred or derived data which is the outcome of additional investments into assigning values or insights from the data' are not included in the scope of Chapter, particularly with regard to the data holder's obligations. The wording leaves a doubt as to whether this limitation applies to all types of derived or inferred data, or only information resulting from additional investments. The purpose of the limitation indicates a willingness of the legislator not to intervene with IP protection on algorithms or software.[183] The wording is quite remarkable, as copyright protection to software does not extent automatically to the data generated by this software, which this sentence does suggest.[184]

Due to this vagueness, the exclusion is criticised in legal doctrine. For example, Joseph Drexl and others argue that such derived and inferred data is necessary in order to carry out repair and maintenance services.[185] By way of illustration, they use the example of sensors that measure a product's temperature.[186] While these data types give information

[178] Data Act, Art 1(2)(a).
[179] The contribution will not develop upon the data types that are excluded from the Data Act's scope, as these are not generally relevant for repair and maintenance purposes. Such excluded data types are f.e. data stemming from prototypes and content such as films, music, etc. generated by the connected product.
[180] Data Act, recital 15. This also includes data from virtual assistants (Data Act, recital 32 and Art 1(4)).
[181] This is also clear form the definition of a 'connected product' as 'an item that obtains, generates or collects data concerning its use or environment and that is able to communicate product data via an electronic communications service, physical connection or on-device access, and whose primary function is not the storing, processing or transmission of data on behalf of any party other than the user' (Data Act, Art 2(5)). The idea conforms with the proposal of the Commission. See Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act) 2022 (COM(2022) 68 final) Art 3(1).
[182] The limitation is not further included in the Articles of the Data Act.
[183] Data Act, recital 15 stats: "By contrast, information inferred or derived from such data, which is the outcome of additional investments into assigning values or insights from the data, in particular by means of proprietary, complex algorithms, including those that are a part of proprietary software, should not be considered to fall within the scope of this Regulation and consequently should not be subject to the obligation of a data holder to make it available to a user or a data recipient, unless otherwise agreed between the user and the data holder." (emphasis added).
[184] See Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (Codified version) (2009) OJ L111/16 Art 5 (Software Directive).
[185] The opinion statement was based on the proposal of the Commission, but these provisions did not change in substance, as derived and inferred data are still excluded from the scope. Hence, their considerations are still relevant.
[186] These data types can be qualified as 'source' or 'pre-processed data' under the Data Act.

on the temperature, they do not state whether or not the product is overheated. For this, additional information is necessary, such as a range of temperatures that would problematic and thus, in which repair or maintenance is desirable.[187]

With 'data of a related' service, the Data Act essentially refers to software embedded within or connected with the connected product.[188] Data generated by such software application shall also fall within the scope of Chapter II Data Act.

As established in the previous paragraphs, the data access and transfer rights under chapter II Data Act provide for one of the components of the right to repair *sensu lato*, specifically applied to connected products. Importantly, derived or inferred data fall outside the data act's scope. As such data may give valuable information (independent) repairers, this exclusion necessarily hurts the effectiveness of the right to repair. This is aggravated by the legal uncertainty brought upon by the inclusion of different data types.

Another uncertainty is the impact that IP and trade secret rights will have on data access and transfer rights for repair and maintenance purposes. The EU legislator has made clear that it does not intend to touch upon IP rights. This intention is reflected in a number of provisions. Most notably, Art 1(8) Data Act explicitly states that the Data Act is 'without prejudice to Union and national legal acts providing for the protection of intellectual property rights. It is further included in Article 49(1)(e) Data Act, which obliges the Commission, during its review, to verify that there is no impact on IP rights. However, this does not preclude domain- or specific legislation from imposing further restrictions on IP rights. For example, the European Health Data Space Regulation[189] does not provide in a similar exception to IP rights for access to electronic health data.[190] In reality, although they fall outside the scope of this contribution, trade secret rights will be more relevant for repair and maintenance information of connected products.

Despite the aim to protect IP rights, the Data Act does contain a specific provision on *sui generis* database rights.[191] This *sui generis* protection regime was created by the

[187] Josef Drexl and others, 'Position Statement of the Max Planck Institute for Innovation and Competition of 25 May 2022 on the Commission's Proposal of 23 February 2022 for a Regulation on Harmonised Rules on Fair Access to and Use of Data (Data Act)' [2022] SSRN Electronic Journal 10-11.
[188] Art 2(6) Data Act defines it as 'a digital service, other than an electronic communications service, including software, which is connected with the product at the time of the purchase, rent or lease in such a way that its absence would prevent the connected product from performing one or more of its functions, or which is subsequently connected to the product by the manufacturer or a third party to add to, update or adapt the functions of the connected product'.
[189] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (2025) OJ L.
[190] Which is a much broader term than 'data on health' under GDPR, Art 3, also including IP protected data.
[191] For an extensive discussion, see Josef Drexl and others, 'Position Statement of the Max Planck Institute for Innovation and Competition of 25 May 2022 on the Commission's Proposal of 23 February 2022 for a Regulation on Harmonised Rules on Fair Access to and Use of Data (Data Act)' [2022] SSRN Electronic Journal 74-79; Charlotte Ducuing and others, 'White Paper on the Data Act Proposal' [2022] SSRN Electronic Journal 111 254-266.

Database Directive[192] in 1996.[193] This IP right favours a database 'maker' who puts in substantial investment in the obtaining, verification or presentation of the contents of a database. It enables the maker to take action against the unauthorised extraction and/or re-utilisation of the whole or a substantial part of its contents, which would necessarily have consequences for data access and use provisions under the Data Act.[194] Art 43 Data Act thus aims to prevent a *sui generis* database rightsholder from invoking these exclusive rights to avoid complying with its data access obligations for data from connected products.

The Commission recognises that the possibility to invoke such rights on *machine-generated data* is contested in EU case law, and that this clarification would therefore improve legal certainty.[195] However, the wording of the provision raises another legal certainty issue relating to its nature. One could argue that it was the aim of the EU legislator to *clarify* the scope of Art 7 Database Directive. This would imply that databases including machine-generated data would not be subject to the *sui generis* database protection at all, even outside the context of the Data Act's data sharing rights for connected products.[196] Nevertheless, the use of the term 'shall not apply' suggests that the limitation to *sui generis* database rights only applies to situations falling under the data access rights and obligations of the Data Act.[197] This is further supported by the last sentence of recital 112 Data Act, that confirms the *sui generis* database rights can still apply to databases containing connected product data falling outside the Data Act's scope.[198]

A second uncertainty relates to the scope of application of the limitation within the Data Act itself. Art 43 Data Act states that the 'limitation' applies *with* respect to the data access and data transfer rights of the user.[199] The wording implies a broader scope,

[192] Directive No 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (1996) OJ L77/20 (Database Directive).
[193] Art 43 of the Database Directive states the following: "The sui generis right provided for in Article 7 of Directive 96/9/EC shall not apply when data is obtained from or generated by a connected product or related service falling within the scope of this Regulation, in particular in relation to Articles 4 and 5 thereof." (emphasis added).
[194] Database Directive, Art 7(1).
[195] EUROPEAN COMMISSION, 'Commission Staff Working Document - Impact Assessment Report: Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on Harmonised Rules on Fair Access to and Use of Data (Data Act)' (Hart Publishing Ltd 2022) SWD(2022) 34 final 133-134, referring to Case BGH I ZR 47/08 *Autobahnmaut* (25 March 2010), in which it was accepted that sensor-generated data of a road-toll system could be protected by *sui generis* database rights.
[196] The specific wording of the SWD suggested such an interpretation, as it stated that: "the risk exists that the current situation of unclarity as to whether machine-generated data are covered by the *sui generis* right could be opportunistically exploited by equipment manufacturers to claim IP protection beyond the intended purpose of the database protection provided for in EU law." (EUROPEAN COMMISSION, 'Commission Staff Working Document - Impact Assessment Report: Accompanying the Document Proposal for a Regulation of the European Parliament and of the Council on Harmonised Rules on Fair Access to and Use of Data (Data Act)' (Hart Publishing Ltd 2022) SWD(2022) 34 final. 133).
[197] To the contrary, Data Act recital 112 states that the provision is aimed at 'clarifying' that the *sui generis* database right does not apply to databases with machine-generated (read: IoT) data.
[198] Provided that these databases comply with the validity conditions under Art 7 Database Directive.
[199] Data Act, Art 4 and Art 5.

also covering other rights/obligations of other chapters in the Data Act, and not only Chapter II Data Act.[200]

Third, the Data Act does not extent the limitation to copyright protection *sensu stricto*, which can also apply to databases[201] and/or to works[202] generated by the connected product. To the contrary, as was stated above, the Data Act explicitly excludes such *content* from its scope.

4 Conclusion

The 'right to repair' aims to enhance (consumer) access to affordable and accessible repair services. While the R2RD marks the first introduction of this concept in EU legislation, it operates in a broader policy framework that seeks to encourage circular operations. This framework[203] delineates a network of rights and corresponding obligations for various parties within a product's value chain. Different laws intervene at different levels. However, they also complement and interact with each other. For example, delegated acts under the ESPR may oblige manufacturers to make spare parts and repair tools available to professional (independent) repairers or to include repair information within a DPP that must also be made available to them. In addition to the information to be included in the DPP, the Data Act further imposes data sharing rights and obligations regarding data from connected products, including for the purposes of repair. To complement these measures, the R2RD adds that such independent repairers should not be prevented from using original, second-hand, and 3D printed spare parts. Also, it adds that these should be offered at a 'reasonable price'.

Each instrument has a different goal, a different scope, and more importantly, a different mechanism to deal with exclusionary control regimes such as IP rights and trade secrets. For example, while the ESPR mentions differentiated access to *information* within the DPP that is protected by IP rights, the R2RD provides for a real carve-out for such types of rights. This divergence is important, as the ESPR may require manufacturers to make a certain quantity of spare parts available for a certain time period, the carve-out in the R2R allows for manufacturers to still do this at high, unreasonable prices whenever the spare part's subject-matter is covered by IP rights. Arguably, this may incentivise a further push to seek out IP protection on such components.[204] The current version of the

[200] *Sui generis* rights are also referred to within the context of B2G data sharing in the Data Act. However, this falls outside the scope of the contribution. Data Act, recital 71.
[201] Provided that they fulfil the condition of originality.
[202] F.e.: photos, videos, etc. that would fulfil the requirements of copyright protection.
[203] Consisting of consumer, product, IP, competition and data governance legislation.
[204] With the caveat that such protection is only possible when the validity conditions for IP protection are fulfilled. This statement is not further supported by any data, as the creation of rights and obligations for the right to repair *sensu lato* has been a relatively recent phenomenon.

right to repair is mainly access-based[205] and not competition-based, where IP rights exert their main influence.

Beyond the new repair clause under EU design law[206] and the clarification on the protection of *sui generis* database rights for access rights on connected product data under the Data Act, the initiatives discussed above do not include solutions to further address specific IP barriers identified in Chapter II above.[207] Further research on how IP rights can accompany the shift to an effective and balanced shift to a 'right to repair' and, more broadly, a well-functioning CE, is thus needed.

[205] Meaning that the EU legislator wants to guarantee that there is access to repair and maintenance services, independently whether this access is given by the manufacturer or authorised repairers, or independent repairers. On the other hand, a competition-based right to repair would further limit obstacles to independent repairers, resulting in a higher consumer choice for repair services.

[206] Although with a limited scope, see section 2.1 above.

[207] The contribution does not further state that such a change is desirable. Taking account of the protection of IP rights (which is also a fundamental right under Art. 17(2) of the Charter of the European Union on fundamental rights), effectively addressing such IP barriers might be disproportionate as to the rights of the IP holders. However, this necessitates further research.

Enrico Pernice[*]

GENERAL SECTION

AI MODEL TRAINING: CONSENT OR LEGITIMATE INTEREST?

GUIDANCE ON CHOOSING THE MOST APPROPRIATE LEGAL BASIS

Abstract

ChatGPT, Gemini, CoPilot are just some among the most talked-about examples of large generative AI models whose functioning relies on algorithms trained by means of large amounts of data. Acknowledging that such data may also include "information relating to an identified or identifiable natural person", AI developers should then address the issue of the compliance of such models with personal data protection legislation. In this regard, this article seeks to identify, from an accountability perspective, the most appropriate legal basis for the collection and processing of personal data for AI training purposes. Specifically, after noting that - except in very limited cases - the choice should narrow between the prior consent of data subjects and a legitimate interest pursued by the controller or a third party, the article will first explore the pitfalls of a consent-only approach which indeed risks making data processing extremely burdensome for controllers. Next, the article will deal with the possibility of recognising and accepting legitimate interest as an appropriate legal basis for the pursuit of algorithm training purposes, through the implementation of sophisticated mitigation measures that can make the use of this basis as safe as possible for data subjects. Finally, assuming that legitimate interest can be used as a legal basis for algorithm training purposes, the article suggests overcoming the separation between the AI model development and deployment stages in order to choose the most appropriate legal basis between consent and legitimate interest.

JEL CLASSIFICATION: K240

SUMMARY

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10.13135/2785-7867/12836

appropriate legal basis for AI model training purposes? - 2.4 Implementing sophisticated mitigation measures: a key condition for making legitimate interest a viable legal basis - 3 Conclusion: development and deployment, two stages of processing with a single common purpose

1 Introduction: data as the main source for training the AI models' algorithms

Artificial intelligence, just like any other form of intelligence, needs to be nurtured, fed, or – more properly – trained.

Building, and especially training, powerful, accurate and high-quality algorithms, *i.e.*, capable of responding correctly to a wide variety of inputs received from the user, requires a large amount of data[1], which indeed constitutes nowadays the fuel – or, as it has been repeatedly stated, "*the new gold*"[2] – necessary for the successful development of AI models. A few examples of such data-driven frameworks can be found, *inter alia*, in the GPT-3 model[3], which was trained using 570 gigabytes of text data, corresponding to about 300 billion words[4], or in the algorithm underlying most image generation AI apps, such as DALL-E, Lensa and Midjourney, which was trained by means of the LIAON-5B dataset, consisting of 5.8 billion image-text pairs[5]. From a purely technical standpoint, the training of an AI model involves the following steps:

I. *data mapping and selection*: at this stage the data is collected and cleaned by taking out information that is irrelevant or may otherwise lead the machine to mistakes (*e.g.*, due to its low quality). The data thus selected are then usually divided into two groups: a training dataset and a test dataset;
II. *model creation*: at a second stage, an AI model capable of adapting to the previously selected data is created – or otherwise chosen, if an existing model is opted for;
III. *model training:* the model is then "trained" using the training dataset. Notably, during this process, the model tries to optimise its parameters to make predictions that are as accurate as possible;
IV. *model evaluation and fine tuning*: after the first training phase, the AI model is tested by means of the test dataset to evaluate its performance. The use of the test dataset allows the model's performance to be evaluated in an "unknown" context, *i.e.*, with data that was not used during the training, thus allowing it to test how well the model

[1] Iman H Sarker, 'Machine Learning: Algorithms, Real-World Applications and Research Directions' (2021) 2 SN Computer Science 160.
[2] Neelie Kroes, 'Data is the New Gold' (Press Conference on Open Data Strategy, Speech/11/872, 2011).
[3] Luciano Floridi and Massimo Chiriatti, 'GPT-3: Its Nature, Scope, Limits, and Consequences' (2020) 30 Minds and Machines 681.
[4] Irene Solaiman and Christy Dennison, 'Process for Adapting Language Models to Society (PALMS) with Values-Targeted Datasets' <https://openai.com/research/improving-language-model-behavior> accessed 30 July 2025.
Brown T B and others, 'Language Models Are Few-Shot Learners' [2020] ArXiv <https://arxiv.org/abs/2005.1416>accessed 30 July 2025.
[5] Beaumont R, 'Laion-5B: A New Era of Open Large-Scale Multi-Modal Datasets' (Large-scale Artificial Intelligence Open Network (LAION), 2022).

is able to implement what it has learned from new data and providing indications on how it might behave in a real-world environment. If performance is not satisfactory, the model can be further trained or adjusted;

V. *model release*: finally, once the AI model has reached an acceptable level of performance, it is definitely rolled out.

It is therefore clear that where algorithms are trained through an insufficient amount of data, they will deliver inaccurate outputs[6]. However, data availability alone is not sufficient: data quality is equally crucial, since low quality data, such as unverified public data or fuzzy photographs – although certainly easier to find and collect – is in fact not suitable for ensuring high-performing AI models[7]. In this sense, the European AI Act[8] itself expressly recognises that "*if the AI system is not trained with high-quality data, [...], it may single out people in a discriminatory or otherwise incorrect or unjust manner*"[9] and "*access to high-quality data plays a vital role in providing structure and in ensuring the performance of many AI systems, especially when techniques involving the training of models are used, with a view to ensure that the high-risk AI system performs as intended and safely and it does not become a source of discrimination prohibited by Union law*"[10].

On the other hand, the use of "good" and verified information still does not exempt AI models from errors, and in particular from biases that, being inherent to society, may be embedded in AI ingested data (*e.g.*, opinions on race, gender, biological sex, age, or culture) and, as such, potentially replicated by artificial intelligence models. More specifically, the reference is to the case in which a certain model, by analysing the data made available to it, learns - and consequently reproduces - discriminatory behaviours against certain groups of people. Such biases carry with them not only ethical issues (as in the case of the "Tay" chatbot, which was programmed in 2016 by Microsoft to allow automatic interaction on Twitter and has been taken down following racist responses[11]), but also the risk of social implications (such as the "COMPAS" algorithm - Correctional Offender Management Profiling for Alternative Sanctions - used in U.S. court systems to predict the likelihood of a defendant becoming a recidivist, which incorrectly predicted a higher risk for black defendants than white ones[12]). To avoid wrong or biased output, some

[6] European Parliamentary Research Service, 'The Impact of the General Data Protection Regulation (GDPR) on Artificial Intelligence' (Scientific Foresight Unit 2020) 16.
[7] Sedir Mohammed and others, 'The Effects of Data Quality on Machine Learning Performance on Tabular Data' (2025) 132 Information Systems 1.
[8] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (AI Act).
[9] Recital no 59 of Regulation (EU) 2024/1689.
[10] Recital no 67 of Regulation (EU) 2024/1689.
[11] Peter Lee, 'Learning from Tay's Introduction' (*Office Microsoft Blog*, 25 March 2016) <https://blogs.microsoft.com/blog/2016/03/25/learning-tays-introduction/> accessed 30 July 2025.
[12] Julia Angwin, Jeff Larson, Surya Mattu and Lauren Kirchner, 'Machine Bias' (*ProPublica*, 23 May 2016) <https://www.propublica.org/article/machine-bias-risk-assessments-in-criminal-sentencing> accessed 30 July 2025.

AI developers (including OpenAI[13] and Google[14]) then rely on the so-called "*reinforcement learning with human feedback*" (RLHF) method, which is a machine learning technique that incorporates human feedback within ML models so that they can learn more efficiently and perform tasks more closely aligned with human goals and needs[15]. In this regard, it would, for instance, be arduous (if not outright impossible) for an algorithmic system to define abstract notions such as "fun", hence, in order for the machine to learn such concepts, it is aided by some human feedback to guide its interpretation. Such a learning technique, however, also brings with it some critical issues since, on the one hand, humans themselves, more often than not, do not agree on what the general and unquestionable interpretation of an abstract concept should be, and on the other hand, the inclusion of external human feedback exposes the machine to human errors (whether in good or bad faith), which are not rare. Nevertheless, such a function is what has allowed, among others, OpenAI to work properly and avoid repeating the mistakes made by the aforementioned "Tay" model[16].

As a result of the foregoing, although human intervention continues to be crucial for its proper development and training, it is blatant that AI without data remains an empty box incapable of effective use. Once acknowledged the importance of data for AI development and accepted that the data used for AI models' training may also include "*information relating to an identified or identifiable natural person*"[17], each AI developer (*rectius*, data controller) should then address the issue of the compliance of such models with personal data protection legislation, and, in particular - for the purposes of this article - of the choice of the most appropriate legal basis for such data processing.

2 What is the most appropriate legal basis for training AI models?

2.1 The choice of a lawful legal basis under the GDPR

In determining the most appropriate legal basis for AI training purposes and setting aside any, and certainly more complex, processing of information belonging to special

[13] Long Ouyang and others, 'Training Language Models to Follow Instructions with Human Feedback' [2022] ArXiv <https://arxiv.org/abs/2203.02155> accessed 15 September 2025; OpenAI, 'Aligning Language Models to Follow Instructions' [2022] <https://openai.com/research/instruction-following>accessed 30 July 2025.

[14] James Manyika and Sissie Hsiao, 'An Overview of Bard: An Early Experiment with Generative AI' [2023] Scientific Research <https://ai.google/static/documents/google-about-bard.pdf>accessed 30 July 2025.

[15] Paul Christiano and others, 'Deep Reinforcement Learning from Human Preferences' [2023] ArXiv <https://arxiv.org/abs/1706.03741> accessed 15 September 2025; Harrison Lee and others, 'RLAIF: Scaling Reinforcement Learning from Human Feedback with AI Feedback' [2023] ArXiv <https://arxiv.org/abs/2309.00267> accessed 15 September 2025.

[16] OpenAI, 'Learning from Human Preferences' [2017] <https://openai.com/research/learning-from-human-preferences> accessed 30 July 2025.

[17] Article 4(1) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (GDPR).

categories of personal data[18] (*i.e.*, "sensitive data", such as data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs) or relating to criminal convictions and offences[19], there is no reason to exclude *a priori* the applicability of any of the legal bases provided by Art. 6 of the GDPR. More specifically, such processing shall indeed be lawful if and to the extent that one of the following conditions applies:

I. *the data subject has given consent to the processing of his or her personal data*: although there is no hierarchy among legal bases[20], consent is often implicitly regarded as the legal ground that offers the highest level of protection for the rights and freedoms of data subjects - even in the context of AI training - as it provides individuals with greater control over their personal data, provided that the conditions for valid consent are met (*i.e.* consent is freely given and complies with all other requirements of the GDPR[21]);

II. *processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract*: this legal basis applies when processing with the aid of an AI system is strictly necessary to provide a contractual service to the data subject, or to take actions prior to entering into a contract at the data subject's request. In this regard, the French Data Protection Authority has, for instance, expressly given the example of a controller who asks professional actors to perform certain scenes and to collect specific images for the purpose of training an AI system: if the purpose of the contract entered into is to collect images in order to constitute a dataset for training the algorithms, then it can be considered, subject to the specific features of the data processing, to be necessary for the performance of that contract[22]. However, some concerns about the applicability of this legal basis arise with regard to the provision of services to an indeterminate number of users (*e.g.*, the provision of an online service). In such contexts, according to the latest binding decisions of the European Data Protection Board[23], an AI system can indeed perform properly without being trained on the personal data of a single individual who signs up or otherwise just uses a certain service (since AI models are typically built using very large datasets), with the consequence

[18] Article 9 of Regulation (EU) 679/2016.
[19] Article 10 of Regulation (EU) 679/2016.
[20] European Data Protection Board (EDPB), 'Guidelines 1/2024 on Processing of Personal Data under Article 6(1)(f) GDPR', Version 1.0, adopted 8 October 2024, para 1.
[21] Article 4(11) and 7 of Regulation (EU) 679/2016.
Also, European Data Protection Board (EDPB), 'Guidelines 05/2020 on Consent under Regulation (EU) 2016/679', adopted 4 May 2020.
[22] Commission Nationale de l'Informatique et des Libertés (CNIL), 'Ensuring the Lawfulness of the Data Processing' <https://www.cnil.fr/en/ensuring-lawfulness-data-processing#:~:text=An%20organisation%20that%20wishes%20to,collecting%20or%20reusing%20the%20data> accessed 30 July 2025.
[23] European Data Protection Board (EDPB), 'Urgent Binding Decision 01/2023 Requested by the Norwegian SA for the Ordering of Final Measures Regarding Meta Platforms Ireland Ltd (Art 66(2) GDPR)' 7 December 2023.
Data Protection Commission (DPC), 'Meta Platforms Ireland Limited (Facebook Service) – Decision on Inquiry IN-18-5-5' (Redacted) (31 December 2022).

that the inclusion or non-inclusion of that individual's data in the training dataset has a negligible effect on the performance of the entire system, hence contract performance cannot be considered a lawful legal basis for that purpose. The above has been confirmed by the French Data Protection Authority which held that an operator of an online social network that indicates in its general terms and conditions its intention to reuse users' personal data to develop and improve new products (including the purpose of AI systems training), even if useful for those users, cannot actually rely on the legal basis of contract performance, since such processing is not objectively necessary to offer the online social network service to users[24];

III. *processing is necessary for compliance with a legal obligation to which the controller is subject*: in some cases, a data controller may be required to process personal data (including for the purpose of AI models training) in order to comply with a legal obligation to which it is subject, provided that it demonstrates that it is actually bound by a legal obligation and that such processing is necessary for the fulfillment of that obligation[25];

IV. *processing is necessary in order to protect the vital interests of the data subject or of another natural person*: in a very limited number of cases, the processing of data might be necessary for the protection of individuals' vital interests (e.g., for emergency medical diagnosis of patients otherwise unable to provide consent). However, it is quite challenging for a data controller to demonstrate that the development and training of AI models was carried out for the protection of data subjects' vital interests. This legal basis should in fact be interpreted narrowly: the expression "vital interest" appears to restrict the scope of application to situations involving life-threatening circumstances or, at the very least, a serious and imminent threat to the health of the data subject or of a third party[26]. In any case, prior to relying on this legal basis, an attempt to obtain consent should be made[27];

V. processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller: the existence of a public interest on which AI model training can be based should be expressly provided for by the law of the European Union or of each Member State. However, when determining the existence of a public interest, the legislator, in most cases, merely recognizes that interest without specifying in detail all the specific data processing activities (such as, AI models training activities) that are authorized. In this sense, the Directive (EU)

[24] Court of Justice of the European Union (CJEU), Judgment of 4 July 2023, Case C-252/21, *Meta Platforms Inc v Bundeskartellamt* (ECLI:EU:C:2023:537).

[25] Information Commissioner's Office (ICO), 'How Do We Ensure Lawfulness in AI?' <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/artificial-intelligence/guidance-on-ai-and-data-protection/how-do-we-ensure-lawfulness-in-ai/#:~:text=You%20must%20break%20down%20and,with%20the%20principle%20of%20lawfulness> accessed 30 July 2025.

[26] Article 29 Data Protection Working Party, *Opinion 06/2014 on the Notion of Legitimate Interests of the Data Controller under Article 7 of Directive 95/46/EC* (WP 217, adopted 9 April 2014) 20.

[27] Luca Bolognini and Enrico Pelino, *Codice della disciplina privacy* (2ª edizione, Giuffrè 2024) 92.

2015/849 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing, for example, admits that "the processing of personal data on the basis of this Directive for the purposes of the prevention of money laundering and terrorist financing [...] shall be considered to be a matter of public interest"[28], without providing further details on the manner in which such processing should be carried out. It will therefore be up to the data controller to define the methods of data processing and demonstrate that the development and training of AI models, as carried out, are actually necessary for the pursuit of the public interest identified by law;

VI. *processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party*: the training of AI models could also be carried out on the basis of a legitimate interest of the controller or a third party, except where such interest is overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child. However, the uncertainty in the use of such a legal basis lies in the difficulty for data controllers to demonstrate that their - or a third party's - legitimate interest in training an AI model actually overrides, through a balancing test, any data subjects' interests.

Without prejudice to the applicability (*a priori*) of all the above legal bases, the foregoing shows that, outside of specific and limited cases (*e.g.*, when there is a legal obligation or public interest), the choice between the legal bases that can actually be used narrows in most cases between the prior consent of data subjects and a legitimate interest pursued by the controller or a third party. This conclusion was also reached by the Italian Data Protection Authority in the context of the an enforcement action against OpenAI[29] by ordering – among other corrective measures – to change "*the legal basis of the processing of users' personal data for the purpose of algorithmic training, by removing any reference to contract and relying on consent or legitimate interest as legal bases by having regard to the assessment the company is required to make from an accountability perspective*".

2.2 Constraints and pitfalls of a generalised consent-based approach

Although, in theory, relying on the data subject's consent may always appear to be a legitimate and defensible choice — especially from the standpoint of the controller's accountability, given that it is unlikely a supervisory authority would challenge the decision to base a processing operation on properly obtained consent[30] — its suitability as

[28] Art 43, Directive (EU) 2015/849 of the European Parliament and of the Council of 20 May 2015 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing, amending Regulation (EU) No 648/2012 of the European Parliament and of the Council, and repealing Directive 2005/60/EC and Commission Directive 2006/70/EC (Fourth Anti-Money Laundering Directive).
[29] Garante per la protezione dei dati personali, *Judgment no 114 of 11 April 2023, doc web no 9874702*.
[30] Commission Nationale de l'Informatique et des Libertés (CNIL), 'Restricted Committee Deliberation No SAN-2022-019 of 17 October 2022 concerning Clearview AI' (restricted committee, 17 October 2022).

the primary legal basis for training artificial intelligence models demands a careful assessment, grounded in the strict conditions governing its validity[31].

First and foremost, consent must be freely given — *i.e.*, it must result from a genuinely voluntary choice, not compromised by contractual, technical, or psychological pressure, whether explicit or implicit. In this sense, data controllers should therefore leave each data subject free to accept or decline the possibility of using their data to train AI models, with no adverse consequences for them. From this perspective, any form of coercion — such as making access to a service or some of its functionalities conditional on the provision of consent for additional purposes (e.g., AI model training) — would make the consent invalid, as it deprives the data subject of the ability to make an autonomous and free decision[32].

Furthermore, consent must be specific, meaning that it must be distinctly granted for each individual and specific purpose of the data processing activity[33]. A blanket or generic authorization — such as a consent merely referring to a vague and undifferentiated purpose like "AI model training" — would be insufficient and would make the consent collected invalid[34]. Accordingly, in cases where data processing pursues multiple and heterogeneous purposes (e.g., the same AI model is used to pursue different purposes that require the consent of the data subject), it is therefore necessary to obtain separate and unambiguous consent for each of these purposes. This may ultimately result in the need to collect a significant number of consents from data subjects. Also, if one endorses the view that the development phase of an AI system constitutes an independent processing activity, pursuing an autonomous purpose (*i.e.*, the very purpose of training the model), distinct from the purposes guiding the entire process of developing and implementing the model[35], the data controller would then be required not only to collect as many consents as there are purposes pursued through the use of AI models but, for each of them, to further distinguish between consent for the "development" phase (training) and consent for the "dissemination" phase of the model used.

For consent to be free and specific, it must also be "informed." Providing detailed information about the processing that the data controller intends to carry out is a key

Garante per la protezione dei dati personali, Decision of 9 March 2022, doc web no 9751323.

[31] Article 4(11) of Regulation (EU) 2016/679.

[32] European Data Protection Board (EDPB), 'Guidelines 05/2020 on Consent under Regulation 2016/679', adopted 4 May 2020, para 67; European Data Protection Board (EDPB), 'Opinion 08/2024 on Valid Consent in the Context of Consent or Pay Models Implemented by Large Online Platforms' adopted 17 April 2024, para 115.

[33] EDPB Guidelines 05/2020 on consent under Regulation 2016/679 adopted on 4 May 2020, para 55.

[34] Garante per la protezione dei dati personali, Decision of 23 February 2023, doc web no 9870014.

[35] European Data Protection Board (EDPB), 'Report of the Work Undertaken by the ChatGPT Taskforce', adopted 23 May 2024, para 14.

European Data Protection Board (EDPB), *Opinion 28/2024 on Certain Data Protection Aspects Related to the Processing of Personal Data in the Context of AI Models*, adopted 17 December 2024, para. 18 stating "*[...] for the purpose of this Opinion, the EDPB refers to the "development phase" and to the "deployment phase". The development of an AI model covers all stages before any deployment of the AI model, and includes, inter alia, code development, collection of training personal data, pre-processing of training personal data, and training. The deployment of an AI model covers all stages relating to the use of an AI model and may include any operations conducted after the development phase*".

element for the validity of consent; if the data controller does not provide adequate information, the user's control becomes illusory and consent does not constitute a valid basis for processing[36]. Indeed, unlike other legal bases, if the information is missing or not sufficiently detailed, the entire processing would be unlawful, not merely vitiated by a procedural defect[37]. In this sense, consent obtained through a generic reference to "AI model training" purposes, not supported by clear and analytical information about the concrete methods of data processing and the actual purposes pursued, would certainly not be considered valid.

Finally, consent must be capable of being withdrawn at any time without detriment to the data subject. Although it is true that withdrawal does not have retroactive effect, in the sense that data processing carried out prior to withdrawal remains lawful[38], it is equally true that, once this right has been exercised, the data controller must cease all further processing based on that legal basis and erase the data, unless another legal ground justifies their retention (e.g. compliance with a legal obligation or archiving for public interest purposes)[39]. In these terms, for an AI model to be considered effectively anonymized, it must be reasonably excluded, using all possible measures, that any personal data (including probabilistic data) relating to identifiable individuals can be extracted or returned as a result of queries to the model; this risk should be assessed taking into account all means that the controller or another person could reasonably use including the risk of (re)use or inadvertent disclosure of the model itself[40]. However, once personal data has been included in training datasets and has contributed to the calibration of model parameters, its removal does not always undo the effects already produced, since even when data is deleted retrospectively, the model may continue to reproduce inferences derived from it, thus compromising the principle of effective erasure following withdrawal[41]. The safest mitigation measure would therefore be to update the training data sets by excluding the data of subjects who have withdrawn their consent and retraining the model from scratch accordingly. However, such a process is likely to become computationally expensive and technically overly burdensome for the controller. In most cases, the model would indeed require time and exposure to new volumes of data

[36] EDPB Guidelines 05/2020 on consent under Regulation 2016/679 adopted on 4 May 2020, para 62.
[37] Luca Bolognini and Enrico Pelino, *Codice della disciplina privacy* (2ª edizione, Giuffrè 2024) 96.
Commission Nationale de l'Informatique et des Libertés (CNIL), 'Deliberation No SAN-2019-001 of 21 January 2019'.
[38] Article 7(3) of Regulation (EU) 2016/679.
[39] Luca Bolognini and Enrico Pelino, *Codice della disciplina privacy* (2ª edizione, Giuffrè 2024) 147.
Court of Justice of the European Union (Grand Chamber), *Google Spain SL and Google Inc v Agencia Española de Protección de Datos (AEPD) and Mario Costeja González*, Case C-131/12, *ECLI:EU:C:2014:317* (13 May 2014).
[40] European Data Protection Board (EDPB), 'Opinion 28/2024 on Certain Data Protection Aspects Related to the Processing of Personal Data in the Context of AI Models' (adopted 17 December 2024) para 43.
[41] Alexandria Ginart, Melody Y Guan, Gregory Valiant and James Zou, 'Making AI Forget You: Data Deletion in Machine Learning' [2019] ArXiv <https://arxiv.org/abs/1907.05012> accessed 15 September 2025.

sufficient to gradually overwrite the previous influence, making effective erasure difficult to implement in the immediate term[42].

All of the above illustrates that, in processing operations such as AI model training — which, by nature, require large-scale data collection — obtaining valid consent poses a significant challenge for controllers. They must constantly strike a delicate balance between acquiring valid consent (to avoid enforcement risks) and gathering as many consents as possible to train effective AI models (even though the consent rate among individuals is typically low[43]), since without data, such models would remain empty shells, more subject to errors and bias. These difficulties become even more acute when personal data are not collected directly from the data subjects, but indirectly — e.g., through web scraping. In such scenarios, where the controller has no direct interaction with the individuals and where, at the time the data were made publicly available, the subjects could not reasonably have foreseen their use for AI training purposes[44], the controller would be required — at the first possible contact — to provide adequate information and find a way to obtain valid consent from all data subjects, a task that is often impracticable, if not impossible.

2.3 Could the legitimate interest be an appropriate legal basis for AI model training purposes?

Given the aforementioned concerns surrounding a generalised reliance on consent, it is reasonable to question whether and to what extent the legal basis of "legitimate interest" may constitute a viable alternative for processing personal data in the context of AI model training[45]. On closer inspection, a similar solution has also been adopted in other European regulations, such as the EU Copyright Directive[46], where, apart from the extraction of text and data for scientific research purposes[47], the legislator acknowledges that copyrights may be more generally excepted or restricted for the purposes of any text and data extraction (and thus AI model training), provided that such content are lawfully accessed and "*on condition that the use of works and other subject matter [...] has not been expressly reserved by their rightholders in an appropriate manner*"[48]. As is clear, the EU Copyright Directive thus encourages a system whereby rights holders do not have to give

[42] Youyang Qu and others, 'The Frontier of Data Erasure: Machine Unlearning for Large Language Models' (2025) 58 Computer 45.
[43] Marko Saric, 'Only 9% of Visitors Give GDPR Consent to Be Tracked' (*Marko Saric site*, 6 July 2020) <https://markosaric.com/gdpr-consent/> accessed 30 July 2025.
[44] Information Commissioner's Office (ICO), 'How Do We Ensure Lawfulness in AI?' <https://ico.org.uk/about-the-ico/what-we-do/our-work-on-artificial-intelligence/response-to-the-consultation-series-on-generative-ai/the-lawful-basis-for-web-scraping-to-train-generative-ai-models/> accessed 30 July 2025.
[45] Péter T Kramcsák, 'Can Legitimate Interest Be an Appropriate Lawful Basis for Processing Artificial Intelligence Training Datasets?' (2023) 48 Computer Law & Security Review 1.
[46] Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC.
[47] Article 3 of Directive (EU) 2019/790.
[48] Article 4 of Directive (EU) 2019/790.

prior consent (*i.e.*, opt-in) in order for their works to be used for text and data mining, but retain the right to "reserve" the use of them thus effectively exercising a right of opposition (*i.e.*, opt-out).

From a data protection perspective, the validity of legitimate interest as an appropriate legal basis for AI model training purposes was initially addressed by some local supervisory authorities. The French Data Protection Authority, for instance, referred to the case of a company developing an AI system aimed at evaluating public appreciation of artworks, trained on publicly accessible user comments posted on online forums, blogs, and websites: in this sense, the collection of such feedback could be deemed necessary for model development, particularly given the large data volumes required, and the commercial interest in developing and marketing such a system qualifies as a legitimate interest[49]. The Italian Data Protection Authority, as mentioned above, expressly acknowledged — within the context of its proceedings against OpenAI[50] — the need to identify a legal basis either in consent or legitimate interest, thereby formally allowing the use of this legal basis. Similarly, the UK Information Commissioner's Office, when addressing AI models training via web scraping, went so far as to declare that: "*legitimate interests remains the sole available lawful basis for training generative AI models using web-scraped personal data based on current practices*"[51].

After a period of interpretative uncertainty, the European Data Protection Board (EDPB), in responding to a request by the Irish Supervisory Authority[52], has now provided a more definitive position, clarifying that legitimate interest, under certain circumstances, may be invoked as a valid legal basis for AI training purpose[53]. More specifically, the EDPB first reiterated that the GDPR does not establish a hierarchy among the legal bases listed in Article 6(1)[54]; rather, it is up to the controller to determine the most appropriate basis, depending on the specific purpose and context of the processing. Furthermore, the EDPB went on to state that legitimate interest, as with any data processing, can be relied upon only if the so-called "three-part test" is fulfilled: *(1)*

[49] Commission Nationale de l'Informatique et des Libertés (CNIL), 'Ensuring the Lawfulness of the Data Processing' <https://www.cnil.fr/en/ensuring-lawfulness-data-processing#:~:text=An%20organisation%20that%20wishes%20to,collecting%20or%20reusing%20the%20data> accessed 30 July 2025.
Commission Nationale de l'Informatique et des Libertés (CNIL), 'Legal Basis: Can Legitimate Interest Be Used to Develop a System?' <https://www.cnil.fr/fr/base-legale-interet-legitime-developpement-systeme> accessed 30 July 2025.
[50] Garante per la protezione dei dati personali, *Judgment no 114 of 11 April 2023, doc web no 9874702*.
[51] Information Commissioner's Office (ICO), 'The Lawful Basis for Web Scraping to Train Generative AI Models' <https://ico.org.uk/about-the-ico/what-we-do/our-work-on-artificial-intelligence/response-to-the-consultation-series-on-generative-ai/the-lawful-basis-for-web-scraping-to-train-generative-ai-models/#:~:text=Legitimate%20interests%20remains%20the%20sole,%2Dpart%20test%2C%20including%20necessity> accessed 30 July 2025.
[52] Irish Data Protection Commission (DPC), 'Request for an Opinion of the European Data Protection Board Pursuant to Article 64(2) GDPR', 6 November 2024 <edpb.europa.eu> accessed 15 September 2025.
[53] European Data Protection Board (EDPB), 'Opinion 28/2024 on Certain Data Protection Aspects Related to the Processing of Personal Data in the Context of AI Models', adopted 17 December 2024.
[54] European Data Protection Board (EDPB), 'Guidelines 1/2024 on Processing of Personal Data under Article 6(1)(f) GDPR', Version 1.0, adopted 8 October 2024, para 1.

identifying a legitimate interest pursued by the controller or a third party, which must be lawful, concrete, and sufficiently specific; *(2)* demonstrating that the processing is necessary to achieve that interest, meaning it is suitable and there are no less intrusive alternatives; and *(3)* ensuring that the data subject's rights and freedoms do not override the interest pursued, through a careful and context-specific balancing exercise[55]. This approach, consistent with the case law of the Court of Justice of the European Union[56], confirms that while legitimate interest is not universally applicable, it remains a legal basis that can also be used for AI model training, provided that appropriate safeguards are in place and the assessment resulting from the three-step test is robust and well-documented.

The first step in applying the legitimate interest basis is to verify whether the controller indeed pursues such an interest. In this respect, reference must be made to the original conception of "legitimate interest" as laid out in Article 7(f) of Directive 95/46/EC. To qualify as a relevant interest, it must: *(i)* be lawful, meaning consistent with applicable EU and national laws[57]; *(ii)* be sufficiently clear and specific to enable a meaningful balancing test; and *(iii)* represent a real and present interest, not a hypothetical or speculative one[58]. While the GDPR[59] and CJEU[60] have recognised a wide range of interests as potentially "legitimate"[61], the determination remains inherently contextual and must be conducted on a case-by-case basis. However, the EDPB has outlined examples of interests that may be considered legitimate in the context of AI development, including: *(i)* building conversational agents to support users in completing tasks; *(ii)* deploying AI

[55] European Data Protection Board (EDPB), 'Guidelines 1/2024 on Processing of Personal Data Based on Article 6(1)(f)' *GDPR*, Version 1.0, adopted 8 October 2024, para 6.

[56] Court of Justice of the European Union (CJEU), *Meta Platforms Inc v Bundeskartellamt*, Case C-252/21, ECLI:EU:C:2023:537, Judgment of 4 July 2023, para 106.
Court of Justice of the European Union (CJEU), *Asociația de Proprietari bloc M5A-ScaraA*, Case C-708/18, ECLI:EU:C:2019:1064, Judgment of 11 December 2019, para 40.
Court of Justice of the European Union (CJEU), *Valsts policijas Rīgas reģiona pārvaldes Kārtības policijas pārvalde v Rīgas pašvaldības SIA "Rīgas satiksme"*, Case C-13/16, ECLI:EU:C:2017:336, Judgment of 4 May 2017, para 28.

[57] Court of Justice of the European Union (CJEU), *Koninklijke Nederlandse Lawn Tennisbond*, Case C-621/22, ECLI:EU:C:2024:857, Judgment of 4 October 2024, para 49.

[58] European Data Protection Board (EDPB), 'Guidelines 1/2024 on Processing of Personal Data Based on Article 6(1)(f) GDPR', Version 1.0, adopted 8 October 2024, para 17.
Article 29 Data Protection Working Party, *Opinion 06/2014 on the Notion of Legitimate Interests of the Data Controller under Article 7 of Directive 95/46/EC* (WP 217, adopted 9 April 2014) 24–25.
Court of Justice of the European Union (CJEU), *Asociația de Proprietari bloc M5A-ScaraA*, Case C-708/18, ECLI:EU:C:2019:1064, Judgment of 11 December 2019, para 44.

[59] Recital 47 of Regulation (EU) 2016/679.

[60] Court of Justice of the European Union (CJEU), *Koninklijke Nederlandse Lawn Tennisbond*, Case C-621/22, ECLI:EU:C:2024:857, Judgment of 4 October 2024, para 49, stating: "*a commercial interest [...] could constitute a legitimate interest, within the meaning of point (f) of the first subparagraph of Article 6(1) of the GDPR, provided that it is not contrary to the law. It is, however, for the referring court to assess, on a case-by-case basis, whether such an interest exists, taking into account the applicable legal framework and all the circumstances of the case*".

[61] European Data Protection Board (EDPB), 'Guidelines 1/2024 on Processing of Personal Data Based on Article 6(1)(f) GDPR', Version 1.0, adopted 8 October 2024, paras 21–25.

systems to detect fraudulent activities or harmful content; and *(iii)* improving cybersecurity through more effective threat identification mechanisms[62].

Turning to the second prong of the test, it should be clarified that the concept of 'necessary for the purposes of the legitimate interests pursued by the controller or by a third party' does not simply encompass what is useful for pursuing those interests. The concept of necessity has an autonomous meaning in EU legal framework, which must be interpreted in such a way as to fully reflect the aims of data protection law[63]. According to the CJEU, the condition relating to the necessity of the processing should therefore be examined in light of the fundamental rights and freedoms of the data subjects, as well as in relation to the principle of data minimization[64], taking into account both the nature of the processing and its potential effects[65]. In particular, the necessity test should involve two critical inquiries: *(i)* whether the processing is suitable for achieving the intended purpose[66], and *(ii)* whether less intrusive means exist to accomplish that same purpose[67]. If there are reasonable, just as effective, but less intrusive alternatives, the processing may not be considered to be "necessary"[68]. In the context of AI models training, this requires first assessing whether the same result could be achieved without processing

[62] European Data Protection Board (EDPB), 'Opinion 28/2024 on Certain Data Protection Aspects Related to the Processing of Personal Data in the Context of AI Models', adopted 17 December 2024, para. 69.
[63] Court of Justice of the European Union (CJEU), *Huber*, Case C-524/06, ECLI:EU:C:2008:724, Judgment of 16 December 2008, para 52.
[64] Article 5(1)(c) of Regulation (EU) 2016/679.
[65] Court of Justice of the European Union (CJEU), *Meta Platforms Inc v Bundeskartellamt*, Case C-252/21, ECLI:EU:C:2023:537, Judgment of 4 July 2023, paras 108–109.
Court of Justice of the European Union (CJEU), *Asociația de Proprietari bloc M5A-ScaraA*, Case C-708/18, ECLI:EU:C:2019:1064, Judgment of 11 December 2019, para 48.
Court of Justice of the European Union (CJEU), *Volker und Markus Schecke GbR and Hartmut Eifert v Land Hessen*, Joined Cases C-92/09 and C-93/09, ECLI:EU:C:2010:662, Judgment of 9 November 2010, paras 85–86.
Court of Justice of the European Union (CJEU), *Latvijas Republikas Saeima*, Case C-439/19, ECLI:EU:C:2021:504, Judgment of 22 June 2021, paras 98, 109–110 and 113.
[66] Court of Justice of the European Union (CJEU), *Heinz Huber v Bundesrepublik Deutschland*, Case C-524/06, ECLI:EU:C:2008:724, Judgment of 16 December 2008, para 66.
Opinion of Advocate General Poiares Maduro, *Heinz Huber v Bundesrepublik Deutschland*, Case C-524/06, ECLI:EU:C:2008:194, delivered on 3 April 2008, para 16 stating: "*the proper test here is one of effectiveness, and it is for the national court to apply it. The question it must ask is whether there are other ways of data processing by which the immigration authorities could enforce the rules on residence status. If it answers that question in the affirmative, the centralised data storage and processing for Union citizens should be declared unlawful. It is not necessary for the alternative system to be the most effective or appropriate; it is enough for it to be able to perform adequately. Put differently, even if the central register is more effective or convenient or user-friendly than its alternatives (such as the decentralised, local registers), the latter are clearly to be preferred if they can be used to indicate the residence status of Union citizens*".
[67] Court of Justice of the European Union (CJEU), *Peter Puškár*, Case C-73/16, ECLI:EU:C:2017:725, Judgment of 27 September 2017, para 113 stating: "*It is thus for the national court to ascertain whether the establishment of the contested list and the inclusion of the names of the data subjects in such a register are suitable for achieving the objectives pursued by them and whether there is no other less restrictive means in order to achieve those objectives*".
[68] Court of Justice of the European Union (CJEU), *Meta Platforms Inc v Bundeskartellamt*, Case C-252/21, ECLI:EU:C:2023:537, Judgment of 4 July 2023, para 108.
European Data Protection Board (EDPB), 'Guidelines 2/2019 on the Processing of Personal Data under Article 6(1)(b) GDPR in the Context of the Provision of Online Services to Data Subjects', Version 2.0, adopted 8 October 2019, para 25.

personal data, for example by using synthetic or anonymised datasets. If so, the necessity criterion would not be satisfied.

The third prong — balancing the competing interests of the controller and the data subject — is the most nuanced and context-dependent part of the analysis. This step involves identifying and describing the various competing rights and interests at stake, *i.e.*, on the one hand, the interests, fundamental rights, and freedoms of the data subjects and, on the other hand, the interests of the data controller or third parties[69]. Therefore, in order to demonstrate that the legitimate interest constitutes a suitable legal basis for the processing activities in question, the specific circumstances of the case should be considered[70], including the impact of the processing on the data subjects and their reasonable expectations.

As regards impact, in the context of AI development, the rights potentially affected primarily include the data subject's right to informational self-determination and control over the use of their personal data. At the same time, the balancing test must also take into account any concrete benefits for the data subject: if the processing yields demonstrable advantages for the individual — such as enhanced security, improved functionality, or greater accessibility — these may weigh in favor of the data controller, provided they are substantiated and not speculative. In any case, controllers must always evaluate this impact by considering factors such as, the nature of the data processed for AI training purposes, the context in which the AI model is developed, and any further potential consequences (and their likelihood) arising from such processing. In this regard, as a general rule, the more sensitive or private the nature of the data to be processed, the more likely it is that the processing of such data will have a negative impact on the data subject and the greater the weight that should be given to that impact in the balancing[71]. Similarly, in order to assess the actual context and possible consequences of the processing, the controller should duly take into account, among other things, the following factors: the scope of the processing and the amount of personal data to be processed (in terms of the overall volume of data, the volume of data per data subject, and the number of data subjects involved), the status of the controller in relation to the data subject (e.g., an employment relationship is likely to require a different assessment than a relationship between a service provider and a customer), whether the personal data to be processed are combined with other data sets, the degree of accessibility and/or publicity of the data to be processed, and the status of the data subject (e.g., vulnerable persons).

[69] European Data Protection Board (EDPB), 'Guidelines 1/2024 on Processing of Personal Data Based on Article 6(1)(f) GDPR', Version 1.0, adopted 8 October 2024, para 32.
[70] European Data Protection Board (EDPB), 'Guidelines 1/2024 on Processing of Personal Data Based on Article 6(1)(f) GDPR', Version 1.0, adopted 8 October 2024, para 32, also referring to Court of Justice of the European Union (CJEU), *Meta Platforms Inc v Bundeskartellamt*, Case C-252/21, ECLI:EU:C:2023:537, Judgment of 4 July 2023, para 110.
[71] European Data Protection Board (EDPB), 'Guidelines 1/2024 on Processing of Personal Data Based on Article 6(1)(f) GDPR', Version 1.0, adopted 8 October 2024, para 41.

On the other hand, reasonable expectations play a key role in assessing the balance between the interests at stake, mainly because of the complexity of the technology used in AI models and the difficulty people may have in understanding the different ways in which an AI model can be used and how their data will be processed[72]. When determining the expectations of data subjects, it should again be borne in mind that these may vary depending on the relationship between the controller and the data subjects, or depending on whether the data have been provided directly to the controller (e.g., in the context of using the service) or whether the controller has obtained them from another source (e.g., through third parties or scraping activities). In this regard, where data have been made publicly accessible or obtained by the controller through indirect means, such as web scraping, the CJUE, dealing with a famous dispute between Google and a Spanish data subject over indexing and web scraping[73], has pointed out that the commercial interests of a company could not generally override the interests of the individual. Specifically, the Court upheld the complaint against Google, holding that the individual's legitimate interest "*override not only the economic interest of the operator of the search engine but also the interest of the general public in finding that information upon a search relating to the data subject's name*"[74] and ordering it to take the necessary measures to remove from its indexes certain personal data concerning said data subject and to prevent future access to said data. A few years later, the Court seemed to have provided some guidance to the contrary by admitting that, in balancing the interests of all the parties involved, "*it is possible to take into consideration the fact that the seriousness of the infringement of the data subject's fundamental rights resulting from that processing can vary depending on the possibility of accessing the data at issue in public sources*"[75]. In other words, the fact that the data are freely accessible to the public, while it may not in itself constitute an independent legal basis[76], could nevertheless constitute an element

[72] Court of Justice of the European Union (CJEU), *Meta Platforms Inc v Bundeskartellamt*, Case C-252/21, ECLI:EU:C:2023:537, Judgment of 4 July 2023, para 123, stating: "*while the CJEU found that 'product improvement' cannot in principle be ruled out as a legitimate interest, it also found that it is 'doubtful whether [...] the 'product improvement' objective, given the scale of that processing and its significant impact on the user, as well as the fact that the user cannot reasonably expect those data to be processed [...] may override the interests and fundamental rights of such a user, particularly in the case where that user is a child*".

[73] Court of Justice of the European Union (CJEU), *Google Spain SL and Google Inc v Agencia Española de Protección de Datos (AEPD) and Mario Costeja González*, Case C-131/12, ECLI:EU:C:2014:317, Judgment of 13 May 2014.

[74] Court of Justice of the European Union (CJEU), *Google Spain SL and Google Inc v Agencia Española de Protección de Datos (AEPD) and Mario Costeja González*, Case C-131/12, ECLI:EU:C:2014:317, Judgment of 13 May 2014, para. 97.

[75] Court of Justice of the European Union (CJEU), *Valsts policijas Rīgas reģiona pārvaldes Kārtības policijas pārvalde v Rīgas pašvaldības SIA 'Rīgas satiksme'*, Case C-13/16, ECLI:EU:C:2017:336, Judgment of 4 May 2017, para 32.
Court of Justice of the European Union (CJEU), *Asociación Nacional de Establecimientos Financieros de Crédito and Federación de Comercio Electrónico y Marketing Directo v Administración del Estado*, Joined Cases C-468/10 and C-469/10, ECLI:EU:C:2011:777, Judgment of 24 November 2011, para 44, stating: "*in relation to the balancing which is necessary pursuant to Article 7(f) of Directive 95/46, it is possible to take into consideration the fact that the seriousness of the infringement of the data subject's fundamental rights resulting from that processing can vary depending on whether or not the data in question already appear in public sources*".

[76] Garante per la protezione dei dati personali, Decision of 29 May 2003, Doc web no 1589969.
Article 29 Data Protection Working Party, Opinion 1/2000 on Certain Data Protection Aspects of Electronic Commerce, adopted 3 February 2000.

on which to carry out a balancing test aimed at assessing whether a legitimate overriding interest actually exists.

That being said, the balancing test should not be viewed as a fixed or binary determination, but rather as a dynamic process that may evolve in light of the safeguards effectively put in place. In this sense, where an initial outcome of the balancing test suggests that the data subjects' fundamental rights and freedoms outweigh the interests pursued by the controller, this does not automatically preclude reliance on "legitimate interest" as a lawful basis. In such circumstances, controllers should indeed assess whether it is possible to adopt mitigating measures capable of reducing the adverse impact of the processing on data subjects and making "legitimate interest" as an appropriate legal basis for the controller. By implementing such measures, the controller may be indeed able to demonstrate that the risks to the data subjects' rights and freedoms have been sufficiently mitigated, thereby shifting the balance in favor of the controller's (or third-party's) legitimate interest.

2.4 Implementing sophisticated mitigation measures: a key condition for making legitimate interest a viable legal basis

What has been illustrated so far shows that reliance on legitimate interest as a legal basis for AI training purposes may represent not only a viable alternative to consent, but in some cases, a necessary one — especially in light of the potentially stifling effects that a consent-only approach could have. While it is true that this legal basis does not entail an active self-determination of data subjects, thus limiting their direct control over the processing of their personal data and increasing the possibility of an adverse impact on them, this shortcoming can be significantly mitigated through the implementation of robust mitigation measures. These measures enhance the protection of individuals and ensure that the use of legitimate interest remains consistent with the fundamental principles provided by the European data protection regulations. However, such safeguards should not be mistaken for the baseline obligations that controllers are required to fulfil under the GDPR regardless of the legal basis invoked[77]; rather, they represent context-specific additional measures aimed at ensuring that the processing does not disproportionately infringe upon the rights and freedoms of data subjects.

That being clarified, in the context of AI training activities, the following measures play a key role in ensuring that the legitimate interests of the data controller or a third party prevail:

I. *Ensuring the quality and reliability of training data*. Controllers must ensure that datasets are accurate, representative, and free from distortions, as this is critical not

[77] European Data Protection Board (EDPB), 'Opinion 28/2024 on Certain Data Protection Aspects Related to the Processing of Personal Data in the Context of AI Models', adopted 17 December 2024, para. 97.

only for model performance, but also for mitigating potential risks to data subjects[78]. To achieve this, robust pre-processing techniques — including data filtering, validation, normalisation, and deduplication — should be systematically implemented. For instance, if a dataset includes inconsistent terminology, heterogeneous formats, or unbalanced representation of relevant categories (such as demographic segments, linguistic groups, or behavioural classes), normalisation and rebalancing procedures can be applied to prevent the model from internalising distorted correlations[79]. Similarly, validation protocols — including, where appropriate, mandatory human review mechanisms[80] — can be used to detect and exclude logically inconsistent, incomplete, or anomalous data entries before they affect the model's behaviour. Such measures would perform a fundamental legal role in supporting an overriding legitimate interest held by the controller, insofar as they contribute to minimising the risk of adverse effects on data subjects, such as discriminatory outcomes, damage to reputation, or unjustified inferences; indeed, they contribute directly to satisfying the balancing condition that underpins the legitimate interest basis, by demonstrating that appropriate safeguards are in place to substantially reduce the impact of the processing on individuals' rights and freedoms. Moreover, by enhancing the accuracy, fairness, and transparency of the AI system, these practices also help to align the processing with the reasonable expectations of data subjects, thereby strengthening the need for the controller to rely on legitimate interest, especially in contexts where obtaining valid consent is impractical or unfeasible.

II. *Preventing the misclassification of data as anonymous*. Controllers must adopt stringent safeguards to avoid the erroneous classification of personal data as anonymous[81] — a misstep that can lead to unlawful processing and deprive data subjects of appropriate protections. To that end, controllers should implement rigorous testing and validation protocols aimed at ensuring both that: *(i)* personal data included in the training set cannot be extracted, inferred, or reconstructed using means that are reasonably likely to be available, and *(ii)* the model's outputs do not permit any form of direct or indirect re-identification of individuals. For example, controllers may adopt adversarial testing techniques, where simulated inference attacks are deployed to determine whether individual data points can be linked back to the training corpus. If such tests reveal successful reconstruction, additional mitigation measures — such as the application of differential privacy techniques or calibrated noise injection — may be necessary to prevent re-identification. Likewise,

[78] Information Commissioner's Office (ICO), 'Generative AI Third Call for Evidence: Accuracy of Training Data and Model Outputs' (2025) <https://ico.org.uk/about-the-ico/what-we-do/our-work-on-artificial-intelligence/generative-ai-third-call-for-evidence/accuracy-of-training-data-and-model-outputs> accessed 30 July 2025.
[79] Justin K Miller and Wenjia Tang, 'Evaluating LLM Metrics Through Real-World Capabilities' (13 May 2025).
[80] Mark Johnson and Rose Hoover, 'The Role of Human Oversight in Responsible AI Systems' (29 November 2024).
[81] Isabel Barberá, 'AI Privacy Risks & Mitigations: Large Language Models (LLMs) Support Pool of Experts Programme' (European Data Protection Board (EDPB) 2025) 68.

output monitoring tools can be employed to verify that the model does not inadvertently reproduce verbatim fragments of the training data, such as rare name combinations, telephone numbers, or unique text sequences, which may allow for the reverse identification of specific individuals. These measures play a fundamental role in demonstrating that the data controller only processes data that is strictly necessary for the intended purposes and does so in the least intrusive manner possible, as required by the "necessity test" aimed at considering the legitimate interest of the controller or third party to be valid.

III. *Avoiding unlawful or excessive data processing*. Controllers must proactively curate datasets to exclude categories of personal data that involve elevated risks or are irrelevant to the specific training purpose pursued. In particular, training datasets should not include sensitive data — such as information concerning health status, political opinions, religious beliefs, or biometric identifiers — unless their inclusion is strictly necessary and supported by an *ad hoc* legal basis. Moreover, datasets should be cleansed of harmful, misleading, or unauthorised content, including hate speech, disinformation, or other toxic material, which could not only distort model outputs but also amplify systemic risks or social harm. Likewise, unnecessary identifiers — such as names, email addresses, phone numbers, and credit card details — should be systematically removed, and any content likely to disproportionately affect vulnerable individuals or groups should be filtered out[82]. For instance, if a company seeks to build a training dataset using online user reviews in order to develop an AI system that assesses customer satisfaction, the pseudonymisation of user-generated content immediately upon collection may serve as an additional safeguard. This reduces the likelihood that subjective and potentially revealing expressions are traced back to identifiable persons, especially where the content discloses emotional states, behavioural patterns, or social vulnerabilities. Again, such measures directly reinforce the principle of data minimization and play a central role in meeting the necessity requirement within the three-step test: by ensuring that only data that is strictly relevant, non-excessive, and proportionate is processed, and that identifiers or sensitive data are removed, controllers can demonstrate that they have carefully limited the scope of processing to what is truly required.

IV. *Enhancing transparency and user awareness*. Controllers should go beyond the minimum transparency obligations set out under GDPR[83] by proactively informing data subjects about the nature, origin, and purposes of the processing activities. This is particularly important where the processing may involve individuals in vulnerable positions — such as children or persons subject to asymmetries of power (e.g., employees) — whose ability to understand or foresee how their data is used may be

[82] George Feretzakis and others, 'V.S. Privacy-Preserving Techniques in Generative AI and Large Language Models: A Narrative Review' (2024) 15(11) Information 697.
[83] Articles 13 and 14 of Regulation (EU) 679/2016.

limited. To ensure that transparency is not merely formalistic but meaningful and effective, controllers should adopt a diversified set of communication strategies adapted to the needs and literacy levels of different audiences. These may include frequently asked questions (FAQs), "model cards" summarising the purpose, architecture, and limitations of AI systems, interactive dashboards, visual and narrative explanations, and public-facing disclosures regarding data usage, training practices, and model behaviour. From a legal and practical perspective, enhanced transparency significantly strengthens the legitimacy of relying on legitimate interest. By clearly explaining the purpose, functioning, and safeguards of the processing, it helps align the operation with the reasonable expectations of individuals, making it more acceptable even in the absence of consent.

V. *Implementing effective opt-out mechanisms.* Controllers should ensure the deployment of clear, accessible, and technically enforceable opt-out mechanisms enabling data subjects to object, in a practical and effective manner, to the use of their personal data for the training of AI systems. These mechanisms should be easily reachable — for example, via a dedicated section on the controller's website[84] — and must be supported by proactive and intelligible communication strategies. A checkbox interface or a preference management dashboard constitutes an effective tool to operationalise the exercise of the right to object. For instance, users of an online service whose data may be used to develop or refine AI functionalities should be able to promptly access a dedicated page allowing them to opt out of such data uses — without this choice impacting their access to the service. Crucially, the controller must ensure that the objection leads to the effective and timely cessation of any further use of the individual's data for training purposes, including by withdrawing the data from subsequent model iterations or, where feasible, excluding it from future dataset updates. These procedures should be documented and auditable. Moreover, in contexts where data is sourced from publicly accessible online content, controllers should design or adopt technical infrastructures capable of recognising and respecting opt-out signals upstream, *i.e.*, prior to the collection or ingestion of data. This may include the implementation of machine-readable refusal lists, standardised metadata, or equivalent protocols that allow individuals to declare in advance that their data must not be collected or reused for AI training[85]. From a legal standpoint, such mechanisms are essential to reinforce the legitimacy of relying on legitimate interest as a legal basis for processing: they help to re-establish a balance of power between

[84] Garante per la protezione dei dati personali, *Judgment No 114 of 11 April 2023, Doc web no 9874702*. Indeed, the Italian Data Protection Authority ordered the company to make: "*available, on the Company's website, at least to users who are connected from Italy, an easily accessible tool by which to exercise their right to object to the processing of their own data as acquired when using the service for the purpose of training algorithms, where the legal basis chosen [...] is the Company's legitimate interest*".

[85] Commission Nationale de l'Informatique et des Libertés (CNIL), 'Legal Basis: Legitimate Interest for Developing an AI System' (19 June 2025) <https://www.cnil.fr/fr/base-legale-interet-legitime-developpement-systeme> accessed 30 July 2025.

the controller and the data subject, ensuring that individuals retain meaningful agency over their data. Offering realistic and effective means to opt-out from processing, and guaranteeing that such objections are fully respected in practice, contribute decisively to a favourable outcome in the balancing test.

VI. *Avoiding the unlawful repurposing of personal data*. Controllers must avoid vague, excessively broad, or open-ended processing purposes — such as generic references to "developing and improving AI systems" — which fail to provide sufficient clarity about how data will be used and for what specific ends. Instead, the purpose of the processing should be clearly defined and technically delimited, taking into account the concrete functionality of the AI model, its expected outputs, and the nature of the data used. This requirement becomes particularly important in cases where the training is outsourced to third-party providers. In such scenarios, controllers must ensure that appropriate legal and technical safeguards are in place — including data processing agreements, purpose limitation clauses, and contractual prohibitions on unauthorised reuse — to prevent the repurposing of personal data beyond the originally defined and communicated scope. From a technical perspective, additional safeguards can be implemented at the design stage to prevent downstream misuse. These may include, for example, the insertion of digital watermarks into model outputs, in order to monitor and restrict unauthorised secondary uses, or the architectural exclusion of certain functionalities that could enable misleading or unlawful applications of the system[86]. Similarly, contractual restrictions on unethical or deceptive uses of the model or dataset — particularly those that data subjects could not reasonably foresee — can provide enforceable boundaries that materially limit the scope of data reuse. This limits the risk of function creep and reduces the likelihood that data subjects will suffer harm or surprise due to unintended uses of their data. Moreover, purpose-specific design choices and legal constraints help to maintain consistency with the reasonable expectations of individuals, which is essential when processing occurs without consent.

The rigorous adoption of such mitigation measures enables a structured and legally robust justification that the balance of interests tips in favour of the data controller - or third parties – over the rights of data subjects, thereby legitimising the reliance on this legal basis for AI training activities.

[86] Isabel Barberá, 'AI Privacy Risks & Mitigations: Large Language Models (LLMs), Support Pool of Experts Programme' (European Data Protection Board (EDPB) 2025) 72.

3 Conclusion: development and deployment, two stages of processing with a single common purpose

The analysis conducted above confirms that a data controller, following a successful three-step test and the implementation of appropriate mitigation measures, may also rely on legitimate interest as a legal basis for training AI models. However, it is important not to generalize this possibility: recognizing legitimate interest as an option does not imply that it can replace consent by default. For instance, if a data controller intends to develop an AI model aimed at improving the sending of profiled marketing communications[87] or performing facial recognition for commercial purposes[88], it would be challenging, even with the implementation of several sophisticated mitigation measures, to argue that such an interest outweighs the legitimate interests of the data subjects. Allowing a "free-for-all" approach would indeed risk undermining the core principles established by the EU data protection regulations.

When determining the appropriate legal basis for AI-related data processing, controllers should then shift their focus to the ultimate purpose underlying the entire lifecycle of the model. Although development and deployment are often treated as separate and distinct processing activities[89], in practice they are generally bound together by a single overarching purpose: it is that purpose which should guide the determination of the most suitable legal basis — whether consent or legitimate interest. Indeed, while it is true in abstract terms that an AI model may be trained for one purpose and later used for another — such as an image recognition system initially developed for commercial applications and subsequently repurposed for law enforcement — these cases remain the exception rather than the rule. In the overwhelming majority of cases, indeed, anyone who designs and trains AI models does so with a clear awareness of such model's intended use from the outset, as this inevitably shapes not only the choice of input data but also the architecture and logic of the training process itself[90]: for example, if the developer intends to deploy

[87] Commission Nationale de l'Informatique et des Libertés (CNIL), 'Deliberation of the Restricted Committee No SAN-2019-001 of 21 January 2019 pronouncing a financial sanction against Google LLC'.
[88] Commission Nationale de l'Informatique et des Libertés (CNIL), 'Deliberation of the Restricted Committee No SAN-2022-019 of 17 October 2022 concerning Clearview AI'.
Garante per la protezione dei dati personali, *Decision of 9 March 2022, doc web no 9751323.*
[89] European Data Protection Board (EDPB), 'Report of the Work Undertaken by the ChatGPT Taskforce', adopted 23 May 2024, para 14.
European Data Protection Board (EDPB), *Opinion 28/2024 on Certain Data Protection Aspects Related to the Processing of Personal Data in the Context of AI Models*, adopted 17 December 2024, para. 18 stating "*[...] for the purpose of this Opinion, the EDPB refers to the "development phase" and to the "deployment phase". The development of an AI model covers all stages before any deployment of the AI model, and includes, inter alia, code development, collection of training personal data, pre-processing of training personal data, and training. The deployment of an AI model covers all stages relating to the use of an AI model and may include any operations conducted after the development phase*".
[90] Commission Nationale de l'Informatique et des Libertés (CNIL), 'How to Deploy Generative AI: CNIL Provides Initial Clarifications' (18 July 2024) <https://www.cnil.fr/en/how-deploy-generative-ai-cnil-provides-initial-clarifications> accessed 30 July 2025.
Information Commissioner's Office (ICO), 'Annex A: Fairness in the AI Lifecycle' (Guidance on AI and Data Protection, updated 15 March 2023) <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/artificial-intelligence/guidance-on-ai-and-data-protection/annex-a-fairness-in-the-ai-lifecycle/> accessed 30 July 2025.

an AI model to prevent fraud among its users, the model will be trained from the outset using data pertinent to achieving that purpose (e.g., country of residence, payment methods, etc.), excluding any information that does not contribute to the model's development or improvement for that specific purpose. Conversely, attempting to use the same model for unrelated purposes — such as profiling users for marketing communications — would be not only practically ineffective, but would in fact require entirely different training and data inputs. The above considerations also apply to the so-called general-purpose AI models (GPAI), defined as AI models "*capable of competently performing a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of downstream systems or applications*"[91]. In this sense, large generative AI models are a typical example for a general-purpose AI model, given that they allow for flexible generation of content, such as in the form of text, audio, images or video, that can readily accommodate a wide range of distinctive tasks[92]. However, although general-purpose AI models are by their very nature designed to enable a multiplicity of downstream uses and applications, both their initial and subsequent training are always guided by an overarching purpose. In the case of initial training, this purpose lies in the developer's intention to place on the market — typically for commercial ends — a model that is as high-performing as possible and can therefore be used by a broad range of subsequent users. Similarly, downstream users who seek to integrate and further customize the training of such models will do so with the aim of achieving the specific purposes for which they have chosen to use the underlying model (for example, to generate content for a marketing campaign).

Furthermore, treating the development phase and the implementation phase as two autonomous purposes, each requiring a distinct legal basis, would entail evident and problematic consequences for the exercise of data subjects' rights. Consider, for example, the scenario in which individuals consent to the processing of their data for one phase, such as implementation, but refuse or subsequently withdraw their consent (or raise an objection) for another, such as training. This would generate a logical impasse whereby the controller might be authorized to deploy a model that, paradoxically, it is not permitted to develop, or conversely, to train a model that it is not subsequently entitled to use.

Upon closer scrutiny, it is clear that whenever a model is developed, the fundamental question that must be asked is: "For what purpose is this model being developed?". By contrast, developing a model without a clearly defined and concrete initial purpose — based merely on the abstract intention to "train an AI model" for undefined purposes — is inherently at odds with fundamental data protection principles. This interpretation is fully in line with the GDPR itself, which, when choosing the most appropriate legal basis,

[91] Article 3(63) of Regulation (EU) 2024/1689.
[92] Recital 99 of Regulation (EU) 2024/1689.

always focuses on the purposes rather than the various processing stages through which the controller pursues those purposes. Indeed, recital 32 makes clear that consent must cover all processing activities carried out for the same purpose and that, only where multiple purposes are involved, separate and specific consent must be obtained for each.

Ultimately, when choosing between legitimate interest and consent as the most appropriate legal basis for AI model training, one must move beyond the rigid conceptual divide between the training and deployment phases, and focus instead from the outset on the single overarching purpose for which the model is conceived, developed, trained, improved, and ultimately deployed. This purpose — provided it remains consistent throughout the entire model's lifecycle — should be the key criterion for determining the most appropriate legal basis.

*Emanuele Scattarreggia**

GENERAL SECTION

AI-DRIVEN SMART CONTRACTS

ENHANCING CONSUMER PROTECTION OR EXACERBATING CONSUMER PROTECTION CHALLENGES?

Abstract

The integration of artificial intelligence (AI) into smart contracts holds the potential to both enhance and exacerbate consumer protection challenges. Since the AI system embedded within the contract's code enables a high degree of contractual personalisation – by tailoring the legal agreement to the unique characteristics of the targeted individual consumer, thanks to its capacity to process large amounts of personal and behavioural data in real time – it opens the door not only to scenarios of AI-powered consumer manipulation, but also to the promising opportunity of a consumer-centric AI. Such an AI would serve the consumer's best interests by adapting the contract to their specific needs and preferences, while protecting them from – rather than exploiting – their information, cognitive, and digital vulnerabilities. This research aims to assess whether the EU legal framework – particularly the UCPD, UCTD, AI Act, GDPR, and DSA – adequately ensures that these technologies are designed and deployed with the consumer's well-being at their core. The paper explores AI-related risks such as digital manipulation, personal data exploitation, and the black-box problem inherent in algorithmic opacity, while also addressing the liability challenge in cases of consumer harm. Ultimately, it seeks to answer whether AI-driven smart contracts can truly foster a high level of consumer protection in the AI era, by offering novel interpretations of the existing legal framework and advancing proposals for reform aligned with the fairness-by-design approach and informed by behavioural science insights.

JEL CLASSIFICATION: K11, K12, K13, K15, K24, K38, K42

SUMMARY

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10.13135/2785-7867/12837

1 Introduction

The integration of artificial intelligence (AI) into smart contracts marks a significant shift in digital legal agreements, with the potential to both enhance and complicate consumer protection[1] within the European Union (EU). Smart contracts – self-executing agreements based on predefined rules (*if* a condition is met, *then* the obligation is performed) – have long been praised for their efficiency[2], automation[3], and ability to reduce transaction costs[4]. However, these advantages also introduce legal and ethical challenges, particularly in consumer protection[5]. The EU has sought to safeguard consumers through legal acts – such as the Unfair Commercial Practices Directive (UCPD[6]), Unfair Contract Terms Directive (UCTD[7]), General Data Protection Regulation (GDPR[8]), AI Act[9], and Digital Services Act (DSA[10]). Yet, as AI-driven smart contracts evolve, they present new complexities that existing legal frameworks struggle to address, highlighting the pressing need for future-proof regulation.

AI-driven smart contracts bring greater adaptability and compliance monitoring, potentially improving fairness and transparency by dynamically adjusting contract terms and predicting legal risks. AI can automate compliance with EU (and domestic) laws, ensuring contracts respect consumer rights, privacy, and non-discrimination principles. However, these contracts also introduce new risks, including opacity in decision-making (black-box AI), potential biases, and challenges in accountability and liability.

This paper examines whether AI-driven smart contracts ultimately enhance consumer protection or exacerbate regulatory challenges, by addressing the following overarching research question:

- Can AI-driven smart contracts ensure a high level of consumer protection in the EU?

[1] *See* Pınar C Aksoy, 'AI and Smart Consumer Contracts' in Larry A DiMatteo and others (eds), *The Cambridge Handbook of AI and Consumer Law* (Cambridge University Press 2024) 99-115.
[2] Ohm Patel, 'AI-Driven Smart Contracts' (2024) 3(4) Journal of Artificial Intelligence & Cloud Computing 1-4.
[3] Alexander Savelyev, 'Contract Law 2.0: «Smart» Contracts As the Beginning of the End of Classic Contract Law' (2016) Higher School of Economics Research Paper No. WP BRP 71/LAW/2016 <https://ssrn.com/abstract=2885241> accessed 28 May 2025.
[4] *See* Lin W Cong and others, 'Scaling Smart Contracts via Layer-2 Technologies: Some Empirical Evidence' (2023) 69 (12) Management Science 7306-7316. Cf. Massimiliano Vatiero, 'Smart contracts and transaction costs' (*Oxford Law Blogs*, 10 October 2018) <https://blogs.law.ox.ac.uk/business-law-blog/blog/2018/10/smart-contracts-and-transaction-costs> accessed 28 May 2025.
[5] *See* Geraint Howells, 'Protecting Consumer Protection Values in the Fourth Industrial Revolution' (2020) 43 Journal of Consumer Policy 154-158.
[6] Directive 2005/29/EC.
[7] Council Directive 93/13/EEC.
[8] Regulation (EU) 2016/679.
[9] Regulation (EU) 2024/1689.
[10] Regulation (EU) 2022/2065.

To answer this question, it explores manipulative AI practices, privacy risks, transparency concerns, and the need for regulatory adaptation, drawing on interdisciplinary insights from law, economics, and behavioural science. Finally, this paper proposes a fairness-by-design approach as a possible regulatory solution to ensure that AI-driven smart contracts align with EU consumer protection goals.

2 AI-Driven Smart Contracts & Manipulation Risks

The integration of AI into smart contracts[11] introduces novel consumer protection concerns, particularly in relation to manipulative practices that rely on algorithmic, data-driven analyses to tailor contract terms to the individual consumer they address[12]. Unlike traditional smart contracts, which operate on predefined and unmodifiable rules without adaptability, AI-driven smart contracts can dynamically modify contract terms and conditions based on real-time data[13]. By analysing and profiling consumers, including their online behaviour[14], they enable a high degree of contractual personalisation. While this adaptability can enhance efficiency and fairness – especially when these flexible features are used to better protect consumers from their information, cognitive, and digital vulnerabilities – it also has the potential to create new asymmetries of power between traders and consumers[15].

One of the most pressing concerns is *digital manipulation*[16]. AI-driven smart contracts can leverage machine learning to detect patterns in consumer behaviour, preferences, and decision-making processes, allowing firms to optimise contract terms in ways that

[11] *See* Gérardine Goh Escolar, 'Addressing Digital Vulnerability Through Private International Law' in Camilla Crea and Alberto De Franceschi (eds), *The New Shapes of Digital Vulnerability in European Private Law* (Nomos 2024) 344.

[12] AI's ability to process data and personalise outputs for its individual recipient may further expose the vulnerability condition, which is an intrinsic characteristic of all human beings. This could lead to a shift in consumer protection standards, where the vulnerable consumer becomes the norm rather than the exception, challenging the traditional average consumer standard. Cf. Geraint Howells (n 1) 5. On vulnerability as a universal human condition, *see* e.g. Martha A Fineman, 'The Vulnerable Subject: Anchoring Equality in the Human Condition' (2008) 20 Yale Journal of Law & Feminism 1, 1-23.

[13] On the adaptability potential of smart contracts interacting with real-time data, *see* e.g. Oluwafemi Elias and others, 'The evolution of green fintech: Leveraging AI and IoT for sustainable financial services and smart contracts implementation' (2024) 23 World Journal of Advanced Research and Reviews 1, 2717. *See* also OECD, 'Artificial Intelligence, Machine Learning and Big Data in Finance. Opportunities, Challenges, and Implications for Policy Makers' (2021) <https://www.oecd.org/en/publications/artificial-intelligence-machine-learning-and-big-data-in-finance_98e761e7-en.html> accessed 28 May 2025, 34-35.

[14] The technique is similar to that employed by recommender systems: the AI system analyses consumer data to deliver a personalised output – namely, contract clauses. Moreover, the visual representation of the legal agreement and the way information is highlighted may be tailored to the specific consumer targeted by the trader. Given this, the effectiveness of the output in terms of the consumer's well-being depends on two key factors: 1) the quality of the data processed and the efficiency of the processing system; and 2) the good intentions of the traders, who must prioritise consumer interests over merely maximising corporate profits. Cf. Luigi Portinale and Alessandro Abuton, 'Artificial Intelligence for Consumers. Advances in Recommendation Systems' in Larry A DiMatteo and others (eds) (n 1) 9-18. *See* also Hal R Varian, 'Computer Mediated Transactions' (2010) 100 The American Economic Review 2, 6.

[15] Cf. Mateja Durovic, 'AI and Existing EU Consumer Law' in Larry A. DiMatteo and others (eds) (n 1) 49-50.

[16] i.e., behavioural manipulation in a digital environment. It involves the use of digital technologies to exploit consumer emotional and cognitive vulnerabilities. *See* Philipp Hacker, 'Manipulation by algorithms. Exploring the triangle of unfair commercial practice, data protection and privacy law' (2023) 29 Eur Law J. 142-175.

benefit traders at the expense of consumers[17]. For example, AI could enable more sophisticated trader strategies of personalised pricing, adjust fees based on an individual's willingness to pay, or introduce exploitative terms tailored to specific consumer vulnerabilities[18]. Moreover, the use of *dark patterns*[19] – user interface designs that nudge users into making decisions they would not have otherwise made, to the detriment of their well-being – becomes particularly problematic, when incorporated into AI-driven smart contracts, as AI personalises these tactics through psychological profiling.

Finally, it is crucial to underscore that efficient markets rely on consumers making efficient choices. If AI-driven manipulation distorts the consumer decision-making process, competition risks devolving into a scenario where *the best manipulator wins*. Preventing such risks is essential to ensuring a healthy digital single market.

2.1 The role of the UCPD and the UCTD

Framing effects[20] and persuasive designs raise significant issues. AI-driven smart contracts could present information in ways that subtly influence consumer choices, steering them towards less favourable terms without explicit coercion. For instance, an AI-powered contract might emphasise certain benefits while downplaying hidden costs, shaping consumer decisions through the selective presentation of terms, thereby leveraging the *framing effect*. Such persuasive techniques challenge informed consent, the principle of good faith, and professional diligence, raising concerns about the validity[21] and fairness of AI-driven legal agreements.

Under the UCPD, a commercial practice is deemed *unfair* – and consequently, any contract resulting from such a practice may also be considered unfair – if it is contrary to *professional diligence* and distorts consumer economic behaviour, as established by

[17] In October 2024, the EU Digital Fairness Fitness Check identified pressing concerns: dark patterns, manipulative design and data-driven personalisation tactics are exploiting cognitive vulnerabilities, while existing laws lack adequate safeguards for consumers in today's digital age. Moreover, it highlighted that smart contracts pose significant risks: reduced control, hidden biases, and challenges in complying with pre-contractual requirements. As AI becomes increasingly central to consumer transactions, updating regulatory frameworks for AI and unfair commercial practices is vital to ensure a high level of consumer protection in the digital market.

[18] AI's potential to understand consumers better than they understand themselves – enabled by its capacity to process vast amounts of data – exposes them to the trader's intentions, whether benevolent or exploitative. This creates a new form of power imbalance, as traders can probabilistically predict consumer behaviour and leverage this asymmetry for profit. Cf. Serge Gijrath, 'Consumer Law as a Tool to Regulate Artificial Intelligence' in Hans-W Micklitz and others, *Constitutional Challenges in the Algorithmic Society* (Cambridge University Press 2021) 281.

[19] Recital 67 DSA describes them as follows: "Dark patterns on online interfaces of online platforms are practices that materially distort or impair, either on purpose or in effect, the ability of recipients of the service to make autonomous and informed choices or decisions".

[20] The framing effect occurs when information is presented to the consumer in a way that manipulates their perception and, consequently, their decision. For instance, this occurs when the trader highlights the benefits while obscuring the costs associated with a proposed transaction.

[21] If a valid contract necessitates consent, and the consumer's consent is the result of trader manipulation, can it truly be considered genuine consent – especially when the consumer might have acted differently, perhaps even choosing not to sign the contract, had there been no manipulation? Cf. Maria Arango-Kure and Marcel Garz, 'Manipulation: An integrative framework of unethical influence in marketing' (2025) 197 (5) Journal of Business Research 115476.

Article 5(2). Furthermore, Article 5(3) recognises the (intrinsic) vulnerability (of certain groups) of consumers, due to their cognitive or physical state (*"infirmity*[22]*"*), age, or credulity "in a way which the trader could reasonably be expected to foresee".

In the case of dark patterns and other manipulative strategies, traders deliberately design digital choice architectures to steer consumer economic behaviour in ways that maximise business profits: consumers are viewed merely as tools to increase their wealth, deprived of their human dignity. Rather than engaging in fair competition based on the quality and price of products, businesses increasingly prioritise consumer manipulation as a *competitive advantage*[23]. As a result, market success is no longer determined by the superior value of a product, but rather by the trader's ability to exploit consumer vulnerabilities, thereby shifting the competitive market away from its foundational principles of transparency and informed consumer choice.

This critical situation highlights the pressing need for a harmonised EU legal framework that explicitly acknowledges the importance of behavioural sciences in interpreting and applying consumer protection norms[24].

Indeed, a behaviourally informed interpretation of the UCPD should consider traders' use of AI-driven smart contracts as an unfair commercial practice, *when* the AI system integrated into the smart contract has the purpose or material effect of manipulating consumers to the trader's advantage, through the dynamic adjustment of the contract's design based on real-time behavioural and personal data, by:

a) Distorting consumer economic behaviour, especially through the exploitation of their vulnerabilities – Article 5;
b) Deceiving consumers through the overall presentation of contractual information, by leveraging, e.g., the framing effect – Article 6;
c) Impeding rational decision-making, by failing to clearly present relevant information – Article 7;
d) Impairing the "consumer's freedom of choice or conduct" through undue influence, by adopting, e.g., dark patterns – Article 8.

On the other hand, Article 3(1) UCTD explicitly states that a term is *unfair* if it is contrary to good faith and "causes a significant imbalance in the parties' rights and obligations" at the expense of consumer well-being, when it is not individually negotiated.

[22] Emphasis added.
[23] As highlighted by Jon D Hanson & Douglas A Kysar, 'Taking Behavioralism Seriously: Some Evidence of Market Manipulation' (1999) 112 Harv. L. Rev. 1420: "Once one accepts that individuals systematically behave in nonrational ways, it follows from an economic perspective that others will exploit those tendencies for gain". Consequently, it is fundamental that legal frameworks adequately address the risk of consumer manipulation. *See* Ryan Calo, 'Digital Market Manipulation' (2014) 82(4) The George Washington L. Rev. 995, 1000-1001.
[24] Regarding the need for a new interpretation of the UCPD that takes into account the consumer decision-making process and a behavioural law and economics approach, *see*, e.g., Anne-Lise Sibony, 'Can EU Consumer Law Benefit from Behavioural Insights? An Analysis of the Unfair Practices Directive' (2014) 6 European Journal of Private Law 901-942.

AI-driven smart contracts are forms of *contracts of adhesion*[25]: the contract is drafted by the trader – who predetermines the code and the AI system that operates within it, adjusting contract terms – whereas the consumer merely adheres to unilaterally drafted legal terms and conditions[26]. When a trader designs the contract with the sole intent of manipulating consumer behaviour, such conduct runs counter to the principle of good faith[27]. Indeed, this principle imposes upon parties a standard of conduct inspired by an ideal of loyal cooperation – one that weighs even more heavily on the trader, given the contractual power imbalance that physiologically characterises B2C contractual relationships.

Moreover, Article 4(1) establishes that the *unfairness assessment* shall include "all the circumstances attending the conclusion of the contract". In this context, AI-driven smart contracts deserve special scrutiny. These technologies – capable of knowing consumers better than they know themselves, thanks to AI-enhanced analyses of consumer behavioural profiles[28] – may be designed in ways that push consumers towards agreeing to "individually negotiated" clauses, thereby blurring the line of authentic consent[29]. If consumers are behaviourally nudged into accepting binding terms by bypassing their conscious deliberation, can we still speak of genuine consent? And if so, to what extent? If the answer is negative, then no valid agreement has been reached, and such clauses should be considered legally ineffective[30].

Finally, if we adopt a behaviourally informed approach to the interpretation of the UCTD as well[31], we should not hesitate to consider unfair any term that causes a significant imbalance to the detriment of the consumer, when it results from AI-enhanced behavioural manipulation that exploits information, cognitive, and digital consumer vulnerabilities. As a consequence, such terms should not be considered binding, and the contract should be balanced – "if it is capable of continuing in existence without the unfair terms[32]" – by recognising as effective only those terms and conditions that the consumer would have agreed to in the absence of digital manipulation.

[25] Cf. Oscar Borgogno, 'Usefulness and Dangers of Smart Contracts in Consumer Transactions' in Larry A DiMatteo and others (eds), *Smart Contracts, Blockchain Technology and Digital Platforms* (Cambridge University Press 2019) 294.
[26] *Rectius*: the consumer agrees to enter into a legal agreement whose terms are generated and adjusted by an AI system integrated into the smart contract's code, as implemented by the trader.
[27] On the other hand, in this writer's view, the use of AI within a smart contract may be consistent with the principle of good faith where behavioural profiling is employed to nudge consumers towards choices that genuinely serve their interests – provided that the AI system respects consumer autonomy.
[28] Stefano Faraoni, 'Persuasive Technology and computational manipulation: hypernudging out of mental self-determination' (2023) 6 Front. Artif. Intell. 2.
[29] On the subtle strategies companies may employ to obtain consent manipulatively, *see* e.g. Neil Richards and Woodrow Hartzog, 'The Pathologies of Digital Consent' (2019) 96(6) Washington University Law Review 1489. For the reasons why manipulated consent should not count as proper consent, *see* David Alm, 'Manipulation, Responsibility and Rights' (2013) 47 J Value Inquiry 4-10.
[30] Faraoni (n 28) 7-11.
[31] *See* Aleksa Radonjić, 'Behavioral approach to unfair terms and conditions in EU consumer law' (2018) 62(8) Strani pravni zivot 7-21.
[32] Article 6(1) UCTD.

In conclusion, AI-driven smart contracts challenge the future-proof nature of the UCPD and UCTD. Since these directives were not designed with AI technologies in mind, it is worth questioning whether they are capable of adequately protecting consumers in the AI era. While their application to AI contexts can be extended through an evolutive interpretation, legislative updates may be necessary to fully address the nuanced interactions between AI and consumers in the contractual realm. At the same time, it is important to recognise that AI can also play a positive role in enhancing consumer protection, through consumer-centric applications[33] designed to ensure compliance with EU law, by proactively flagging or blocking potential violations before harm occurs and explaining where and why such breaches have been detected[34].

2.2 The role of the AI Act

The AI Act plays a critical role in addressing manipulation risks[35], highlighting the vital need to ensure that AI systems and applications are *human-centric*[36] and respectful of *human dignity*[37] and *personal autonomy*[38]. At its core, this regulation aims to ensure that AI is designed and employed in a manner that serves people and foster their well-being[39]. To achieve this goal, it adopts a *risk-based approach*, which categorises AI systems into four risk categories – *unacceptable*, *high*, *limited*, and *minimal* – and follows the motto: "the higher the risk, the stricter the rules[40]".

Given the potential behavioural manipulation risks posed by AI-driven smart contracts, a critical question arises:

- Should AI-driven smart contracts be considered high-risk AI systems or prohibited AI practices under the EU AI Act?

[33] Marco Lippi and others, 'Consumer protection requires artificial intelligence' (2019) 1 Nature Machine Intelligence 168-169.
[34] *See*, e.g., the Claudette Project, "a research project aiming at automation of personal data and consumer law enforcement using machine learning": <http://claudette.eui.eu/index.html> accessed 28 May 2025. Cf. Federico Ruggieri and others, 'Detecting and explaining unfairness in consumer contracts through memory networks' (2022) 30 Artificial Intelligence and Law 59-92.
[35] Particularly, Recital 28 AI Act acknowledges that AI "can also be misused and provide novel and powerful tools for manipulative, exploitative and social control practices". Recital 29 addresses "AI-enabled manipulative techniques" that "can be used to persuade persons to engage in unwanted behaviours, or to deceive them by nudging them into decisions in a way that subverts and impairs their autonomy, decision-making and free choices".
[36] Recital 1 and Article 1(1) AI Act.
[37] The §11 Asilomar AI Principle – part of a set of guidelines developed during the 2017 Asilomar conference, which convened experts in AI, economics, law, ethics, and philosophy to discuss beneficial AI – states that "AI systems should be designed and operated so as to be compatible with ideals of human dignity, rights, freedoms, and cultural diversity": <https://futureoflife.org/open-letter/ai-principles/> accessed 28 May 2025. This principle supports the argument that a just legal framework should promote human-centric AI and allow only such systems to be deployed and maintained in real-world applications.
[38] Recital 27 AI Act.
[39] ibid.
[40] Martin Ebers, 'Truly Risk-based Regulation of Artificial Intelligence. How to Implement the EU's AI Act' (2025) 16 (2) European Journal of Risk Regulation 684-703.

As previously discussed, these technologies can potentially distort consumer behaviour. To determine their appropriate regulatory classification, it is essential to evaluate the risks they pose.

Article 5 AI Act establishes that prohibited AI practices are those that pose an *unacceptable risk*[41]. The relevant prohibitions include:

1. Subliminal techniques *beyond* a person's consciousness, or *purposefully* manipulative or deceptive techniques: AI systems "with the *objective*, or the *effect* of materially distorting the behaviour of a person or a group of persons by appreciably impairing their ability to make an informed decision[42]". Moreover, to be prohibited, these AI practices must cause individuals to make a decision that – in the absence of such practices – they would not have made[43];
2. Exploitation of vulnerabilities: AI systems that exploit people's vulnerabilities "with the objective, or the effect, of materially distorting" the vulnerable person's behaviour.

In both cases, to be prohibited, the AI practice should:

a) cause significant harm, or

b) be reasonably likely to cause significant harm[44].

Consequently, AI-driven smart contracts that are designed to – or materially have the effect to – target and exploit (digitally and cognitively) vulnerable consumers, and (are reasonably likely to) cause *significant* harm[45] should be considered prohibited, under Article 5.

On the other hand, it is more plausible that they may fall under the high-risk category, as defined in Article 6(2) and Annex III. Article 6(2) refers to Annex III, which classifies certain AI systems as high-risk, in addition to those classified as such by Article 6(1).

In particular, Annex III(1) classifies as high-risk AI systems those that are listed in the area of biometrics[46]. Within the context of AI-driven smart contracts, two categories are specifically relevant:

[41] Recital 179 AI Act.

[42] Article 5(a) AI Act. Emphasis added.

[43] This formulation strongly echoes the provisions of the UCPD regarding: 1) the unfairness of a commercial practice, Article 5(2b); 2) misleading actions, Article 6(1); 3) misleading omissions, Article 7(1); 4) aggressive commercial practices, Article 8(1).

[44] Whenever an AI system processes consumers' personal data to behaviourally manipulate them against their own well-being – thereby partially or entirely impeding conscious decision-making – the practice itself constitutes a harm to, or a threat against, human autonomy. Cf. Shoshana Zuboff, 'The Age of Surveillance Capitalism. The Fight for a Human Future at the New Frontier of Power' (PublicAffairs 2019) 127.

[45] The European Commission, Brussels, 4.2.2025, C(2025) 884 final, ANNEX, 28, highlighted that the concept of harm includes "physical, psychological, financial, and economic harms that may compound with broader societal harms in certain cases".

[46] The notion of "biometric data" under the EU AI Act should be interpreted consistently with the definitions provided in Article 4(14) GDPR, Article 3(18) of Regulation (EU) 2018/1725, and Article 3(13) of Directive (EU) 2016/680, as explicitly referenced in Recital 14 of the AI Act. These instruments uniformly define biometric data as "personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person".

a) "AI systems intended to be used for biometric categorisation[47]";
b) "AI systems intended to be used for emotion recognition[48]".

Moreover, Article 6(3) specifies that for an AI system to be labelled as high-risk, it must pose "a *significant* risk of harm to the health, safety, and fundamental rights of natural persons[49]", including "materially influencing the outcome of decision making". However, if the AI system employs biometric categorisation or emotion recognition, performing the profiling of consumers, it "shall always be considered to be high-risk".

Consequently, the crucial question now is:

- Except when prohibited, should AI-driven smart contracts always be classified as high-risk?

An affirmative answer to this question is the most likely. Within the EU legal framework, an AI-driven smart contract is inherently high-risk if it behaviourally profiles the consumer. For the purposes of the AI Act, profiling involves the "automated processing of personal data" to use such data, particularly for analysing or predicting personal preferences, interests, and behaviour – among other characteristics – of a natural person[50], such as the consumer. Considering that the personalisation functionalities of the smart contract rely on the capabilities of the AI system, integrated into its computer code, to adapts terms and conditions for the individual person by inferring their behavioural patterns, vulnerabilities, needs, and preferences, the AI-driven smart contract is by nature high-risk under the AI Act.

2.3 Algorithmic Vulnerability

The evaluation of risks associated with AI systems embedded in smart contracts must also take into account the emerging dimension of *digital vulnerability*, sometimes referred to as *algorithmic vulnerability*[51]. This concept captures how AI-driven personalisation can exploit consumers' cognitive biases and behavioural tendencies, thereby increasing their susceptibility to manipulation and undue influence.

In the contractual landscape, this emerging risk demands a robust regulatory response to ensure that AI-powered contracts do not become instruments of behavioural manipulation, but rather tools that empower and protect consumers. To this end, strengthening transparency obligations, prohibiting exploitative AI practices, and aligning

[47] AI used for biometric categorisation within a smart contract may process personal data to classify individuals into behavioural or psychological categories. This can inform the dynamic adaptation of contract terms, effectively tailoring the agreement on the individual consumer addressed by the contract.
[48] Emotion recognition AI technologies integrated into smart contracts may infer or detect a consumer's emotional state through the analysis of personal data and their online behaviour. Such insights can be used to personalise or influence the contractual offer – for instance, by adapting terms to the consumer's emotional context or by prompting a decision to conclude a contract based on their inner state.
[49] Emphasis added.
[50] Article 3(52) AI Act and Article 4(4) GDPR.
[51] Teresa Rodríguez de las Heras Ballell, 'Digital Vulnerability and the Formulation of Harmonised Rules' in Camilla Crea and Alberto De Franceschi (eds), *The New Shapes of Digital Vulnerability in European Private Law* (Nomos 2024) 291.

AI-enhanced contracting systems with existing EU consumer protection frameworks are essential safeguards for mitigating such risks. As the EU's regulatory framework on AI continues to evolve, particular attention must be paid to the intersection of automated contracting, AI-driven personalisation, and consumer rights. This must be done in a manner that preserves space for innovation while upholding the fundamental rights of individuals.

In this context, it is critical to recognise that consumers do not always act in fully rational ways[52], and that AI systems, when exploiting cognitive vulnerabilities, may amplify these irrational tendencies. Ensuring a high level of consumer protection in the digital market therefore requires that AI-driven smart contracts are designed not to take advantage of these vulnerabilities, but to guide consumers towards choices that maximise their well-being. In doing so, AI not only respects consumer autonomy but also contributes to the development of more efficient and fair markets[53]. A digital economy in which competition is based on the quality of goods and services – rather than on a business's capacity to manipulate consumer behaviour – is ultimately more sustainable and aligned with the broader public interest[54].

The overarching objective should remain clear: AI must be designed and employed as a tool that serves humanity, ultimately fostering a fair, just and consumer-centric digital market.

3 Ai-Driven Smart contracts & GDPR compliance

AI-driven smart contracts rely on the processing of consumer data to function effectively, raising significant concerns regarding their compliance with the GDPR. Unlike traditional smart contracts, which operate based on predefined and immutable rules, AI-enhanced versions can analyse consumer behaviour and preferences to dynamically adjust contractual terms and conditions based on real-time personal data analysis. While this capability enhances adaptability and contract personalisation, it simultaneously introduces substantial risks of personal data exploitation[55].

[52] *See*, e.g., Daniel Kahneman, *Thinking fast and slow* (Farrar, Straus and Giroux 2011); Richard Thaler, *Misbehaving: The Making of Behavioral Economics* (W. W. Norton & Company 2015); Oren Bar-Gill, 'Consumer Transactions' in Eyal Zamir and Doron Teichman (eds), *The Oxford Handbook of Behavioral Economics and the Law* (OUP 2014) 465-490; Botond Koszegi, 'Behavioral Contract Theory' (2014) 4 (52) Journal of Economic Literature 1075-1118.
[53] Ioannis Lianos, 'Value extraction and institutions in digital capitalism: Towards a law and political economy synthesis for competition law' (2022) 1 European Law Open 887-888.
[54] ibid. 869-871.
[55] The integration of AI into a smart contract endows it with dynamic and adaptive capabilities. Through machine learning algorithms, such contracts can autonomously modify their terms and conditions based on the behavioural profile of the consumer with whom they interact – often relying on oracles to retrieve data from external sources. In this context, the AI-driven smart contract functions as a responsive system with two core objectives: (1) to analyse and understand the consumer, and (2) to adapt contractual content accordingly. Personal data thus become the operational 'fuel' that enables the contract to achieve these aims. Cf. Mimi Zou, 'When AI Meets Smart Contracts: The Regulation of Hyper-Autonomous Contracting Systems?' in Martin Ebers and others (eds), *Contracting and Contract Law in the Age of Artificial Intelligence* (Hart 2022) 48-49.

In particular, to ensure compliance with the GDPR, AI-driven smart contracts that collect and process consumer data must adhere to the following principles:

a) **Lawfulness, fairness, and transparency:** personal data processing must be lawful, fair, and transparent[56];
b) **Purpose limitation**[57]: personal data must be collected for "specified, explicit, and legitimate purposes", and further processing is allowed only if compatible with those purposes. If further processing serves a public interest – i.e., ensuring a high level of consumer protection and market efficiency – it shall "not be considered to be incompatible with the initial purposes[58]";
c) **Data minimisation**[59]: personal data must be "adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed[60]";
d) **Contractual necessity**: personal data processing is lawful *if* it is "necessary for the performance of a contract to which the data subject is party[61]";
e) **Consent**: if personal data processing is based on the data subject's (i.e., the consumer's) consent[62], the controller (i.e., the trader) must be able to demonstrate it[63].

Consequently, the key question is:

- Can AI-driven smart contracts comply with the GDPR?

3.1 The privacy-by-design solution

The compliance of AI-driven smart contracts with the GDPR ultimately hinges on their design and implementation. A robust approach to ensuring such compliance may involve the adoption of the *privacy-by-design* approach, as enshrined in Article 25. This possible solution entails the integration of data protection principles into the architecture of the AI system that is incorporated within the smart contract itself[64].

First, to comply with the principle of **lawfulness, fairness, and transparency**, a privacy-by-design model should:

- Embed explainability and interpretability mechanisms to ensure that consumers can understand how and why their data are processed. This may include the integration of explainable AI techniques that provide clear, non-technical, and accessible explanations tailored to the consumer's level of comprehension;

[56] Article 5(1)(a) GDPR.
[57] Cf. W Gregory Voss, 'Data Protection Issues for Smart Contracts' in Marcelo Corrales Compagnucci and others (eds), *Smart Contracts: Technological, Business and Legal Perspectives* (Hart 2021) 97-98.
[58] Article 5(1)(b) GDPR.
[59] Gregory Voss (n 57) 98.
[60] Article 5(1)(c) GDPR.
[61] Article 6(1)(b). *See*, also, Recital 44 GDPR.
[62] Article 6(1)(a) GDPR.
[63] Article 7(1) GDPR.
[64] Cf. Lokke Moerel, 'Blockchain and Data Protection' in Larry A DiMatteo and others (eds) (n 25) 224-225.

- Provide user-friendly interfaces that enable consumers, as data subjects, to access information on the processing of their personal data and to effectively exercise their rights under Articles 13-22 GDPR.

Second, the proposed approach has the potential to enforce the **purpose limitation** principle by:

- Embedding purpose-binding protocols within AI-driven smart contracts, ensuring that data are processed solely for pre-defined contractual purposes;
- Impeding *function creep* – where data processing goes beyond its original purposes – through the incorporation of data governance mechanisms into the design of smart contracts.

Third, in relation to the principle of **data minimisation** – which requires the processing of only strictly necessary data – AI-driven smart contracts may, by their nature, risk excessive behavioural profiling and data collection. A privacy-by-design approach can mitigate this risk by:

- Preventing the processing of personal data that are not strictly relevant to achieving the contract's pre-defined purposes;
- Enforcing automatic data retention policies that restrict the unnecessary storage of personal information (storage limitation[65]).

Fourth, where the processing of personal data is lawful on the basis that it is strictly necessary for the performance of a contract to which the consumer is a party (**contractual necessity**), the privacy-by-design approach can support compliance by embedding the *necessity assessments* within the AI system to ensure that each instance of personal data processing is genuinely essential for the execution of the contract.

Fifth, when AI-driven smart contracts rely on **consumer consent** as the legal basis for personal data processing, the privacy-by-design approach should enhance compliance through:

- Embedding dynamic consent management mechanisms that allow consumers to review, modify, or withdraw consent at any time[66];
- Providing granular consent options, enabling consumers to approve specific data processing activities while rejecting others;
- Implementing tamper-proof consent logs that document the history of consent, thereby strengthening trust, accountability, and verifiability;

[65] Article 5(1)(e) GDPR.

[66] Article 7(3) GDPR establishes the right for data subjects to withdraw their consent at any time. Consequently, consumers must be able to revoke consent at any point, even after the contract has been executed, provided that the data controller – i.e. the trader – continues to maintain access to their personal data. In the context of AI-driven smart contracts, which are typically designed to automatically execute once the "if" condition is met, consumers must have the ability to review, modify, or withdraw their consent where their personal data continues to be retained post-execution. Additionally, consumers should be able to determine the specific purposes for which their data is used – whether to facilitate future transactions or for any other reason. Ultimately, the privacy-by-design approach seeks to empowers consumers, enabling them to maintain control over the use of their personal data throughout the entire lifecycle of the contract.

- Ensuring that any secondary use of data (e.g., for AI model training) is subject to explicit consumer consent[67] or to a legitimate interest assessment[68].

3.2 Automated decision-making

Another key legal question is whether AI-driven smart contracts qualify as *automated decision-making* (ADM) under Article 22 GDPR[69]. Article 22(1) states that the "data subject shall have the *right not to* be subject to a decision based solely on automated processing, including profiling, which produces legal effects[70]" that concern them. AI-driven smart contracts fall within this category[71] because they autonomously adjust contract terms and conditions based on real-time consumer data analysis – which may include behavioural profiling – thereby tailoring contractual obligations to the individual consumer they address.

As previously discussed, these contracts typically function as *contracts of adhesion*, where the sole decision consumers face is *whether* they want to enter into the agreement, without any (or significant) negotiation power. Consequently, consumers are asked to make a binary decision: to accept or reject the contract as is. If they accept, they enter into a legal agreement that has been tailored for them. The AI system within the smart contract has processed their data and dynamically shaped the contract, determining an automated decision that produces legal effects concerning them – e.g. by establishing the reciprocal contractual obligations.

However, Article 22(2)(a) provides an exemption to the applicability of the first paragraph if the decision "is necessary for entering into, or performance of, a contract between the data subject and a data controller". In this context:

- The data subject is the consumer, whose personal data are collected and processed by the AI system embedded within the smart contract;
- the data controller is the trader, who "determines the purposes and means of the processing of personal data[72]".

For instance, an AI-driven smart contract may determine whether the consumer can enter into the contract – for example, by assessing their creditworthiness. Moreover, the ADM process could shape contractual obligations, thereby directly involving the contract's performance. In this context, the ADM is integral to the contract's performance, as it dynamically determines the content of the reciprocal obligations and, once the encoded condition is met (e.g., the consumer pays the price), executes them automatically.

[67] Article 6(1)(a) GDPR.
[68] Article 6(1)(f) GDPR.
[69] *See* Michèle Finck, 'Smart Contracts and Article 22 GDPR' (2019) 9 (2) International Data Privacy Law 82-84.
[70] Emphasis added.
[71] Cf. Olumide Babalola, 'Viewing Smart Contracts Through GDPR Lenses' (2022) 10(4) Global Journal of Politics and Law Research 78.
[72] Article 4(7) GDPR.

However, under the European Data Protection Board's narrow reading of *necessity*, the question is whether "other effective and less intrusive means[73]" could be adopted in place of ADM to achieve the contractual purposes. Controllers "must be able to show that this type of processing is necessary, taking into account whether a less privacy-intrusive method could be adopted[74]". A stricter interpretation may, therefore, exclude that the ADM is necessary for the performance of AI-driven smart contracts, on the basis that a traditional, entirely human-made contract remains a viable alternative. Yet, AI integration into the smart contract's code enables what humans cannot achieve (within reasonable timeframes), such as analysing consumer data in real time to deliver a contract individually tailored to the specific characteristics of the targeted consumer – which is the very reason why traders opt for this kind of technologies to shape their legal agreements. In sum, while a less privacy-intrusive method could theoretically be adopted, in the context of AI-driven smart contracts, such an alternative would undermine the defining contractual objective – the dynamic, real-time tailoring of terms and conditions to the individual consumer – and thus it should not be considered a functionally equivalent "means to achieve the same goal[75]".

Additionally, as an alternative to the *necessity assessment* required by Article 22(2)(a), another exemption to the first paragraph is provided under letter (c), which requires that the decision "is based on the data subject's explicit consent".

In both cases, the trader must "implement suitable measures to safeguard the data subject's rights and freedoms and legitimate interests[76]". At minimum, the following data subject's rights must be guaranteed:

- the right to obtain human intervention in the decision-making process;
- the right to express their point of view;
- the right to contest the decision[77].

Furthermore, Article 22(4) establishes that decisions "referred to in paragraph 2 shall not be based on special categories of personal data referred to in Article 9(1), unless point (a) or (g) of Article 9(2) applies and suitable measures to safeguard the data subject's rights and freedoms and legitimate interests are in place".

Article 9(1) categorises *biometric data* – defined as data "resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person[78]" – as a special category of personal data whose processing is, in principle,

[73] European Commission, Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679, 23.
[74] ibid.
[75] ibid.
[76] Article 22(3) GDPR.
[77] ibid.
[78] *See* (n 46).

prohibited. AI-driven smart contracts may, indeed, process this type of data to behaviourally profile consumers and, consequently, draft the contract accordingly.

However, this prohibition is not absolute. It does not apply when "the data subject has given explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject[79]". As a result, if the consumer has *explicitly* agreed to the processing of their data – for example, to allow the AI system to adjust the contract to better serve the consumer's interests – the prohibition is lifted. It is crucial, however, that the explicit consent relates to one or more clearly defined purposes.

Additionally, the prohibition does not apply *if* the processing of special categories of personal data "is necessary for reasons of substantial public interest[80]". The concept of public interest may include the objective of ensuring a high level of consumer protection, particularly when the AI-driven smart contract is designed to maximise the consumer's well-being, autonomy, and rights.

In this case, it is essential:

a) a proportionality assessment to the aim pursued;
b) respect for "the essence of the right to data protection[81]";
c) the safeguarding of the data subject's fundamental rights and interests through "suitable and specific measures[82]".

3.3 A legal crossroads

Ultimately, the compliance of AI-driven smart contracts with the GDPR depends on their design: how they are conceived and implemented determines their legitimacy. Moreover, assessing their actual purposes is essential to evaluate their compatibility with the EU legal framework.

If designed and implemented in a consumer-friendly manner, aiming at achieving consumer protection goals – such as safeguarding consumer rights, privacy, and autonomy – AI-driven smart contracts can contribute to the supranational objective of ensuring a high level of consumer protection.

Furthermore, if these technologies are designed in a way that fosters consumer trust in AI-driven transactions and the digital market, a privacy-by-design approach may also serve as a tool to enhance market efficiency. By protecting consumers – for instance, by nudging them towards optimal decision-making and more informed contractual choices[83] – the market itself is protected, as an efficient market depends on efficient consumers.

[79] Article 9(2)(a) GDPR.
[80] Article 9(2)(g) GDPR.
[81] ibid.
[82] ibid.
[83] Cass R Sunstein, 'The Ethics of Nudging' (2015) 32(2) Yale Journal on Regulation 434.

However, to achieve these goals, it is essential that consumers trust these technologies. Such trust can only be established if consumers feel that AI-driven smart contracts process their personal data in ways that comply with the GDPR and genuinely serve their interests.

Additionally, concerning the relationship between consumer protection law and data protection law, it is important to note that their boundaries are becoming increasingly blurred in our digitalised world[84]. When consumers engage in the digital market, they are not only potential contracting parties but also data subjects[85]. Therefore, ensuring that their personal data are processed lawfully and in their best interests is a vital condition for safeguarding consumer protection against data exploitation and digital manipulation[86].

A key question remains: should the EU introduce a dedicated regulation to address the unique opportunities and risks posed by AI systems and their integration into smart contracts, particularly in the context of personal data? If their use becomes more widespread in the future, the answer seems increasingly likely to be affirmative. Given their adaptive and dynamic nature, a specific regulation could provide legal certainty, balancing innovation with the principles and objectives of consumer and data protection[87].

4 Ai-Driven Smart contracts & the DSA

Online platforms may provide user-friendly web or mobile interfaces where consumers can access and interact[88] with AI-driven smart contracts. In this context, another relevant EU regulation is the DSA, which establishes a comprehensive legal framework for online platforms. While it does not directly regulate AI-driven smart contracts, it applies when these contracts are hosted, promoted, or executed via such digital environments.

Particularly, the DSA introduces obligations concerning three key areas, which are relevant to ensuring that AI-driven smart contracts contribute to achieving a high level of consumer protection: 1) platform liability, 2) content moderation, and 3) algorithmic transparency and fairness.

[84] Natali Helberger, 'The Perfect Match? A Closer Look at the Relationship between EU Consumer Law and Data Protection Law' (2017) 54(5) Common Market Law Review 1428.
[85] ibid 1430-1431.
[86] ibid 1458.
[87] It is essential that any future regulatory framework addressing AI and its integration into smart contracts not only mitigates the specific risks posed to personal data but also fosters human-centric innovation. Striking this balance requires a normative approach that ensures innovation is directed towards serving humankind – just as the processing of personal data must, according to the values enshrined in Recital 4 GDPR. In this light, innovation and data protection are not opposing forces but can be aligned through a legal framework that channels technological progress towards human- and consumer-centric goals. In this regard, a future-proof and innovation-oriented regulation should be capable of actively reinforcing GDPR compliance by harnessing the potential of AI within the evolving context of AI-driven contracting. *See* Michèle Finck, 'Blockchains and Data Protection in the European Union' (2018) 4 European Data Protection Law Review 32-35.
[88] Cf. Folkert Wilman and others, 'General Provisions' in Folkert Wilman and others (eds), *The EU Digital Services Act* (OUP 2024) 16.

4.1 Platform liability

The central question of this sub-paragraph is whether online platforms – that facilitate AI-driven smart contract transactions – could be held liable for non-compliant or harmful contractual terms and conditions under the DSA. Indeed, online platforms can serve as marketplaces – virtual spaces where AI-driven smart contracts are hosted and promoted, enabling consumers to enter into such legal agreements[89]. Consequently, if an AI-driven smart contract contains unfair terms, constitutes an unfair commercial practice, or violates the GDPR, should the platform hosting it be held liable[90]?

Under Article 3(i) DSA, online platforms are *hosting services* "that, at the request of a recipient of the service," store and disseminate information to the public. In particular, the recipient of the service may be a *trader*[91] – who advertises or sells products and services online – or a *consumer*[92] – who makes purchases online or views ads on social media platforms. In this context, AI-driven smart contracts can be hosted by an online platform, where traders can incentivise – and consumers can choose to enter into – this type of legal agreements[93].

According to Article 6(1), hosting service providers – for example, those who, enable traders to upload their smart contracts onto online platforms and consumers to visualise and agree to these contracts – are not liable "for the information stored at the request of a recipient of the service", provided that they are unaware that the content hosted is illegal or, once aware, act expeditiously "to remove or to disable access" to it.

However, this exemption from liability does not apply, and the hosting service provider can be held liable in the following cases:

1) When "the recipient of the service is acting under the authority or the control of the provider" – Article 6(2);
2) If the online platform allows B2C distance contract transactions[94] in such a way that it misleads the average consumer into believing that the information or the product/service (the object of the transaction) is being provided by the online platform or by a recipient of the service acting under its authority or control[95] – Article 6(3).

[89] Cf. ibid. 39-40.
[90] According to Article 3(h) DSA, "illegal content" refers to any information that is not in compliance with EU or domestic law. Accordingly, contractual clauses embedded in AI-driven smart contracts – when hosted and promoted by online platforms – may qualify as illegal content if they infringe the UCPD, UCTD, GDPR or AI Act. *See* ibid. 38–39.
[91] Article 3(f) DSA.
[92] Article 3(c) DSA.
[93] Cf. (n 88) 34.
[94] Indeed, B2C distance contract transactions fall within the scope of the DSA when concluded on online platforms. These platforms facilitate interaction between traders and consumers: the former promote and offer contracts, which the latter may choose to enter into. Ibid. 42.
[95] Under Article 31(1) DSA, online platforms providers – excluding micro and small enterprises – that facilitate B2C distance contract transactions must ensure that the design and organisation of their online interface enable traders "to comply with their obligations regarding precontractual information, compliance and product safety information". More broadly, they must comply with the provisions set out in Articles 29-32.

Additionally, Article 7 clarifies that if the intermediary service provider has – in good faith and diligently – voluntarily investigated or taken other measures to detect, identify, remove, or disable access to illegal content, the exemptions from liability set out in Article 6 may still apply.

This framework implies that, when an illegal AI-driven smart contract is hosted and/or promoted on an online platform, the platform provider may be held liable in the following cases:

1. **Failure to act**: the provider fails to remove the contract from the platform or disable consumer access to it, upon obtaining knowledge or awareness of the illegal content – namely, the legal agreement;
2. **Misleading design**: the online platform's design leads the average consumer to believe that the AI-driven smart contract, which constitutes a distance contract, is being offered and/or promoted by the online platform itself or by a recipient of the service acting under the provider's authority or control;
3. **Traders acting under the provider's control or authority**: the trader is acting under the authority or control of the provider[96] – i.e. the online platform provider and the trader are not independent entities.

In this context, if an online platform hosts or promotes AI-driven smart contracts that are unlawful – for instance, because they contain unfair terms in violation of the UCTD, constitute an unfair commercial practice under the UCPD, or process and collect data in a way that is not compliant with the GDPR – it is obliged to remove or restrict access to such contracts once it becomes aware of the illegal content on its platform.

Moreover, if the platform at issue is a very large online platform (VLOP) under Article 33, it faces additional duties, including conducting risk assessments and implementing risk mitigation measures[97]. Article 34(1) further establishes that VLOP providers have an obligation to "diligently identify, analyse, and assess any systemic risks", including:

1) "the dissemination of illegal content through their services[98]";
2) "any actual or foreseeable negative effect for the exercise of fundamental rights" – in particular, the fundamental rights to:

- Human dignity – which is at risk when consumers face digital manipulation and are treated merely as tools to increase corporate profits at the expense of their well-being;
- The protection of personal data – which requires strict compliance with the GDPR;
- Non-discrimination – which is threatened when the AI system embedded in the smart contract is biased, leading to suboptimal and harmful decision-making;

[96] Article 6(2) DSA.
[97] Sebastian K Stiković, 'The EU's Digital Services Act and Its Impact on Online Platforms' (2024) 85 European Union Law Working Papers 65-67.
[98] In the context of AI-driven smart contracts, they may be deemed illegal content when they do not comply with EU law (e.g., the UCTD, UCPD, GDPR, or AI Act).

- A high level of consumer protection – an objective that may be fully achieved when contracts are designed to concretely safeguard consumers from their vulnerability and guide them towards efficient economic decisions, thereby not impairing – but strengthening – their rationality, while respecting their autonomy.

Additionally, Article 35 states that VLOP providers have the duty to adopt "reasonable, proportionate, and effective mitigation measures", which must be "tailored to the specific systemic risks" that they address[99].

In sum, online platforms – particularly VLOPs – can be held liable if they knowingly host and/or promote unlawful AI-driven smart contracts, fail to act upon becoming aware of such illegal content, or design their services in a manner that misleads consumers about the platform's role in providing these contracts. This framework contributes to ensuring that AI-driven smart contracts are designed to achieve a high level of consumer protection. Therefore, if a contract fails to be consumer-friendly and foster rational decision-making – by exploiting consumers' vulnerability, manipulating their behaviour, or violating data protection rules – the platform must remove or disable consumer access to it. Failure to do so may result in liability for the platform itself.

4.2 The content moderation challenge

To comply with the DSA, the overall architecture of online platforms must be designed in a user-friendly manner, enabling anyone to report content – including AI-driven smart contracts – that they consider illegal[100]. This implies that platforms must establish mechanisms that allow consumers to flag unfair contract terms, dark patterns, and other forms of digital manipulation they believe they have encountered[101]. As a result, if such reports are substantiated[102] – demonstrating that the contract, hosted by the online platform, contains terms that violate consumer protection laws – and the platform reaches the same conclusion as the reporting consumer, determining that the contract is unlawful, then it has a duty to prevent further consumer interaction with it.

Providers, in turn, must notify the *flagger* of their decision, "providing information on the possibilities to redress in respect of that decision[103]". If providers conclude that the content is illegal, they must notify the recipient of the service – the trader, in the case of B2C AI-driven smart contracts – explaining the reasons behind their decision[104], particularly where on the online platform:

[99] *See* (n 97) 68.
[100] Article 16(1) DSA. Cf. Jorge M Carvalho, 'Introduction to the Digital Services Act, Content Moderation and Consumer Protection' (2021) 3 Revista de Direito e Tecnologia 92-94.
[101] A contractual clause that has been autonomously modified by an AI system integrated into the smart contract may also qualify as illegal content, where such modifications rely on the processing of personal data in breach of the GDPR.
[102] Article 16(2)(a) DSA.
[103] Article 16(5) DSA.
[104] Article 17(1) DSA.

a) the AI-driven smart contract has been removed, demoted, or made inaccessible to consumers[105];
b) the trader's account has been suspended or terminated[106].

Moreover, Article 34 requires VLOP providers to assess whether and how their content moderation systems influence systemic risks[107], while Article 35 demands that they tailor mitigation measures to such risks, "adapting content moderation processes, including […] where appropriate, the expeditious removal of, or the disabling of access to, the content notified[108]".

The primary challenge lies in implementing efficient content moderation mechanisms that allow consumers to report non-compliant contracts. At the same time, providers must proactively neutralise illegal contracts once they become aware of them. Additionally, VLOP providers must identify systemic risks and tailor their content moderation mechanisms to address these risks more effectively. Ultimately, this framework contributes to ensuring contract compliance with EU law.

However, moderating AI-driven smart contracts may be particularly challenging, as they operate autonomously and execute transactions in real time, making pre-emptive intervention difficult. Consequently, providers must assess in advance whether the AI embedded within a smart contract is capable of dynamically modifying contractual terms and conditions in a manner that renders the contract non-compliant with EU law.

In conclusion, within the context of AI-driven smart contracts, content moderation plays a crucial role in fostering a high level of consumer protection. By preventing online platforms from hosting AI-driven smart contracts that violate consumer and data protection laws, and by enabling consumers to report contracts that they perceive as unlawful, content moderation contributes to a more transparent and consumer-friendly digital market[109].

4.3 Algorithmic accountability & transparency obligation

To ensure a high level of consumer protection, recommender systems employed by online platforms can play a crucial role. Specifically, online platforms may prioritise certain AI-driven smart contracts, displaying them more prominently and thereby

[105] Article 17(1)(a) DSA.
[106] Article 17(1)(d) DSA. In particular, under Article 23(1), if the *flagged* trader usually provides "manifestly illegal content", the provider is required to suspend them "for a reasonable period of time and after having issued a prior warning".
[107] Article 34(2)(b) DSA.
[108] Article 35(1)(c) DSA.
[109] As set out in Article 1(1) DSA, the Regulation aims to safeguard the respect of consumer protection principles as a means of ensuring the proper functioning of the internal market. Indeed, the two objectives are closely intertwined: (1) an efficient market requires efficient economic agents; (2) consumers are economic agents who need a "safe, predictable, and trusted online environment" to thrive and make efficient economic decisions. As a result, a regulation that protects consumers ultimately safeguards the market as well. The DSA seeks to achieve this goal while also fostering innovation.

directing consumer attention towards specific legal agreements over others. Their capacity to steer consumer choices in ways that align with consumers' best interests is vital to enhancing individual well-being and, ultimately, to ensuring the proper functioning of the internal market[110].

Article 27 mandates that, when online platform providers utilise recommender systems, they must clearly disclose the main parameters used[111] and the options available "for the recipients of the service to modify or influence those main parameters". Moreover, providers must enable them to select and modify "at any time their preferred option[112]", thereby ensuring greater autonomy over how content is ranked and presented to them.

Under Article 34(2)(a), VLOP providers are also required to assess how the design of their recommender systems impacts systemic risks. Additionally, as part of their mitigation obligations, these systems must be tested and adapted to neutralise such risks[113].

In the context of AI-driven smart contracts, this implies that providers must enable consumers to choose how contracts are ranked and prioritised on online platforms. Moreover, VLOP providers must ensure that their recommender systems adequately protect consumers from contracts that are illegal or detrimental to their well-being[114].

However, an open question remains regarding the efficacy of Article 27 in ensuring a high level of consumer protection. While it empowers consumers to adjust their recommender system preferences, a more effective regulatory approach may require online platform providers to deploy recommender systems that proactively identify and suggest contracts most suitable for the individual consumer. An efficient recommender system should not only highlight the most appropriate contracts but also present them in a consumer-friendly manner – clearly comparing key elements, highlighting relevant information, and using intelligible and accessible language[115]. When combined with adequate human oversight to monitor and refine their performance, such systems could significantly enhance consumer protection. They would help guide consumers towards AI-

[110] Recommender systems can ultimately serve as tools to enhance consumer decision-making, by directing attention to content that best satisfies individual needs and preferences. In the contractual context, this entails matching consumers with the contract – or set of contracts – most closely tailored to their specific circumstances and interests. Cf. Laurens Naudts and others, 'A Right to Constructive Optimization: A Public Interest Approach to Recommender Systems in the Digital Services Act' (2025) 48(3) Journal of Consumer Policy 269.

[111] Article 27(2) DSA further clarifies that providers must at least explain the criteria that determine the "information suggested to the recipient of the service" and "the reasons for the relative importance of those parameters".

[112] Article 27(3) DSA.

[113] Article 35(1)(d).

[114] It has been illustrated that, since recommender systems effectively determine which information reaches consumers and captures their attention, VLOP providers bear a public duty to design and implement these systems in ways that serve the best interests of consumers and promote overall societal well-being. *See* (n 110) 6.

[115] Regarding the importance of contractual information design in improving consumer understanding of their rights and obligations – thereby enhancing their decision-making and economic choices – *see* Joasia Luzak and others, 'ABC of Online Consumer Disclosure Duties: Improving Transparency and Legal Certainty in Europe' (2023) 46 Journal of Consumer Policy 328-329.

driven smart contracts that align with their best interests, while shielding them from potentially harmful legal agreements.

5 Liability: centralised vs. decentralised platforms

The issue of liability in the context of AI-driven smart contracts varies significantly depending on whether they operate within centralised or decentralised ecosystems.

In centralised platforms, the liability issue is more straightforward. In this context, the following can be held liable:

1. The online platform provider under the DSA[116];
2. The trader offering the AI-driven transaction, if the contract:

a. Contains unfair terms under the UCTD[117];
b. Constitutes an unfair commercial practice under the UCPD[118];
c. Violates the GDPR[119];
d. Violates the AI Act[120].

In decentralised platforms, the situation is far more complex due to the absence of a central controlling entity. While the trader can be held liable, as in centralised platforms, there is no platform provider to be held liable under the DSA, since AI-driven smart contracts are hosted and/or promoted in an environment without a central authority. Moreover, the pseudonymous and decentralised nature of these platforms makes it difficult to identify and track traders[121], complicating the enforcement of consumer protection laws[122]. To address this issue, future regulations could mandate that, in the context of B2C contractual relationships, traders always remain identifiable, ensuring consumers have effective access to redress mechanisms in the event of harm[123].

Moreover, it is important to note that traders should not be considered liable only when acting with fault or intent. When the AI embedded in a smart contract causes harm to the consumer, liability should be attributed to the trader[124] – namely, the party who integrated the AI system into the contract – even if the harm was not intentional or foreseeable. This reflects the reality that even diligent traders and AI developers may not be able to anticipate all outcomes of autonomous AI decision-making[125]. For this reason, to guarantee a high level of consumer protection, a strict liability regime may be justified: one that assigns responsibility to the trader simply by virtue of deploying the AI system

[116] *See* paragraph 4.1.
[117] *See* paragraph 2.1.
[118] ibid.
[119] *See* paragraph 3.
[120] *See* paragraph 2.2.
[121] Cf. Alesia Zhuk, 'Beyond the blockchain hype: addressing legal and regulatory challenges' (2025) 5 SN Social Sciences 11, 24.
[122] Cf. ibid. 21-23.
[123] Cf. (n 1) 105.
[124] Cristina Poncibò, 'Remedies for Artificial Intelligence' in Martin Ebers and others (eds) (n 55) 211.
[125] ibid. 212-213.

within the smart contract's code. Since the AI system itself cannot be held accountable or provide redress, liability should rest with those who profit from its use[126]. This, ultimately, underscores the vital importance that even in decentralised systems consumers can identify the trader and be able to seek redress from them.

Another key consideration concerns the liability of AI developers. Since the relationship between the trader and the AI provider is a B2B matter, it does not directly concern the B2C contractual relationship[127]. Therefore, consumers should seek reparations from the trader who offered the AI-driven smart contract, rather than from the AI provider itself.

In conclusion, while centralised platforms provide a clearer liability framework, decentralised platforms present more complex consumer protection challenges, which highlight the need for future regulatory efforts to ensure clear pathways for consumers to seek remedies in the event of harm in decentralised systems.

6 AI-Driven Smart Contracts Transparency

The integration of AI into smart contracts introduces a fundamental tension between automation and the consumer's right to understand how the AI decides. A key issue in this context is the opacity of AI-driven decision-making, commonly referred to as the "black-box problem", which stems from a lack of explainability and transparency in AI-generated outcomes[128]. Unlike traditional smart contracts – which typically operate on predefined and rule-based logic – AI-driven ones are far more complex. Most modern AI models consist of multiple layers of interconnected computational nodes – such as millions of tiny math operations. As a result, they do not follow a simple *if-then* structure; instead, they operate like a giant, tangled web of weighted probabilities, making it difficult to trace how a specific decision is reached[129].

For instance, an AI-driven smart contract may be employed to assess a consumer's creditworthiness by analysing factors such as credit history, behavioural patterns (to determine whether they tend to make rational and balanced choices), financial stability, and projected future income. Based on this assessment, the AI system determines whether the consumer qualifies for a loan, the amount to be granted, and the conditions attached

[126] Baris Soyer and Andrew Tettenborn, 'Artificial intelligence and civil liability – do we need a new regime?' (2022) 30 International Journal of Law and Information Technology 391.

[127] Indeed, the B2C AI-driven smart contract gives rise to a contractual relationship between the trader and the consumer. Consequently, the consumer has no direct contact with, nor claims against, those involved in the preceding B2B relationship. However, within that B2B chain, the AI developer's fault may be relevant for questions of product liability.

[128] The more complex the AI embedded into the smart contract is, and the more precise its predictive capabilities are, the less explainable it becomes. In this context, there is an inherent trade-off between: 1) the performance of AI in accurately analysing consumer data and behavioural patterns, and in evaluating how contractual terms and interface design influence consumer behaviour; and 2) the explainability of the AI's outputs. As things stand, this means that optimal and efficient AI-driven smart contracts tend to function as "black boxes" by their very nature. Cf. Keri Grieman, 'Explainable AI (XAI)' in *Law, Death, and Robots* (Hart 2024) 46.

[129] Jens C. Bjerring, 'Deep learning models and the limits of explainable artificial intelligence' (2025) 4 (22) Asian Journal of Philosophy 6.

to the credit agreement[130]. However, if the AI denies the loan or imposes restrictive conditions without providing comprehensible reasoning, it raises a critical opacity issue, ultimately undermining consumer trust in AI-driven transactions[131]. This lack of transparency prevents consumers from understanding, trusting, or contesting decisions that may have significant implications for their rights and obligations[132].

The following sub-paragraphs aim to critically assess this issue and explore potential solutions by addressing the following research question:

- Can AI-driven smart contracts be designed to ensure transparency and trustworthiness, thereby fostering a high level of consumer protection?

6.1 The black-box problem & a possible solution

AI-driven smart contracts introduce a new level of complexity by analysing vast amounts of data, identifying behavioural patterns, and adjusting contractual terms and conditions in real-time based on probabilistic reasoning. While their adaptability can offer significant opportunities to enhance consumer protection – by tailoring the contract to better protect the individual consumer they address – it also poses substantial risks, particularly when they fail to operate in a transparent and consumer-friendly manner[133].

A key aspect in assessing whether AI-driven smart contracts truly foster consumer well-being or undermine it is understanding their decision-making process. Consumers must be placed in a position to *humanly* comprehend the contractual outcomes that involve them. To achieve this objective, it is crucial to neutralise the AI black-box nature, which arises whenever humans cannot clearly figure out the rationale behind AI decisions. Understanding AI reasoning is fundamental to preventing and reacting against biased, unfair, or discriminatory outcomes. Consequently, to mitigate the black-box problem – i.e. the inherent opacity of AI-driven smart contracts – they should incorporate transparency and explainability mechanisms that allow consumers to both understand and, when necessary, challenge AI-generated outcomes[134]. Moreover, AI transparency empowers consumers to be more aware of the consumer-friendly nature of the AI – verifying whether it is operating in a fair and non-exploitative manner – thereby also reinforcing trust in AI-driven transactions.

[130] Diogo M Rebelo and Filipa C Ferreira, 'AI-based consumer's creditworthiness assessment: era of automation, future of scoring and the EU policymaking on automated decision-making' [2022] E.Tec Yearbook - Industry 4.0: Legal Challenges 79-81.
[131] *See* (n 18) 282.
[132] Regarding AI's potential to enhance consumer trust in the e-commerce context and its associated risks, *see* Minhaz U Akbar, 'The Influence of Artificial Intelligence on Consumer Trust in E-Commerce: Opportunities and Ethical Challenges' (2024) 2(6) European Journal of Theoretical and Applied Sciences 250-257.
[133] Cf. Florian Martin-Bariteau & Marina Pavlović, 'AI and Contract Law' in Florian Martin-Bariteau and Teresa Scassa (eds.), *Artificial Intelligence and the Law in Canada* (LexisNexis 2021) 16-18.
[134] Cf. Karen McGregor Richmond and others, 'Explainable AI and Law: An Evidential Survey' (2024) 3 Digital Society 1, 5-7.

A possible solution lies in Explainable AI (XAI), which shifts the paradigm from an "AI just works this way" approach towards a more consumer-centric model: "here is why AI works this way[135]". XAI's potential to generate explanations – using natural language and/or visual representations – can transform the black-box problem in a white-box opportunity by making AI-generated decisions intelligible to the average consumer[136]. Instead of requiring consumers to blindly trust the AI and the trader – who offered the AI-driven transaction – XAI enables interactive engagement with the AI system, allowing consumers to receive clear and human-friendly justifications for contractual decisions.

For instance, in the online retail context, a consumer-centric AI-driven smart contract might detect emotional overspending and compulsive buying patterns, and temporarily block a transaction to protect the consumer from making impulsive financial decisions[137]. In such cases, it should explicitly communicate the rationale behind its action – for example, by informing the consumer that it has identified a spending anomaly based on their behavioural data.

Furthermore, if the consumer seeks a deeper understanding of the AI's decision-making, they should be able to get to know why and how the AI inferred its conclusion and obtain more information about their behavioural profiling[138].

Therefore, by integrating XAI mechanisms into AI-driven smart contracts, consumers can gain a clearer understanding of how and why contractual terms and conditions are dynamically tailored to their profile. Consequently, they get the opportunity to assess whether and how these AI-driven tools truly serve their best interests.

In conclusion, this approach promotes a high level of consumer protection by ensuring that AI operates in a fair and transparent manner. With the integration of XAI into smart contracts, consumers are empowered to actively monitor and assess the fairness of AI-driven transactions, ensuring that these tools are genuinely designed in a consumer-centric manner. However, it is not sufficient for AI-driven smart contracts to be merely structured with consumer well-being in mind; consumers must also trust the AI systems[139]. Indeed, trust is a key factor – if consumers do not trust these tools, they will be reluctant

[135] XAI aims to produce outputs that are comprehensible to human agents, enabling them to understand why and how an AI system arrived at a specific decision. This transparency is essential to fostering human trust in AI systems, particularly in how they "reason" and "decide". *See* Wenli Yang, 'Survey on Explainable AI: From Approaches, Limitations and Applications Aspects' (2023) 3 Human-Centric Intelligent Systems 162.

[136] Cf. Changdong Chen and others, 'When Post-Hoc Explanation Knocks: Consumer Responses to Explainable AI Recommendations' (2024) 59 (3) Journal of Interactive Marketing 235-236.

[137] As the AI ultimately drafts the final version of the contract, explains the contractual terms and conditions, and interacts with the consumer to stimulate an economic decision, it behaves as a choice architect that designs the consumer's choice environment. Consequently, a consumer-centric AI application is required to direct consumers' attention and actions towards the outcome that best maximises their well-being. Therefore, smart contracts should be developed so that the integrated AI systems are solely capable of nudging consumers with only their interests in mind. Digital nudging should be structured as a tool to enhance consumer economic decision-making, steering them away from decisions that may not align with their long-term goals and financial well-being. Cf. Laurence Devillers and others, 'AI & Human Values. Inequalities, Biases, Fairness, Nudge, and Feedback Loops' in Bertrand Braunschweig and Malik Ghallab (eds), *Reflections on Artificial Intelligence for Humanity* (Springer 2021) 80-81.

[138] *See* (n 1) 113-114.

[139] *See* (n 132) 255.

to engage with them. As such, it is critical for EU law to explicitly recognise the consumer's right to meaningful, human-friendly explanations regarding AI's decision-making processes, especially when these decisions directly impact their rights and obligations. Ultimately, the right to understand how AI-driven decisions affect them should be recognised as an integral part of consumer rights in the digital era[140]. Ensuring that consumers not only benefit from but also *perceive* the benefit of AI systems will be essential to fostering trust and widespread adoption.

6.2 The need for human oversight and intervention

AI-enhanced data processing vastly outperforms human capabilities by analysing large datasets at unprecedented speeds. However, while leveraging this potential can enhance efficiency, it must be accompanied by robust safeguards to mitigate AI-related risks such as biases, unfairness, and discrimination[141]. This is why, to ensure consumer trust in AI-driven smart contracts, a dual approach is required:

1. *Pre-emptive safeguards* to prevent harmful outcomes before contractual decisions are finalised, and
2. *Reactive mechanisms* to rectify unjust decisions after their implementation.

On the pre-emptive side, to prevent biased, unfair, and discriminatory contractual outcomes, human-in-the-loop mechanisms should be embedded within the AI-driven smart contract to enable the human trader to rectify the AI's decisional outcome. Before finalising a contractual decision, consumers should have the opportunity to challenge an AI-generated outcome, prompting human review. If the consumer demonstrates that the AI decision is unjust, the trader should intervene to modify contractual terms and conditions accordingly[142]. This approach offers two important benefits:

1. Consumers can receive fairer contractual terms;
2. Traders can identify and address flaws in the AI system, preventing similar issues from occurring in the future for other consumers.

On the reactive side, if a contractual decision has already been made, human-in-the-loop mechanisms could empower consumers to flag an unjust AI-generated outcome. In such cases, if it is still possible, traders should be required to:

1. Conduct a review to determine whether the AI's reasoning led to an unfair, biased, or discriminatory outcome;
2. Modify the contractual terms and conditions to balance the B2C contractual relationship, if the first assessment is positive;
3. Implement corrective measures to avoid recurring AI errors.

[140] Cf. (n 18) 289-290.
[141] Cf. Konstantinos Tsiakas and Dave Murray-Rust, 'Using human-in-the- loop and explainable AI to envisage new future work practices' in Fillia Makedon, *Proceedings of the 15th International Conference on PErvasive Technologies Related to Assistive Environments* (Association for Computing Machinery 2022) 588-589.
[142] Cf. ibid. 590-591.

In conclusion, AI-driven smart contracts should incorporate explainability and human oversight as core design principles to balance efficiency with fairness. A legal framework that mandates both transparency and human intervention will enable consumers not only to challenge AI-generated decisions but also to receive meaningful, human-friendly explanations of how and why these decisions were made, thereby preventing AI-driven smart contracts from functioning as opaque and unchecked tools of algorithmic power[143]. Additionally, to foster a high level of consumer protection in the context of AI-driven transactions, EU law should explicitly establish a right to both AI transparency and human oversight. As a result, consumers' trust in these transactional tools could potentially thrive. Ultimately, consumer protection, consumer trust, and AI transparency must go hand in hand to foster a consumer-friendly digital market.

7 A possible way forward: the fairness-by-design approach

In May 2022, the European Commission – as part of its Better Regulation agenda, which aims to ensure EU regulations are evidence-based[144] – launched the *Fitness Check of EU consumer law on digital fairness* to determine whether EU laws are adequate to achieve a high level of consumer protection in the digital environment[145].

The Digital Fairness Fitness Check was published in October 2024 and, among other topics, addressed smart contracts and AI-powered contracting, recognising that they "could increasingly automate all stages of the consumer's transactional journey" from contract conclusion to its execution[146]. It highlighted risks involving smart contracts – including reduced consumer control and autonomy[147] and challenges in complying with pre-contractual requirements[148]. Additionally, it underscored the threat posed by digital manipulation through dark patterns[149], manipulative personalisation[150], and AI

[143] As AI-generated decisions may harm consumers – whether through errors, biases, or unfair outcomes – it is essential that both explainability and human intervention are integral to the system's design. Human oversight is critical at both the preventive and corrective stages. Traders must monitor the performance of AI systems in real-world contractual applications and identify any breaches of consumer law. These may take the form of unfair terms, deceptive commercial practices, misuse of personal data, or manipulative algorithmic techniques. Once such a breach is detected, traders must be able to understand how and why the system produced the unlawful outcome – enabled by integrated XAI mechanisms – and take appropriate corrective actions. Crucially, beyond addressing the specific instance, traders must also ensure that the AI system is subsequently optimised to reduce the likelihood of the same error recurring, thereby fostering a cycle of continuous learning and compliance. Cf. Markus Langer and others, 'Effective Human Oversight of AI-Based Systems: A Signal Detection Perspective on the Detection of Inaccurate and Unfair Outputs' (2025) 35 Minds and Machines 1, 3-5.

[144] *See* <https://commission.europa.eu/law/law-making-process/better-regulation_en> accessed 28 May 2025.

[145] *See* <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/Digital-fairness-fitness-check-on-EU-consumer-law_en> accessed 28 May 2025.

[146] European Commission, *Digital Fairness Fitness Check* (2024) 82.

[147] ibid 195-196.

[148] ibid 198-199.

[149] ibid 18-20.

[150] ibid 30.

applications that exploit consumer vulnerabilities, exacerbating power imbalances between traders and consumers[151].

To address these challenges, the *fairness-by-design* approach has been proposed as a solution to achieve a high level of consumer protection in digital environments. It entails embedding digital fairness[152] principles into the architecture of AI systems and smart contracts from the ground up, ensuring that they "incorporate consumer protection considerations at all stages[153]" of their development. This strategy establishes consumer protection not as an afterthought but as a foundational design principle. By integrating this approach into the design, development, and implementation of AI-driven smart contracts, it becomes an efficient way to safeguard consumer rights and well-being, while fostering trust and confidence in AI-powered transactions.

Furthermore, adopting the fairness-by-design approach from the early stages of AI and smart contract development aligns with a *positive duty to trade fairly* – an obligation that the Fitness Check proposes to introduce for traders to strengthen consumer protection. Even if this explicit duty is not formally introduced, it could nonetheless be inferred from the professional diligence standard and the general principle of good faith[154].

Particularly, the fairness-by-design approach could serve as a safeguard, ensuring that AI-driven smart contracts – as a whole and in their components – are designed to comply with EU regulations, detect legal breaches, and prevent consumer harm. One of the most promising applications of AI in smart contracts is its potential to act as a real-time compliance watchdog, monitoring their adherence to EU law. This would shift AI from being a tool of contractual asymmetry to one of consumer empowerment. For instance, if an AI-driven smart contract identifies a potential GDPR violation – such as the processing of consumer data beyond the intended scope – it could automatically halt execution until the issue is resolved, thereby promoting continuous legal compliance monitoring and reducing the risk of regulatory breaches.

Consequently, this approach ensures that AI-driven smart contracts are developed to prevent and mitigate manipulative and exploitative contractual design. To achieve this, the AI system embedded in the smart contract must be capable of probabilistically predicting and detecting potential legal breaches arising from the way it dynamically adjusts contractual terms and conditions. Since these adjustments are tailored to the individual consumer the contract addresses, the AI must be developed to serve and enhance the consumer's well-being, rather than solely advancing the trader's interests. Indeed, in line with the obligation of good faith, the AI's processing of consumer data should not exploit consumer vulnerabilities but instead promote consumer protection.

[151] ibid 82-83.
[152] ibid 1. As explained in the Introduction of the Fitness Check, the concept of "digital fairness" refers to the objective of achieving a high level of consumer protection "in the digital environment, in compliance with the legal standards established in EU consumer law".
[153] ibid 152.
[154] ibid 53.

Ultimately, AI's detection and analysis of consumer vulnerabilities – as well as its behavioural profiling processes – must be aimed at protecting the consumer from information, cognitive, and digital asymmetries.

To empower the consumer and address the inherent contractual imbalance in B2C relationships, the AI must shape the contract in a way that:

1. Highlights relevant information to support informed and aware economic decisions – thereby counteracting information asymmetries[155];
2. Avoids dark patterns and other manipulative designs – thereby protecting consumers from digital manipulation;
3. Safeguards consumers from cognitive biases, heuristics, and emotional responses – thereby preventing the AI from exploiting behavioural patterns.

As a result, the fairness-by-design approach serves as a safeguard to ensure that AI-driven smart contracts are pre-emptively aligned with consumer protection laws, while also enforcing their compliance by designing AI to continuously monitor the contract's adherence to EU law. By requiring AI-powered contracts to be built with fairness-by-design principles, regulatory frameworks ensure that consumer protection considerations are embedded before deployment.

Moreover, this approach offers a balanced regulatory solution by:

- Allowing businesses and AI developers to innovate while ensuring a high level of consumer protection;
- Empowering consumers through AI design that serves and fosters their best interests and well-being;
- Preventing legal conflicts and consumer harm before they arise.

In conclusion, the fairness-by-design approach helps provide a regulatory framework that ensures AI-driven smart contracts remain a tool for consumer well-being rather than a source of new forms of consumer vulnerability. Indeed, embedding the fairness-by-design approach at the core of AI-driven smart contracts ensures that *digital fairness* is not merely a theoretical consumer protection strategy, but elevates itself to a practical safeguard that fosters consumer well-being, without stifling innovation.

8 Conclusion

As AI-driven smart contracts become increasingly widespread in B2C digital transactions, it is evident that existing consumer protection laws – designed for traditional, human-negotiated legal agreements – are no longer sufficient. Although an evolutionary interpretation of current regulations may help uphold a high level of consumer protection in the age of AI-powered legal agreements, these frameworks

[155] Marcelo Corrales and others, 'Smart Contracts and Smart Disclosure: Coding a GDPR Compliance Framework' in Marcelo Corrales and others (eds), *Legal Tech, Smart Contracts and Blockchain* (Springer 2019) 198-200.

struggle to address the complexities of automated, self-executing contracts shaped by opaque algorithms and fuelled by behavioural data.

To effectively safeguard consumer rights in this evolving landscape, a modernised, AI-proof legal framework is urgently needed – one that acknowledges the unique risks arising from human-AI contractual interactions and mandates the integration of consumer protection principles into the very design of these technologies.

This paper does not claim to offer an exhaustive analysis. At this early stage in the development and deployment of AI-driven smart contracts, it remains impossible to fully map their capabilities or anticipate the complete range of challenges they may pose. Rather, the primary aim of this research has been to provide a legal reflection on the current and future dynamics between consumers and AI in the context of B2C AI-driven smart contracts, and to propose initial pathways towards a more comprehensive reform.

Emerging as the natural outcome of this legal analysis, the fairness-by-design approach offers a proactive, consumer-centric regulatory model that embeds ethical, transparent, and autonomy-preserving principles into the architecture of AI and smart contracts from the outset. Rather than responding to harm retrospectively, fairness-by-design anticipates vulnerabilities and helps shape digital marketplaces that support rational decision-making, respect consumer dignity, and foster individual well-being.

Ultimately, by anchoring consumer protection in the very code of AI systems, fairness-by-design lays the foundation for a safer, more trustworthy, and human-friendly digital economy.

Maria Elena Ursitti *

GENERAL SECTION

THE ROLE OF ARTIFICIAL INTELLIGENCE IN CONTRACT RENEGOTIATION.

Abstract

This paper investigates the legal and practical feasibility of entrusting an AI system with a role of third-party decision-maker in contract renegotiation by considering the implications under both the Italian Civil Code and the EU AI Act, as well as the broader question of whether AI can truly replicate the role traditionally performed by a human arbitrator.

In the context of long-term contracts, unexpected factual or legal circumstances arising after the contract's formation may impair its synallagmatic balance. To reduce such effects, parties may mitigate the imbalanced contract recurring to the renegotiation.

The renegotiation of contractual terms can also be entrusted to a third party, based on the principle of contractual autonomy, as provided by Article 1349 of the Italian Civil Code. This provision, according to varying doctrinal interpretations, draws its legitimacy from principles such as contractual good faith (Article 1175) or equity (Article 1374). Thus, Article 1349 not only serves as the legal basis for initially determining the contract's object but also authorizes delegating its redefinition during the contract's term. The text of Article 1349 establishes two approaches: the content can be determined at the third party's sole discretion or based on their equitable assessment. In the first scenario, if the third party fails to make a decision, the contract is void. Moreover, an erroneous decision by the third party cannot be challenged unless made in bad faith. Conversely, where equitable assessment is involved, the failure of the third party to decide transfers the matter to the courts.

An innovative and potentially groundbreaking solution discussed in this abstract involves entrusting the role of third-party arbitrator to an algorithm or artificial intelligence (AI) system. Such a mechanism could redefine contractual terms more effectively by considering the parties expressed interests. This AI-driven system would analyse the interests and actions of the parties involved, determining the appropriate contractual content.

This work aims to analyse the various challenges this tool would face. These will be examined in light of the recently introduced EU AI Act (Regulation 2024/1689), which provides further guidance. The law strengthens the possibility of supporting such a mechanism. Nevertheless, entrusting contract renegotiation to AI raises questions concerning its legality and permissible limits.

Regarding the methodological approach adopted in this work, the sources used in this paper were identified through a progressive reading process, starting from the works of the most authoritative scholars in the field. The references cited in those foundational texts served as a guide to explore the broader debate and to select further contributions that align with the author's critical perspective.

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10.13135/2785-7867/12838

JEL CLASSIFICATION: K12

SUMMARY

1 Renegotiation as a corrective tool in relational contracts

It is widely acknowledged that the Italian Civil Code does not explicitly recognise any general mechanism for contract renegotiation[1]. This omission creates significant challenges about dealing with changed circumstances. While the law offers remedies in cases of breach of contract, it does not provide solutions where unforeseen events alter the contractual balance. As a result, legal scholars, aware of the absence of tools allowing parties to renegotiate and restore equilibrium, have begun to theorise the existence of an implicit principle supporting such renegotiation.

[1] Efforts to introduce a similar mechanism—taking inspiration from the French model—have not been taken up by the Italian legal system. Notably, Draft Delegation Law No. 1151 of 2019 had proposed the recognition of a right to renegotiate for parties to contracts that had become excessively burdensome due to exceptional and unforeseeable events. Where negotiations failed, the draft envisaged a judicial power to adjust the terms of the contract, in order to restore the original balance between the parties' performances. However, the proposal sparked significant debate. Many raised concerns about the idea that a judge could step in and effectively rewrite the contract, arguing that such a development lacks a clear legal basis and risks undermining the principle of contractual autonomy.
For further elements see: Francesco Macario, "Dalla risoluzione all'adeguamento del contratto. Appunti sul progetto di riforma del codice civile in tema di sopravvenienze" (2020) V Foro it. 102 and the following; Ilaria Pagni, "Crisi d'impresa e crisi del contratto al tempo dell'emergenza sanitaria, tra autonomia negoziale e intervento del giudice" (2021) 2 Rivista Trimestrale di Diritto e Procedura Civile 349. For a critical perspective, see Cesare Salvi, "Conclusioni" [2020] Jus 259. The draft aimed at the "*revision and integration of the Civil Code*". However, it has been observed that the draft "*Non emerge una idea forte e unificante (né ve ne è traccia nella relazione che l'accompagna). Esso contiene alcune proposte normative che non hanno un filo conduttore comune, se non il riguardare materie disciplinate dal codice*".
Another noteworthy provision, in force during the COVID-19 pandemic, is Article 10, paragraph 2 of Decree-Law No 118 of 24 August 2021, addressing urgent issues in corporate distress and insolvency. This rule granted entrepreneurs, whose contractual performance had become excessively burdensome, the possibility to request a revision of the terms of ongoing contracts. The law lays down that "*L'esperto puo' invitare le parti a rideterminare, secondo buona fede, il contenuto dei contratti ad esecuzione continuata o periodica ovvero ad esecuzione differita se la prestazione e` divenuta eccessivamente onerosa per effetto della pandemia da SARS-CoV-2. In mancanza di accordo, su domanda dell'imprenditore, il tribunale, acquisito il parere dell'esperto e tenuto conto delle ragioni dell'altro contraente, puo` rideterminare equamente le condizioni del contratto, per il periodo strettamente necessario e come misura indispensabile ad assicurare la continuita' aziendale. Se accoglie la domanda il tribunale assicura l'equilibrio tra le prestazioni anche stabilendo la corresponsione di un indennizzo*".
Although the provision has since been replaced by Article 17, paragraph 5 of the Italian Code of Business Crisis and Insolvency (CCII), which significantly alters its content, Article 10(2) remains applicable to cases of supervening excessive onerousness resulting from the pandemic. For a wider exploration of the provision see Ilaria Pagni and Massimo Fabiani, "La transizione dal codice della crisi alla composizione negoziata (e viceversa)" (2021) November issue Diritto della Crisi 6, and Massimo Fabiani, "Il valore della solidarieta' nell'approccio e nella gestione delle crisi d'impresa" (2022) 1 Fallimento e le altre procedure concorsuali 5, 11; Alessandra Zanardo, "La rinegoziazione dei contratti di durata nelle crisi di impresa" (2023) 1(1) Giurisprudenza Italiana 239; Alberto Guiotto, "Il ruolo dell'esperto nelle trattative con i soggetti rilevanti" [2021] Diritto della crisi 11; Elena Fregonara, "Impresa, contratti di durata, sopravvenienze e assetti adeguati: opportuno o necessario l'intervento dell'autonomia privata?" (2022) 5 Il Nuovo Diritto delle Società 751, 780.

According to some authors, it may be argued that the law implies a duty to renegotiate. For that reason, even in the absence of specific contractual clauses, that duty can be derived from the Article 1467, paragraph 3 c.c.[2] As a consequence, the provision allows one party to offer a modification of the obligation in accordance with equity. As a result, contract termination may be avoided.

Furthermore, some scholars argue the existence of an implied duty to renegotiate. The concrete realisation of the effect depends on the nature of the contractual relationship, as the law works for long-term contracts. In this interpretation, moreover, it appears correct to argue that Article 1467, paragraph 3 of the Italian Civil Code should be read in conjunction with Article 1375, which confirms the legitimacy of identifying the duty to renegotiate as a legal tool for the adjustment of long-term contracts, even in the absence of the parties' express intent[3].

This thesis has been rejected by others scholars: they advocate that this interpretation misunderstands the literal wording of the provision. The existence of a general duty to renegotiate conflicts with the freedom of will: parties should be free to decide if they want to dismiss the contract or preserve it, changing some features in the process. Upon closer analysis, this appears to be a right conferred upon the party holding the right to exercise it in order to avoid termination of the contract.[4] Furthermore, the interpretation advanced by the cited scholarship may lead to an overestimation of the practical impact of the interaction between the powers in question.[5]

[2] Francesco Macario, "*Adeguamento e rinegoziazione nei contratti a lungo termine*" (Jovene 1996) 296. The author argues that the choice of the offeror to exercise the right by avoiding termination through a modifying judgment—opting instead to request a consensual modification of the contract—would not be inconsistent with the classification of Article 1467, paragraph 3 of the Italian Civil Code as conferring a potestative right. In fact, the potestative nature of a right is compatible with its out-of-court and contractual exercise, provided that the exercise of such right is not entirely discretionary, as it is the law that confers upon the holder the power to propose a modification of the contract and defines the discretionary nature of that choice.

[3] Francesco Macario, *Adeguamento e rinegoziazione nei contratti a lungo termine* (Jovene 1996) 296.

[4] This legal situation is called by italian Scholarship "diritto potestativo", and is defined as the power granted to a subject to unilaterally modify, extinguish, or create a legal situation affecting another party, without the latter having a corresponding right to oppose it.

[5] Mario Barcellona, 'Appunti a proposito di rinegoziazione e gestione delle sopravvenienze' (2023) 3 Europa e diritto privato 467. Paper presented at the Conference held in Catania on 13–14 September 2002, in which it is argued that the power to renegotiate and modify the contract merely entails the transformation of a functional element, rather than a normative structure.

From this perspective, it should be clarified that the model set out in Article 1467 of the Italian Civil Code refers to the general contractual framework. For this reason, the provision entrusts the management of risk to the voluntary initiative of the party, adopting a stance of neutrality with respect to the parties' decisions (the so-called abstentionist model). By contrast, other provisions of the Code relate to situations involving a more significant level of risk, as in the case of contracts for work and services, which justify the presence of Article 1664 of the Civil Code. In other words, the abstentionist model is better suited to contractual relationships based on a single exchange. In those cases, the legislature has opted for a more interventionist approach in order to ensure a more efficient allocation of resources: the relevant provision more effectively serves the purpose of preserving the contract.

In the same context, the author argued that consent plays a fundamental role, since it would be unacceptable to consider a party bound by an equilibrium to which it never agreed from the outset. Conversely, one cannot assume that a party may be bound to perform an obligation different from the one it initially accepted. Mentioning his exactly words "*L'alternativa alla risoluzione è così costituita esclusivamente da una ricostruzione dell'equilibrio contrattuale*

Moreover, the Article 1375 of the Italian Civil Code plays another role, compared to Article 1467[6]. The former provides the performance phase of the contract, while the latter addresses the process for determining whether the contract should be adapted or terminated.

However, scholars who support the combination of the mentioned articles ground their replication on the ratio's analysis of Article 1467. The core of the provision, therefore, lies in its function[7] rather than in the instruments it provides to achieve it[8].

Contracts structured in this manner may be subject to a duty to renegotiate, arising from in the principle of good faith, even in derogation of Article 1467 of the Italian Civil Code. That said, it is clear that the provisions in question exhibit structural limitations stemming from their textual formulation.

As explained, Article 1467 c.c. establishes that the right to seek a revision of the contract is granted exclusively to the advantaged party. Conversely, performance of the contract in good faith would require that the same right be available also to the disadvantaged party as well. According to some academics, a potential solution may lie in the legal nature attributed to Articles 1467 and 1375 of the Civil Code.

Article 1467 is generally regarded as a default rule, and as such may be derogated from either by the parties' will or by mandatory provisions of law, which are non-derogable because they serve to protect the general interest. Among such mandatory provisions, the principle of good faith in contractual dealings, embodied in Articles 1175 and 1375 c.c., must undoubtedly be included. As a mandatory rule, the duty to act in good faith cannot be derogated from by the parties nor overridden by default rules[9].

In light of this interpretation, if the duty of good faith requires the parties to renegotiate the original contractual framework in order to adapt its content to changed circumstances and restore its fairness, the remedy of renegotiation—being supported by a

originario ascrivibile in egual misura alla "volontà" di entrambe le parti: a quella della parte svantaggiata dall'eccessiva onerosità sopravvenuta, poiché la modifica delle condizioni contrattuali non fa che ripristinare l'equilibrio da essa inizialmente accettato; ed a quella della parte avvantaggiata, poiché l'incremento quantitativo della sua prestazione risale alla sua stessa offerta".

[6] Mario Bessone, *Adempimento e rischio contrattuale* (Milano 1975) 394. It is beyond doubt that "*i redattori del codice avevano davvero inteso adottare il principio rigoroso secondo il quale, con la sola eccezione del caso di sopravvenienza dell'imprevedibile, il debitore è tenuto fino al limite dell'impossibilita'*''. According to traditional judicial interpretation in bilateral contracts, the party facing supervening excessive onerousness may seek judicial termination of the contract pursuant to Article 1467, paragraph 1, of the Italian Civil Code, provided that their performance has not yet been rendered. However, that party has no right to request an equitable adjustment of the contractual terms. Such adjustment may only be invoked by the defendant in an action for termination, pursuant to paragraph 3 of the same provision.
This interpretation rests on the principle that a party affected by the imbalance cannot compel the other party to accept performance under conditions different from those originally agreed. As an example, reference may be made to Cass. civ, 6 gennaio 2018, n. 2047.

[7] Barcellona (n 5).

[8] Giuseppe Terranova, 'L'eccessiva onerosità nei contratti' in *Il codice civile – Commentario* (Milano, Giuffrè 1995).

[9] Cass., 18 October 1980, no 5610, *Archivio civile* [1981], 133; Cass., 2 November 1998, no 10926, *Foro italiano* [1998], I, 3081, which held that the clause in a leasing contract placing the risk of non-delivery on the lessee violates the principle of good faith in contractual performance and is therefore invalid.

mandatory norm, namely the principle of good faith in performance—should prevail over the remedy of contract termination.

According to other scholars, parties have to behave compliantly in order to allow the prosecution of the contract. It is, in this regard, possible to maintain the validity of the contract.[10]

As previously mentioned, in the event of a contractual supervening event, the party adversely affected and interested in renegotiation may invite the other party to enter into negotiations to redefine the terms of the original contract, or might submit a proposal for an amending agreement. However, the disadvantaged party's initiative may not be accepted. Traditional legal literature supports the position that the other party holds the right to freely accept or reject the proposal.[11]

What has just been outlined, however, refers to negotiations between parties who are not bound by any prior obligation. If, on the other hand, the renegotiation is the object of a specific obligation, whether contractual or statutory, the lack of cooperation in the negotiation process by one of the parties may have significant consequences, both in terms of liability and with preservation of the contract.

The presence of a pre-existing contract and a related duty to renegotiate its terms in good faith imposes upon the other party a corresponding obligation to actively participate in the negotiation process. The immediate purpose of such participation is to safeguard the interest of the party initiating the offer. More fundamentally, however, active engagement in the renegotiation serves the broader function of protecting the parties' shared interest, namely, the continuation of the contractual relationship.

The duty to renegotiate is to be construed as an "*obbligazione di mezzi*":[12] upon the occurrence of certain supervening circumstances, the parties are required to enter into fresh negotiations with a view to restoring the contractual balance. As an *obbligazione di mezzi*, this duty does not bind the parties to conclude a new or amended contract, but it does require them to make a genuine and serious effort to do so, in accordance with the principles of good faith and loyal cooperation[13]. Even when generally framed, this obligation binds both parties symmetrically, under the overarching standard of objective good faith. In this sense, and particularly in the absence of an express contractual provision, objective good faith functions as a normative criterion for identifying specific duties incumbent on the parties.

[10] Francesco Macario, *Adeguamento e rinegoziazione nei contratti a lungo termine* (Jovene 1996) 343.
[11] Francesco Galgano, *Diritto civile e commerciale*, *Le obbligazioni e i contratti*, vol II/1 (CEDAM 2004) 215. The author points out that "*ogni atto di autonomia contrattuale è, in linea di principio, incensurabile e insindacabile*".
[12] An obligation of means is a type of contractual obligation in which the debtor undertakes to perform a given activity with the level of diligence required by the nature of the service, without, however, guaranteeing the achievement of a specific result. Performance is assessed with reference to the conduct exhibited throughout the contractual relationship, rather than the outcome achieved. Any liability on the part of the debtor presupposes proof of fault in failing to meet the required standard of diligence.
[13] Gorni A, "Le clausole di rinegoziazione" in C Vaccà (a cura di), *Il conflitto del Golfo e i contratti di impresa* (Giuffrè 1992) 56. Gianluca Sicchiero, "La rinegoziazione" (2002) 2 Contratto e impresa 796.

Where, by contrast, the parties have explicitly provided for the parameters to guide renegotiation or have agreed that, in the event of failure to reach an agreement, a third party shall intervene to adjust the terms,[14] one may reasonably argue that the duty to renegotiate transcends mere procedural engagement and amounts to an obligation to actually reach a new agreement. In such circumstances, the duty to renegotiate may be characterized as an obligation of result:[15] the concrete aim of the contract,[16] identified with its purpose, becomes the adjustment of the contractual framework to reflect supervening imbalances. It follows that a party's culpable conduct, obstructing such adjustment, may lead to a breach of contract.

According to the scholarly view under examination, it falls to the court to determine whether the conduct of the parties conforms to the standard of good faith. This assessment requires recourse to a *regula iuris* derived from the concrete case at hand, rather than abstract principles of fairness or good faith.[17]

This theory does not solve many issues. Indeed, once the party sends a proposal for renegotiation, the other one can evaluate its options and freely decide to deny the counter party's bid for consensus. In this respect, both an unjustified refusal to enter into contract renegotiations and an unjustified interruption of the negotiation process are to be regarded as conduct contrary to the principle of good faith. A breach of these duties leads to a contractual default on the part of the responsible party. According to the legal scholarship, it is of no consequence whether such an obligation stems directly from the contractual terms or is instead implicitly derived from the overarching duty of good faith. Nevertheless, beyond these hypotheses, the refusal to renegotiate does not give rise to any further legal consequences.[18]

2 Renegotiation entrusted to a third Party: the scope of article 1349 of the Italian Civil Code

As a general rule, parties anticipating the need for contractual revision typically agree that, upon the occurrence of a specific supervening event, a preliminary renegotiation should take place, consisting of joint assessment and an effort to reach a new agreement. Should such an agreement fail to materialise, and the contractual adjustment proves to

[14] so called hetero-integration.
[15] Macario (n 10).
[16] Known as "*causa in concreto*" in Italian scholarship.
[17] In this respect, good faith entails not only a duty of cooperation, but also plays a constitutive role in shaping the content of the parties' conduct: it serves as a normative standard for determining the appropriate means by which each party should pursue their respective interests. Gerardo Marasco, *La rinegoziazione del contratto: strumenti legali e convenzionali a tutela dell'equilibrio negoziale* (2006) 111; Francesco Galgano, *Diritto civile e commerciale. Le obbligazioni e i contratti*, vol II.1 (CEDAM, Padova 2004) 631.
[18] "*ogni atto di autonomia contrattuale è, in linea di principio, incensurabile ed insindacabile*". Francesco Galgano, *Diritto civile e commerciale, Le obbligazioni e i contratti* II,1 (CEDAM 2004) 209.

be unattainable through mutual consent, the revision may be delegated, in a subsidiary manner, to a third party.

Clauses providing for third-party intervention serve a dual purpose: on the one hand, they operate as subsequent remedies, enabling the resolution of negotiation deadlocks through an impartial determination. On the other hand, they perform a preventive function, acting as a deterrent against opportunistic or abusive conduct by the party not adversely affected by the supervening event.

The legal scholarship continues to debate the nature of such third-party intervention. Some commentators argue that it may be qualified as a form of non-binding arbitration,[19] albeit one that performs a function partially distinct from the resolution of legal disputes. The traditional hypothesis of arbitration arises when the parties to a contract, by means of an arbitration clause, entrust one or more arbitrators with the resolution of disputes relating to the contract, with a binding obligation to comply with the arbitrator's decision. In this sense, the arbitrator does not merely settle a conflict of interests, but a genuine legal dispute.[20]

The distinction lies in the fact that a legal dispute presupposes the emergence of conflicting legal claims or obligations, whereas a conflict of interests may simply result from the parties' inability to reconcile their expectations and proposals during the precontractual phase, which is when they enjoy full autonomy in determining their respective performances. Then, the parties remain free to negotiate without any binding commitment to reach a final agreement. Conversely, a conflict of interests can only be resolved through mutual consent between the contracting parties.

If, however, the negotiation takes place pursuant to a contract that has already been concluded, namely, as the execution of a renegotiation obligation, then the situation constitutes a legal dispute. According to this interpretation, the failure to reach a modified agreement may, in general, be attributed to the conduct of one of the contracting parties and, consequently, to a breach of contractual obligation. Specifically, if one party adopts a course of conduct contrary to the principles of good faith, thereby preventing the restoration of contractual equilibrium, such conduct will amount to a breach. This circumstance may give rise to a legal dispute, which may, in turn, be submitted to an arbitrator.[21]

By contrast, those who consider the third party to be a mere arbitrator argue that the third party is not called upon to resolve a legal dispute, but rather to settle a conflict of interests concerning the determination of the content of a modified agreement in a

[19] Arbitrato irrituale.

[20] Aldo Frignani, *Le clausole di hardship, Inadempimento, adattamento, arbitrato. Patologie dei contratti e rimedi, Diritto e prassi degli scambi internazionali* (1992) 360; Michael Joachim Bonell, 'La revisione dei contratti ad opera di terzi: una nuova forma di arbitrato?' (1978) 1 Riv.dir.comm 324.

[21] The primary task of the arbitrator would then be to identify the non-performing party "*di individuare il soggetto inadempiente, indagine rilevante anche ai fini del risarcimento dei danni, per poi procedere ala revisione delle condizioni negoziali*". Vincenzo Maria Cesaro, *Clausola di rinegoziazione e conservazione dell'equilibrio contrattuale*, (Edizioni Scientifiche Italiane 2000) 29.

contract affected by supervening events. In this sense, the parallels with Article 1349 of the Italian Civil Code cannot be denied. Although the cited provision refers to the formation phase of the contract, it is nonetheless well suited to the present context, in which, during a renegotiation process, the arbitrator—on the basis of the parties' will—may determine the content of the amended contractual terms with respect to those aspects the parties have been unable to settle.[22]

In this context, renegotiation is regarded as the primary and preferable means for determining the content of the modified contract. However, it is not the only available option. Where the parties fail to reach an agreement on the terms of the revision, the supplementary provision for the intervention of a third-party arbitrator ensures that the content of the amended contract may nonetheless be established.

In such terms, the case at hand coincides with that governed by Article 1349 of the Italian Civil Code. The intervention of the third party, who is involved during the formation of the amended agreement, makes a determination of the elements of the modified contract to which the parties are bound by virtue of a pre-existing contractual obligation.

The third party, through their involvement, is not necessarily called upon to rewrite the contract in place of the parties. Rather, their role is constrained by what the parties have already defined, whether explicitly or implicitly, through the renegotiation clause and in accordance with the nature of the principal obligation.[23]

Moreover, the parties may guide the decision-making of the third party by specifying the criteria to be followed. In the absence of such indications, the default standards provided by the Civil Code shall apply, pursuant to which the third party may proceed on the basis of equitable assessment.

Finally, where expressly agreed, the parties may completely defer to the decision of the third party. Nonetheless, the third party remains bound to act in accordance with the principles of good faith and on the basis of objective elements that reflect the overall fairness and balance of the contractual arrangement.[24]

Once the third party has made their determination, it shall be binding upon the parties, who may subsequently challenge it before a judicial authority or, where provided, before an arbitrator, in order to challenge any potential defects or irregularities. In such a case, however, a true legal dispute arises, which necessitates the intervention of an arbitrator.[25]

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[22] A Gorni, "Le clausole di rinegoziazione" in C Vaccà (ed), *Il conflitto del Golfo e i contratti d'impresa: esecuzione, adattamento e risoluzione in uno scenario di crisi* (Egea 1992) 64.
[23] Massimo Bianca, *Diritto civile, il Contratto* (Giuffrè 2000) 330.
[24] Vincenzo Maria Cesaro, *Clausola di rinegoziazione e conservazione dell'equilibrio contrattuale* (Edizioni Scientifiche Italiane 2000) 237: "*Anche in questo caso, come del resto per al integrazione del contrato ala stregua del criterio della buona fede in executivis, il programma contrattuale rappresenta li valore ed al tempo stesso li limite ni relazione la quale deve necessariamente essere svolto li giudizio del terzo. Dal regolamento contrattuale ni cui è contenuta la clausola di rinegoziazione, il terzo riceve non solo li potere di determinare li nuovo assetto negoziale, ma soprattutto i criteri di riferimento sula base dei quali è tenuto a procedere nella determinazione delle nuove condizioni negoziali*".
[25] Vincenzo Roppo, *Il contratto, in Trattato di diritto privato* (Giuffrè 2001) 354. The Author supports that the limitated reference to the bad faith doesn't erase the juridical relevance of the objective balance of the contract.

3 Article 1349 of the Italian Civil Code as a legal basis for AI-assisted renegotiation: advantages and challenges of the machine's progressive becoming autonomous

Recent scholarship has begun to consider the possibility of entrusting renegotiation to artificial intelligence. This analysis, however, aims to assess whether such a thesis may find normative grounding as well in Article 1349 of the Italian Civil Code, as well. To this end, it is necessary to draw a preliminary distinction between smart contracts[26] and AI-based contracting.

These two technologies raise new questions regarding their legal classification, giving rise to potentially divergent issues in the field of contract law. Beginning with so-called data-oriented contracts, these classifications may be defined as agreements whose content is processed by a computer. As a consequence, their execution is likewise carried out through computational processes. These operations determine a specific mode of contract performance; nonetheless, it is regarded as a formal contract, in which the intent to produce legal effects remains with the parties.

Moreover, the parties retain control over the formation of the legal agreement, insofar as each stage is subject to human oversight. Indeed, the parties may suspend the performance of the contract whenever it leads to outcomes that diverge from their expectations. This form of contract, however, constitutes the foundation for the development of smart contracts. At this point, certain clarifications are necessary.

[26] The smart contracts are defined in paragraphs 1 and 2 of Article 8-ter of Decree-Law No. 135 of 14 December 2018 (converted into Law No. 12 of 2019). Specifically, the provision states that "*gli smart contracts sono programmi per elaboratori che operano su tecnologie basate su registri distribuiti e la cui esecuzione vincola automaticamente due o piu' parti sulla base di effetti predefiniti dalle stesse*".
Furthermore, additional specifications are provided with regard to the requirement of form, according to which smart contracts shall meet the requirement of written form, provided that the parties involved are identified by digital means, "*attraverso un processo avente i requisiti fissati dall'Agenzia per l'Italia Digitale con le linee guida da adottarsi entro 90 gg dall'entrata in vigore della legge di conversione del decreto legge*". For a more detailed discussion of the definitions examined herein, see Remotti, 'Blockchain, smart contract: primo inquadramento e prospettive di indagine (commento all'art. 8 ter d.l. 14 dicembre 2018, n. 135)' [2020] *Oss. dir. civ.* 189 and the following; M Maugeri, "La Risoluzione del Parlamento europeo del 20 ottobre 2020 sugli Smart Contracts nella prospettiva del diritto dei contratti e della concorrenza" [2021] Contr. impr. Eu. 27.
For further discussion on the topic of cryptography and distributed ledger technologies, see Elsa Anna Stefania Bivona, "Smart contracts e "interferenze" con la disciplina sui contratti: il sistema dei rimedi alla prova degli algoritmi" [2021] Persona e Mercato 78.
Moreover, it is necessary to mention the Resolution of 20 October 2020 entitled "*Raccomandazioni alla Commissione sulla legge sui servizi digitali: adeguare le norme di diritto commerciale e civile per i soggetti commerciali che operano on line*". This resolution also makes more specific reference to blockchain technology and to smart contracts. It constitutes a source of soft law. Nonetheless, it is of particular relevance insofar as it performs an interpretative function in relation to both existing and prospective legislative acts across the different legal systems operating in the relevant sector.
M Maugeri, *Smart contracts e disciplina dei contratti* (Bologna 2021); Roberto Pardolesi e Antonio Davola, 'Smart contract: lusinghe ed equivoci dell'innovazione purchessia' (2019) Foro it. 195 and the following; D Di Sabato, 'Gli smart contract: robot che gestiscono il rischio contrattuale' [2017] Contratto e impresa 378; G Finocchiaro, "Il contratto nell'era della intelligenza artificiale" [2018] Riv. trim. dir. e proc. civ. 441; F Delfini, "Blockchain, smart contracts e innovazione tecnologica: l'informatica e il diritto dei contratti" [2019] Riv. dir. priv. 167; S Orlando, "Gli smart contracts come prodotti software" in [2021] Osservatorio Giuridico sull'Innovazione Digitale 41; A Zoppini, *Considerazioni generali su contratto e nuove tecnologie, in Internet, contratto e persone: quale futuro?* (Milano 2021) 29.

A smart contract is known as a computer program to which the performance of the contract is delegated.[27] Such performance may, but need not, be integrated into AI-based systems, and most often makes use of blockchain technologies. What characterises this tool, upon closer inspection, is its nature as a pre-programmed system that operates according to pre-defined rules set by the parties in a contractual scheme, which is translated into computer code. For these reasons, it cannot be considered a system capable of adapting to subsequent contingencies, nor does it possess any autonomy. Its function is, rather, to enable the automatic implementation of obligations during the performance phase.[28]

AI systems,[29] by contrast, possess autonomous processing capabilities, even in the absence of instructions from human agents. As such, they raise numerous legal and ethical questions, since they are capable not only of executing pre-determined commands, but also of evaluative functions, including decisions concerning the very purpose of the contract, and of determining essential elements of the agreement.[30]

It follows that the emerging phenomenon of algorithmic renegotiation raises further issues. The main concern relates to the extent of these systems' autonomy in contracting. Indeed, some scholars have theorised the possibility of a full replacement of human agents by machines, on the basis that such systems are capable of learning through the evolution of experience.

As a consequence, the human party would be able to anticipate the system's decisions. For that reason, the legal effects of such decisions would remain imputable to that party.[31]

The foregoing commentary has been considered with regard to the principal distinctions between the two categories, it is now necessary to examine if Article 1349 of the Italian Civil Code may be adapted, within the framework outlined above, to scenarios involving renegotiation through artificial intelligence.

Article 1349 of the Italian Civil Code outlines two distinct modalities for third-party determination: one based on the third party's unlimited discretion, and the other on an equitable assessment. In the former, the contract is rendered void should the third party

[27] For a deeper analysis about the relationship between unpredictable change of circumstances and smart contracts see E Maio, 'The Management of Contractual Non-Performance in Smart Contract' (2022) 16 Actualidad Jurídica Iberoamericana; C Attanasio, 'Inadempimento dello Smart Contract, sistema rimediale e tutela effettiva' (2024) 4 Riv. Diritto civile; G Bevivino, 'Smart Contracts e "Assestamenti" della Disciplina Generale del Contratto' (2024) 2 Contratto e impresa.

[28] Francesco Di Giovanni, 'Attività contrattuale e intelligenza artificiale' (2019) 7 Giur. It 1677.

[29] Generally, artificial intelligence is defined as the field of computer science concerned with the development of tools—both software and hardware—capable of performing tasks that are typically associated with natural intelligence ascribed to human beings. See R Kurzweil, *The age of intelligent machines* (Cambridge 1990).
As defined in the European AI Act regulation 2024/1689 under Article 3 (1) "*Artificial intelligence system*" means "*a machine-based system designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments*".

[30] Francesco Di Giovanni, 'Attività contrattuale e intelligenza artificiale' (2019) 7 Giur. It 1681.

[31] Ugo Ruffolo e Andrea Amidei, *Diritto all'intelligenza artificiale, Vol. I, Responsabilità. Contratto. Regolazione. Veicoli autonomi* (LUISS University Press 2024) 251.

fail to perform the determination, and any decision rendered, however flawed, remains binding unless vitiated by bad faith. By contrast, where the determination is to be made according to equity, the third party's failure to act does not nullify the contract but instead results in judicial intervention to fill the gap[32].

In light of this legislative provision, at least two critical issues clearly emerge: the compatibility of such a framework with the delegation of decision-making to a machine, and the delineation of the boundaries within which the machine's decision-making autonomy may be legitimately exercised.

Starting with the issue of compatibility, no significant obstacles arise in entrusting a machine with the determination of certain contractual elements, provided that the parties have identified the principal terms of the agreement. From this perspective, the determination of the essential elements of the contract would remain attributable to the will of the parties, without causing substantial deviation from the ordinary contractual framework. As leading scholars have pointed out, the demands of contemporary society and the advancement of technology have long contributed to the erosion of the traditional understanding of *agreement* as derived from the original reading of Article 1321 of the Italian Civil Code. In other words, the conception of a contractual agreement as the necessary result of a bilateral and dialogical exchange has been progressively abandoned.[33]

Moreover, the gradual reduction of at least one of the parties' volitional domain has been evident since the introduction of so-called standardised contracts. In contracts of adhesion, one party presents the other with a contract whose terms and conditions are predetermined. As a result, the counterparty, far from forming a fully autonomous and conscious will, lacks control over the contractual content and is merely faced with the option of accepting or rejecting the pre-established terms proposed by the offeror.[34]

Ultimately, technological progress has contributed to the decline of the freedom of will theory as a rigid *dogma*[35], in favour of an increasingly objectivized conception of contractual exchange. In other words, what becomes legally relevant is the objective dimension of the parties' declarations, rather than a reconstruction of their inner volitional intent.

For these reasons, it is possible to infer that, where the parties have previously given their consent to delegate the decision-making process to an AI system, the renegotiation

[32] While not exhaustive, for more detailed discussion of the provision's use in Italian law, see E Del Prato, 'Il contratto e il suo oggetto nel diritto italiano' (2012) 1 Riv. trim. dir. proc. civ. 23 .

[33] Ugo Ruffolo e Andrea Amidei, *Diritto all'intelligenza artificiale, Vol. I, Responsabilità. Contratto. Regolazione. Veicoli autonomi* (LUISS University Press 2024) 252.

[34] Francesco Di Giovanni, 'Attività contrattuale e intelligenza artificiale' (2019) 7 Giur. It. 1677.

[35] E Gabrielli, 'La nozione di contratto e la sua funzione, Appunti sulla prospettiva di una nuova definizione di contratto' (2019) 2 Gius. Civ. 299. For a historical perspective of the contract's object see E Gabrielli, 'Storia e dogma dell'oggetto del contratto' (2004) 1 Riv. dir. civ. 327. Moreover, for a distinction between *arbitrato rituale and irrituale* see Enrico del Prato, 'Le risoluzioni negoziali delle controversie' in N Lipari e P Rescigno (eds), *Trattato di Diritto Civile* (2009) 560. For a detailed discussion of the arbitrator's error, see Enrico del Prato, 'Le annullabilità', in Gentili (ed), *Trattato del contratto, Roppo* IV, *Rimedi*, I, (Milano 2006) 232.

outcome produced by the machine may be directly attributable to the parties themselves. In such a case, the decision could be equated to an objectivized manifestation of will, legally imputable to those who made use of the system.[36]

Similarly, determinations grounded in equitable considerations would not appear to raise major concerns. Such determinations are in fact guided by objective criteria. AI-based systems can therefore be trained not only to reconstruct the parties' original intent and restore contractual balance following changed circumstances, but also to interpret these elements through the lens of objective standards, ones to which judicial authorities themselves typically adhere.[37]

In any case, it should be noted that the law expressly provides that, in the absence of a determination by the third party, or where such determination is manifestly unfair or erroneous, the matter shall be resolved by the courts. Thus, the process under consideration does not entail a fully autonomous operation of the AI system.

The situation is notably different where the decision is left to the sole discretion of the third party, namely, in this context, the machine. The core issue lies in the fact that such a determination would concern the regulation of the contractual framework, as modified in light of supervening circumstances, and would be, in substance, the product of the machine's autonomous decision-making.

Nonetheless, the recent introduction of the EU Artificial Intelligence Act (Regulation 2024/1689) enables interpreters to partially support the autonomy of AI in renegotiation processes. In particular, Recital 53[38] offers an important distinction: AI systems that support human decision-making, without replacing it, may fall into the category of

[36] Ultimately, such a mechanism would not differ substantially from the functioning of legal representation as governed by Article 1387 of the Italian Civil Code. In this regard, some scholars have indeed suggested that the attribution of will expressed by the machine may be likened to the legal figure of a representative. Nevertheless, it appears preferable to attribute the intent directly to the parties, without the need to resort to an intermediate reconstruction. Ugo Ruffolo e Andrea Amidei, *Diritto all'intelligenza artificiale, Vol. I, Responsabilità. Contratto. Regolazione. Veicoli autonomi* (LUISS University Press 2024) 256.

[37] The arbitrator should proceed to the contract determination by applying objective criteria, in a balanced and rational manner. The application should take into account all relevant circumstances of the case, with the aim of reconciling the interests of the parties. In this sense Alessandro Criscuolo, *Arbitraggio e determinazione dell'oggetto* (Edizioni Scientifiche Italiane 1995) 181; Francesco Macario, *Adeguamento e rinegoziazione nei contratti a lungo termine* (Jovene 1996) 157.

[38] "*It is also important to clarify that there may be specific cases in which AI systems referred to in pre-defined areas specified in this Regulation do not lead to a significant risk of harm to the legal interests protected under those areas because they do not materially influence the decision-making or do not harm those interests substantially. For the purposes of this Regulation, an AI system that does not materially influence the outcome of decision-making should be understood to be an AI system that does not have an impact on the substance, and thereby the outcome, of decision-making, whether human or automated. An AI system that does not materially influence the outcome of decision-making could include situations in which one or more of the following conditions are fulfilled. The first such condition should be that the AI system is intended to perform a narrow procedural task, such as an AI system that transforms unstructured data into structured data, an AI system that classifies incoming documents into categories or an AI system that is used to detect duplicates among a large number of applications. Those tasks are of such narrow and limited nature that they pose only limited risks which are not increased through the use of an AI system in a context that is listed as a high-risk use in an annex to this Regulation. The second condition should be that the task performed by the AI system is intended to improve the result of a previously completed human activity that may be relevant for the purposes of the high-risk uses listed in an annex to this Regulation. Considering those characteristics, the AI system provides only an additional layer to a human activity with consequently lowered risk* […]".

moderate risk. Conversely, when AI systems substitute human deliberation, especially in contexts involving legal consequences, they are likely to be categorized as high-risk, thereby falling under stricter regulatory scrutiny both at the EU level and within member states' domestic legal systems. According to those provisions, the potential delegation of contract renegotiation to AI raises critical questions about legality, legitimacy, and the boundaries of permissible automation in sensitive legal domains.

This regulatory framework is further reinforced by Article 6 and Annex III of the AI Act, which explicitly classify as high-risk those AI systems deployed in activities connected to the administration of justice and democratic processes. These include systems designed to assist judicial bodies or alternative dispute resolution (ADR) mechanisms in fact-finding, interpreting legal norms, and applying the law to specific disputes. Notably, this provision opens the door to the use of AI in extrajudicial renegotiation procedures, particularly when parties seek to restore contractual balance following supervening events, thereby potentially relieving individuals and entities from the burden and cost of litigation. Nevertheless, the law imposes a mandatory condition: human oversight must be ensured. Also, Article 14 underlines this requirement, stipulating that all high-risk AI systems must be subject to appropriate human supervision, aimed at safeguarding fundamental rights and maintaining accountability.

In a general perspective, these provisions reflect a prudent regulatory approach: while the use of AI in high-stakes legal contexts is not prohibited, it is carefully bounded by safeguards and oversight mechanisms. In fact, Recitals 44 and 60[39] of the AI Act affirms the possibility of delegating certain decision-making tasks to AI systems, provided that their deployment is accompanied by proportional risk mitigation measures. This anticipates a gradual evolution towards more autonomous AI involvement, particularly in functions that require complex legal reasoning, without undermining the primacy of human dignity, due process, and individual freedoms.

In this evolving landscape, the prospect of training AI systems[40] to reconstruct the original intent of the parties and to re-establish contractual equilibrium disrupted by unforeseen circumstances becomes increasingly plausible. Such capabilities could allow AI to assume a proactive role in contractual renegotiation, particularly in cases involving hardship or significant changes in circumstances.

The foregoing considerations find further support in several provisions of Regulation (EU), which contribute to shaping a normative framework that does not prohibit, but rather regulates, the use of artificial intelligence systems in high-risk legal contexts. First

[39] Both clearly support the permissible deployment of AI systems, even in high-risk environments such as the legal domain, provided appropriate safeguards are in place. Recital 44 underscores that AI systems may offer substantial benefits, even in sensitive fields such as law, while Recital 60 emphasizes the necessity of designing high-risk AI systems in a manner that permits effective human oversight throughout their lifecycle, ensuring that human values, interests, and rights are duly protected.

[40] For a comprehensive discussion on the subject, see Ugo Ruffolo e Andrea Amidei, *Diritto all'intelligenza artificiale, Vol. I, Responsabilità. Contratto. Regolazione. Veicoli autonomi* (LUISS University Press 2024) 17.

and foremost, Article 9[41] requires providers of high-risk AI systems to adopt appropriate technical and organisational measures aimed at identifying, analysing, and mitigating risks, including those arising during the operational phase of the system. This provision clearly demonstrates that the deployment of AI is not *per se* prohibited, but is instead subject to compliance with duties of preventive diligence and ongoing monitoring, in line with the proportionate regulatory approach underpinning the AI Act.

Within this framework, it may be argued that the use of an AI system in the decision-making phase of contractual renegotiation—even as a central rather than merely ancillary component, is not excluded *ipso iure,* provided that *ex ante* risk mitigation mechanisms are implemented and that human oversight is ensured in the event automated supervision proves ineffective. This requirement is expressly reiterated in Article 14, which mandates the presence of adequate human oversight for all systems classified as high-risk.

Further relevant elements can be drawn from the combined reading of Articles 13[42] and 15[43]. Article 13 enshrines the principle of transparency, requiring that systems be designed in such a way as to make their functioning intelligible to users; Article 15, in turn, provides that such systems must be sufficiently accurate, reliable, secure, and resilient to errors or faults. These are essential safeguards, particularly in fields such as contract law, where automated decisions must rest upon objective legal standards—such as good faith and equity—which are also referenced in Recital 60 as principles that AI may progressively learn and apply through machine learning techniques.

In light of these considerations, the thesis that there exists no legislative prohibition against entrusting AI with the conduct of contractual renegotiation appears not only tenable, but legally well-founded. Where appropriate safeguards are in place and the system is functionally designed in accordance with the principles of transparency, human oversight, and reliability, the use of AI may be deemed fully compatible with the positive legal order. Consequently, algorithmic renegotiation may be legitimised not merely as an ancillary tool, but as a proper locus of decision-making—consistent with the broader evolution of contract law towards increasingly objective, automated, and technologically integrated models.

What has been stated, in any case, appears to be in tension with the second paragraph of Article 1349 of the Italian Civil Code, which provides that a determination entrusted to the mere discretion of a third party cannot be challenged unless bad faith is proven. Furthermore, if the third party fails to make the determination and the parties do not

[41] *"A risk management system shall be established, implemented, documented and maintained in relation to high-risk AI systems* […]".
[42] *"High-risk AI systems shall be designed and developed in such a way as to ensure that their operation is sufficiently transparent to enable deployers to interpret a system's output and use it appropriately […] High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to deployers […]".*
[43] *"High-risk AI systems shall be designed and developed in such a way that they achieve an appropriate level of accuracy, robustness, and cybersecurity, and that they perform consistently in those respects throughout their lifecycle […]".*

agree on a replacement, the contract is deemed void. Within this framework, there seems to be no room for additional forms of control.

However, the same provision expressly allows the parties to agree on a substitute for the third party. In this regard, it becomes possible to theorize a dual-layered control mechanism aligned with the requirements of the EU AI Regulation. On the one hand, entrusting an AI system with such a determination, based on the expressed will of the parties, does not necessarily entail a full abdication of supervisory control over the AI's behaviour. Indeed, should the AI system fail to reach a decision, the parties retain the ability to replace it with another entity of their choosing.

Moreover, even in the absence of a substitute agreement capable of replacing the original contract, the negotiation framework shaped by the AI could be subject to *ex post* evaluation by the third party designated by the parties to oversee or finalise the renegotiation process. In this way, the automated negotiation system does not operate in a legal vacuum, but remains embedded within a broader structure of contractual autonomy, procedural safeguards, and post-intervention human oversight, all consistent with the spirit of the AI Regulation.

A longstanding criticism, considered decisive by some, concerns inherent subjectivity of the system. In other words, making judgment objective does not remove the need to balance conflicting interests according to general principles, which involve not only legal reasoning but also the arbitrator's emotional and intuitive faculties. As a result, humans remain the only true custodians of emotional intelligence, and thus of a form of judgment that is capable of addressing factors that transcend mere factual assessment, thanks to their capacity for empathy.

For this reason, it could be argued that delegating such a delicate evaluative task, such as contract renegotiation, to a machine should be categorically excluded. However, this line of criticism can be challenged on the basis that the introduction of an emotional dimension is not necessarily a guarantee for the quality or fairness in the decision-making process. On the contrary, in certain cases, it may act as an obstacle to achieving a truly objective balance, as human judgments are inevitably shaped by personal experiences, cognitive biases, and the subjective lens through which each individual arbitrator perceives the facts.

These are, in any event, machines designed to self-learn and to develop the capacity to modify their own evolutionary pathways and behavioural responses. To this end, such systems undergo a training phase during which they are provided with so-called datasets, structured inputs through which the machine learns how to learn, progressively acquiring knowledge via the repetition of experiences to which it is exposed.[44]

[44] Ugo Ruffolo e Andrea Amidei, *Diritto all'intelligenza artificiale, Vol. I, Responsabilità. Contratto. Regolazione. Veicoli autonomi* (LUISS University Press 2024) 17.

Moreover, it cannot be ruled out that future developments in artificial intelligence may reach the point where such systems are capable of emulating and learning human emotions. Many researchers are already experimenting on a field of research focused on the development of emotional artificial intelligence[45]. If current systems already possess such capabilities, it is conceivable that future training processes will include the mirroring of human emotions, thereby enabling machines not only to recognise but also to emulate them.

[45] This refers, in particular, to affective computing, now commonly known as emotion AI—a branch of artificial intelligence research concerned with human emotions. Since the 1960s, specific research projects have been developed focusing on human emotions and individual personality traits. The first—and arguably most significant—study in this field can be traced back to the system devised by Paul Ekman at the University of California. See P Elkman, W V Friesen, 'The Reportoire of Nonverbal Behaviour: Categories, Origins, Usage and Coding' (1969) 1 Semiotica 49-98; Id, Constants Across Cultures in the Face and Emotion (1971) 17(2) Journal of Personality and Social Psychology 124; P Elkman W V Friesen, S S Tomkins, 'Facial Affect Scoring Technique: A First Validity Study' (1971) 3 Semiotica 1; P Elkman, 'An Argument for Basic Emotions' (1992) 6 Cognition and Emotion 169-200.
The analytical and systematic classification of human emotions later found definitive expression in the field known as affective computing, particularly within computer science. This innovative domain owes its origins to the pioneering work of Rosalind Picard and the research team at the MIT Media Lab, who were among the first to envision the integration of advances in computational and automated technologies with psychological insights into human emotional responses. Emotions, whether conscious or unconscious, were understood to be susceptible to study, codification, and, ultimately, computational modelling. For further information, S B Daily, 'Affective Computing: Historical Foundations, Current Applications, and Future Trends' in *Emotions and Affect in Human Factors and Human-Computer Interaction* (Elsevier 2017) 213-231.
Its objective is to recognise, classify, and guide machine behaviour in response to emotional input. This is made possible through the analysis of various data points, including facial expressions, body gestures, tone of voice, and even physiological indicators such as heart rate and blood pressure. These systems are developed through deep learning and the use of specifically designed neural networks. Although there is currently no established legal framework, it is conceivable that such experimental technologies will, in the future, be widely applied in various practical contexts. This is already the case in areas such as advertising and driver safety enhancement. Moreover, for some time now, artificial intelligence has been used to infer an individual's emotional state by analysing facial expressions, vocal tone, body movements (including gait), and other biometric signals, through machine learning techniques. On this point, see Stark, Hoei, 'The Ethics of Emotion in Artificial Intelligence Systems' (FAccT 2021) 782.

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GENERAL SECTION

DATASET ASSESSMENT TOOLS FOR THE AI ACT COMPLIANCE OF HIGH-RISK AI SYSTEMS*

Abstract

The European Union's Artificial Intelligence Act (AI Act), effective as of August 2024, introduces stringent data governance requirements for high-risk AI systems. Central to these obligations is the mandate for data used in training, validation, and testing to be subject to rigorous quality controls and governance practices aligned with the system's intended purpose. This paper examines the AI Act's novel emphasis on responsible data handling as a foundation for mitigating bias, ensuring safety, and protecting fundamental rights. It argues that while existing scholarship largely focuses on algorithmic fairness at the model level, insufficient attention has been given to fairness embedded within the data itself. Addressing this gap, the paper explores the complex ethical and epistemological tensions inherent in defining "fairness", and critiques current policy frameworks for their narrow focus on technical fixes. The study highlights the FAnFAIR tool as a pioneering approach to data fairness evaluation, offering a hybrid methodology that integrates automated statistical diagnostics with qualitative, context-aware assessments. FAnFAIR aligns its features with the AI Act's legal mandates and facilitates compliance through continuous bias monitoring, data quality enhancement, and informed decision-making about dataset suitability. This paper provides a socio-legal and technical analysis of data governance under the AI Act, advocating for a shift toward embedded ethical oversight throughout the AI lifecycle and, in particular, in the data processing phase.

JEL CLASSIFICATION: K10, K13

SUMMARY

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10.13135/2785-7867/12840

1 Introduction

Entered into force in August 2024, the Artificial Intelligence Act (AI Act)[1] prescribes several requirements and obligations for high-risk systems, particularly concerning Data Governance. Such systems must adhere to specific quality criteria related to training, validation, and testing, which must be "subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system" under Article 10(2) AI Act. These requirements aim to ensure responsible data handling and mitigate risks related to bias, safety, and security issues that are known to affect AI systems.

Firstly, data governance must reflect the design choices made during the creation of the AI system, aligning data processing practices with the intended purpose of the system, such as considering which data sources and processing methods are most appropriate for achieving the system's goals. The processes for data collection must be transparent and well-documented, for example regarding the origin of the data.

Data governance also involves a continuous oversight of data preparation activities. This includes operations such as annotation, labelling, cleaning, updating, enrichment, and aggregation of data. These processes must ensure that the data is of high quality and suitably transformed for the AI system's requirements. Additionally, there must be a clear understanding of the assumptions made about what the data is intended to measure or represent, with an evaluation of whether it accurately reflects the real-world phenomena it aims to model.

Another essential aspect of the data governance framework is assessing the availability, quantity, and suitability of the data. This assessment helps to verify that the data used is complete and reliable, minimising the risk of errors and deficiencies. The AI Act places great emphasis on identifying potential biases within the data that could affect the health and safety of individuals, infringe on fundamental rights, or lead to discrimination prohibited under Union law, deeming that addressing these biases is important to mitigating unfair or harmful outcomes.

In instances where biases are detected, the AI Act prescribes that appropriate measures must be taken to prevent and mitigate their effects. This could involve revising the data collection processes, enhancing the quality of the data, or implementing fairness checks throughout the AI system's development. Moreover, it is vital to identify any gaps or shortcomings in the data that might hinder compliance with the AI Act. Once these issues are acknowledged, strategies can be developed to address them, ensuring that the AI system maintains a high level of quality.

The predominant focus in the academic literature has been on uncovering biases within the models themselves and biases in the use of AI systems, as opposed to biases inherent

[1] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act).

in the data. This focus has resulted in creating a wide array of metrics designed to assess the fairness of algorithmic results. Assessing algorithmic fairness within the data context was relatively limited, primarily focusing on transparency and documentation procedures.

The examination of algorithmic fairness within datasets has followed two primary research directions. One strand of research is concerned with scrutinizing data curation processes, and the other one with the empirical analysis of fairness-related data aspects, such as how data can impact the fairness of algorithms.

The case law about discrimination in datasets is scarce since parties tend to settle out of court to avoid negative publicity. This has been the case in the United States, as seen in the agreement approved by the Southern District Court of New York between Meta and the Department of Justice concerning discrimination in social housing advertising, which violated the Fair Housing Act[2]. In Europe, a notable example of tools for detecting algorithmic bias is the Dutch experience with the Algorithm Audit conducted by DUO (Dienst Uitvoering Onderwijs)[3]. This audit was used to review scholarship recipient selection procedures to identify racial bias against applicants with a migration background.

As highlighted by the European Digital Rights (EDRi) report, current policy frameworks often adopt a constrained understanding of fairness in AI, focusing narrowly on the technical remediation of datasets, such as eliminating bias or ensuring that data is "representative, error-free, and complete", without addressing the broader societal structures in which AI systems operate.[4] This approach, while necessary, is not sufficient. AI systems trained on "debiased" datasets may still replicate and legitimise existing inequalities embedded in the institutions, processes, and ideologies that shape the data in the first place. Thus, a technically fair dataset may nonetheless contribute to inequitable outcomes.

This limitation points to a deeper epistemological and ethical tension in the field of algorithmic fairness. As Hanna et al. argue, the discourse must shift from an exclusive focus on the algorithmic layer toward a systemic analysis of the social, political, and institutional contexts in which AI is designed, deployed, and governed.[5] Indeed, while the literature acknowledges the critical role of data quality, representativeness, and statistical soundness in shaping model performance,[6] it simultaneously calls for an

[2] Agreement between Meta and the Department of Justice <https://about.fb.com/wp-content/uploads/2022/06/June_2022_HUD_Settlement_Agreement.pdf> accessed 16 September 2025.
[3] 'Profiled Without Protection - Students In The Netherlands Hit By Discriminatory Fraud Detection System' Research Briefing (Amnesty International 2024).
[4] Agathe Balayn and Seda Gürses, 'Beyond Debiasing: Regulating AI and Its Inequalities' EDRi Report (EDRi 2021).
[5] Alex Hanna and others, 'Towards a Critical Race Methodology in Algorithmic Fairness' in *FAT* '20: Proceedings of the 2020 Conference on Fairness, Accountability, and Transparency* (ACM 2020).
[6] Venkat N Gudivada, Amy Apon and Junhua Ding, 'Data Quality Considerations for Big Data and Machine Learning: Going beyond Data Cleaning and Transformations' (2017) 10 International Journal on Advances in Software 1; R Stuart Geiger and others, 'Garbage in, Garbage out? Do Machine Learning Application Papers in Social Computing Report Where Human-Labeled Training Data Comes from?' in *FAT* '20: Proceedings of the 2020 Conference on Fairness, Accountability, and Transparency* (ACM 2020); Divy Thakkar and others, 'When Is Machine Learning Data Good?: Valuing

expanded view of fairness that incorporates normative values and interrogates structural power imbalances.

In practice, this means recognising that unfairness is not intrinsic to data alone but is also a product of the human and institutional decisions surrounding data collection, annotation, and reuse. For instance, ensuring informed consent for data reuse,[7] enforcing transparency in secondary data usage,[8] and conducting extensive ethics assessments that go beyond procedural review boards[9] are all critical measures. These actions must be grounded in foundational ethical principles[10] such as accountability, dignity and self-determination, traceability, stakeholder engagement, risk assessment, and attention to societal impact. Embedding such principles across the AI lifecycle[11], from data design to system deployment, is vital for mitigating harm and advancing a truly equitable AI ecosystem.

In the literature, only few tools have been developed to assess datasets for fairness, among which is the FAnFAIR software.[12] Within its framework, the insights drawn from the aforementioned literature are operationalised through a hybrid methodology that combines autonomously computed statistical properties of datasets with qualitative evaluations manually entered by the user. By integrating both quantitative and normative considerations, FAnFAIR enables a context-aware assessment of data fairness. The tool can inform key decisions during the early stages of AI development, including whether to apply pre-processing techniques or, in cases of significant bias or legal non-compliance, whether to discard the dataset entirely to avoid AI-driven harm. In this way, FAnFAIR serves as a foundational resource for guiding principled data governance and risk mitigation, contributing to the creation of lawful, ethical, and socially responsible AI systems.

FAnFAIR offers a new toolset that aligns with the data governance requirements of the AI Act, which can be important especially in the context of medical applications. By

in Public Health Datafication' in *CHI '22: Proceedings of the 2022 CHI Conference on Human Factors in Computing Systems* (ACM 2022) <https://doi.org/10.1145/3491102.3501868> accessed 15 September 2025.

[7] Chiara Gallese and others, 'Predicting and Characterizing Legal Claims of Hospitals with Computational Intelligence: The Legal and Ethical Implications' in *2022 IEEE Conference on Computational Intelligence in Bioinformatics and Computational Biology (CIBCB)* (IEEE 2022) <https://doi.org/10.1109/CIBCB55180.2022.9863033> accessed 15 October 2025.

[8] Chiara Gallese, 'Legal Aspects of AI in the Biomedical Field. The Role of Interpretable Models' in Bruno Carpentieri and Paola Lecca (eds), *Big Data Analysis and Artificial Intelligence for Medical Sciences* (Wiley 2024).

[9] Emmanuel R Goffi, Louis Colin and Saida Belouali, 'Ethical Assessment of AI Cannot Ignore Cultural Pluralism: A Call for Broader Perspective on AI Ethic' (2021) 1 Arribat-International Journal of Human Rights 151.

[10] S Lo Piano, 'Ethical Principles in Machine Learning and Artificial Intelligence: Cases from the Field and Possible Ways Forward' (2020) 7(1) Humanities and Social Sciences Communications 1; B Giovanola and S Tiribelli, 'Beyond Bias and Discrimination: Redefining the AI Ethics Principle of Fairness in Healthcare Machine-Learning Algorithms' (2023) 38(2) AI & Society 549.

[11] I Dankwa-Mullan and others, 'A Proposed Framework on Integrating Health Equity and Racial Justice into the Artificial Intelligence Development Lifecycle' (2021) 32(2) Journal of Health Care for the Poor and Underserved 300.

[12] Chiara Gallese and others, 'Investigating Semi-Automatic Assessment of Data Sets Fairness by Means of Fuzzy Logic' in *2023 IEEE Conference on Computational Intelligence in Bioinformatics and Computational Biology (CIBCB)* (IEEE 2023) <https://doi.org/10.1109/CIBCB56990.2023.10264913> accessed 15 September 2025.

providing a semi-automatic assessment of dataset fairness, FAnFAIR addresses critical aspects of data quality, bias detection, and pre-processing decisions, all of which are central to regulatory compliance. FAnFAIR's primary utility lies in its rule-based fuzzy inference system, which combines automated statistical analysis with user-provided qualitative insights. This hybrid approach allows the software to evaluate multiple fairness metrics autonomously, reducing the risk of human error and subjective bias. The AI Act mandates a careful examination of data for biases that might impact health, safety, and fundamental rights, and FAnFAIR's capacity to detect issues related to balance, outliers, missing values, and overall dataset quality helps users identify and address potential problems early in the AI development process, thereby mitigating risks before they propagate through the system.

The software's ability to assist in deciding whether to pre-process a dataset, or even discard it entirely, is aligned with the AI Act's focus on data suitability and representativeness. It also allows users to reflect on their organizational measures and compliance procedures: since it integrates fairness considerations into dataset evaluation, it supports compliance with requirements related to the formulation of data assumptions and the detection of data gaps or shortcomings. This ensures that only datasets that meet stringent fairness criteria proceed to the training stage, mitigating the potential for biased or harmful outcomes.

Recent enhancements to FAnFAIR,[13] including simplified data import, improved outlier detection, and analysis of sensitive variables, further align the software with the AI Act's requirements for thorough data examination. These new features allow for a deeper analysis of factors that could contribute to bias, especially in complex datasets with missing or noisy data. For example, FAnFAIR's testing on real-world medical datasets, such as those involving COVID patients, demonstrates its practical application in identifying how pre-processing steps can influence the fairness and predictive performance of AI models.[14] This capability directly supports the AI Act's obligation for continuous assessment and mitigation of biases throughout the AI system lifecycle.

In the case of the COVID dataset, the initial version included 951 patients and 129 fields:

- health history collected at hospital admission (24), such as age, sex, body-mass index, and 21 risk factors (e.g., smoking habits).
- administered therapies (20)- explaining which therapies were administered to the patient, such as drugs (e.g., warfarin), and different types of ventilatory support (e.g., invasive mechanical ventilation).
- complications (21) – identifying complications that occurred to the patient (e.g., acute renal failure).

[13] Michele Rispoli and others, 'Investigating Fairness with FAnFAIR: Is Pre-Processing Useful Only for Performances?' in *2025 IEEE Symposium on Computational Intelligence in Health and Medicine (CIHM)* (IEEE 2025) <https://doi.org/10.1109/CIHM64979.2025.10969477> accessed 15 September 2025.
[14] The detailed methodology is described in Rispoli and others (n 14).

- serial measurements (45) – detailing up to five measurements for each of nine variables, such as physiological quantities (e.g., lymphocytes), and indicators of the status of pulmonary functions (e.g., arterial partial pressure of oxygen to fraction of inspired oxygen ratio).
- dates (18) – detailing variables such as dates of birth, hospitalisation, decease/discharge, sampling of serial values.
- outcome (1) - annotating patient's death.

The ML task addressed in our article is intended to solve a binary classification problem: the resulting algorithm predicts mortality of each patient, based on the data collected during their hospitalisation. We used FanFAIR to evaluate four versions of our dataset, each in a different stage of the data processing pipeline adopted in the original study[15] we referenced:

1) Raw Dataset - (947 rows, 129 columns) in csv, minimal processing was applied, that is datatype enforcement and automated removal of invalid entries of numeric variables.
2) Cleaned Dataset – (825 rows, 79 columns), in which uninformative and highly sparse variables were removed, along with rows corresponding to patients outside the target population—specifically, those not treated with glucocorticoids (GCs) or presenting clearly anomalous values. Of the nine available serially measured variables, only two were retained: the PaO_2/FiO_2 ratio and C-reactive protein (CRP) levels.
3) Re-serialised Dataset – (825 rows, 57 columns), in which date information was removed, and raw serial measurements were transformed into three summary features per series: the first value, the last value, and a binary "improving" indicator. This indicator was derived from the raw measurements using heuristics developed by medical experts.
4) Selected Dataset – (825 rows, 10 columns), in which only the nine predictor variables identified during the variable selection phase of the original study's processing pipeline were used, along with the outcome variable. Additionally, the inclusion of legal compliance as a metric in FAnFAIR helps in supporting adherence to the regulatory framework set forth by the AI Act. By evaluating whether dataset creators have respected the related laws and duties, the software aids in ensuring that data governance practices align with the applicable laws and regulations. This integrated approach reduces the likelihood of non-compliance and enhances the overall accountability and transparency of AI system development.

FAnFAIR thus provides a robust solution for meeting the AI Act's data governance requirements by streamlining the process of fairness evaluation, offering actionable insights, and supporting informed decision-making about dataset suitability. Its combination of automated analysis and human expertise facilitates a nuanced compliance-oriented approach to data management in high-risk AI systems.

[15] F Salton and others, 'A Tailored Machine Learning Approach for Mortality Prediction in Severe COVID-19 Treated with Glucocorticoids' (2024) 28(9) Int J Tuberc Lung Dis 439.

This article is divided as follows: Section 1 presents our work and its context; Section 2 provides a summary of the state of the art related to dataset assessment tools; Section 3 explains why assessment tools are needed; Section 4 describes the FAnFAIR assessment tool; and Section 5 draws some concluding remarks.

2 State of the art

This article focuses on the data assessment[16] instruments developed or studied since the passing of the AI Act in the EU. We start with an analysis of the articles that have been published since the definitive approval of the AI Act by the European Parliament. Scholarship that has since been confronted with the development of data assessment tools can be divided into two groups: on the one hand, some scholars have engaged in theoretical reconstruction in connection with the provisions of the AI Act relating to AI Systems and datasets; on the other hand, some researchers have developed operational tools, which will be briefly reviewed.

On the theoretical side, there are contributions such as that made by Golpayegani and others,[17] which argue that with the enactment of the AI Act, the documentation of high-risk AI systems and related risk management information will become a legal requirement that will play a key role in demonstrating compliance. Despite this, there is a lack of standards and guidelines to help draft AI and risk documentation in line with the AI Act. The authors propose AICat - an extension of DCAT - for representing catalogues of AI systems that provides consistency, machine-readability, searchability, and interoperability in managing open metadata regarding AI systems.

Butt and others[18] refer to a multidisciplinary approach to examine the complicated provisions and implications of the AI Act, which encompasses legal, ethical, socio-economic, and technological dimensions. An important aspect of this research is how the Regulation addresses the identification and mitigation of biases within AI systems.

Hernandez and others[19] propose a terminological mapping of the AI Act to assess the consistency and clarity of the definitions and concepts contained therein, with a view to facilitating compliance and regulatory harmonisation. Indeed, gaps in definitions can affect the consistency of compliance statements across organisations, sectors and applications. This can lead to regulatory uncertainty, particularly for SMEs and public sector bodies that rely on compliance with standards rather than equivalent proprietary

[16] In the context of this article, "data assessment" refers to the rules, tools, or methods that decide which data goes where and how it is used, if it complies with relevant law or ethical principles, if it is biased or otherwise flawed.
[17] Delaram Golpayegani, Harshvardhan J Pandit and Dave Lewis, 'AICat: An AI Cataloguing Approach to Support the EU AI Act' [2024] arXiv:2501.04014 <https://doi.org/10.48550/arXiv.2501.04014> accessed 11 September 2025.
[18] Junaid Sattar Butt, 'Analytical Study of the World's First EU Artificial Intelligence (AI) Act' (2024) 5(3) International Journal of Research Publication and Reviews 7343.
[19] Julio Hernandez, Delaram Golpayegani and Dave Lewis, 'An Open Knowledge Graph-Based Approach for Mapping Concepts and Requirements Between the EU AI Act and International Standards' [2024] arXiv:2408.11925 <https://doi.org/10.48550/arXiv.2408.11925> accessed 11 September 2025.

systems for the development and implementation of compliant high-risk AI systems. The paper offers a simple and repeatable mechanism for mapping terms and requirements related to regulatory statements contained in regulations and standards, such as the AI Act and ISO management system standards, to open knowledge graphs to identify where regulatory steps need to be taken from a technical perspective to promote transparency and explainability of regulatory processes.

Davvetas and others[20] elaborate the TAI Scan Tool, that is a RAG-based self-assessment tool that supports the legal TAI assessment, with a particular emphasis on facilitating compliance with the AI Act. It involves a two-step approach with a pre-screening and an assessment phase. The assessment output of the system includes insight regarding the risk-level of the AI system according to the AI Act, while at the same time retrieving relevant articles to aid with compliance and notify on its obligations.

Ceravolo and others[21] propose a Fundamental Rights Impact Assessment (FRIA) methodology, which aims to assess the human rights impact on high-risk AI systems and ensure compliance with the EU AI Act.

The second group of scholars focused on the practical development of data assignment tools. Focusing on logistics, Marino and others[22] introduce 'Compliance Cards', a system that automates AI compliance analysis by capturing metadata related to AI systems and their datasets. The metadata is then evaluated using an automated algorithm to predict compliance status. This approach enhances the efficiency of regulatory assessments by providing a structured and automated compliance evaluation process. Golpayegani and others[23] show a similar approach with "AI Cards", a tool that aligns with the AI Act's documentation requirements, improving transparency and accountability in AI compliance assessment.

Milaj and others[24] elaborate an open-source compliance tool to be used in migration, asylum and border control management. This study analyses from a legal doctrinal approach the compliance of open-source data from social media platforms with high-quality data and transparency requirements. The authors underline that, since transparency marks the boundary between high-risk and unacceptable-risk AI, using open social media data for border control risk assessment may constitute an unacceptable threat to fundamental rights without proper safeguards.

[20] Athanasios Davvetas and others, 'TAI Scan Tool: A RAG-Based Tool With Minimalistic Input for Trustworthy AI Self-Assessment' [2025] arXiv:2507.17514 <https://arxiv.org/abs/2507.17514> accessed 9 September 2025.

[21] Paolo Ceravolo and others, 'HH4AI: A Methodological Framework for AI Human Rights Impact Assessment under the EUAI Act' [2025] arXiv:2503.18994 <https://arxiv.org/abs/2503.18994> accessed 9 september 2025.

[22] Bill Marino and others, 'Compliance Cards: Automated EU AI Act Compliance Analyses Amidst a Complex AI Supply Chain' [2024] arXiv:2406.14758 <https://doi.org/10.48550/arXiv.2406.14758> accessed 11 September 2025.

[23] Delaram Golpayegani and others, 'AI Cards: Towards an Applied Framework for Machine-Readable AI and Risk Documentation Inspired by the EU AI Act' in Meiko Jensen, Cédric Lauradoux and Kai Rannenberg (eds), *Privacy Technologies and Policy: 12th Annual Privacy Forum, APF 2024, Karlstad, Sweden, September 4–5, 2024, Proceedings* (Springer 2024) 2.

[24] Jonida Milaj and other, 'Transparency as the Defining Feature for Developing Risk Assessment AI Technology for Border Control' (2025) 39 International Review of Law, Computers & Technology 140.

Bogucka and others[25] develop a template for compliance assessment co-designed with AI practitioners and regulatory experts. This template integrates requirements from the AI Act, NIST's AI Risk Management Framework,[26] and ISO 42001,[27] guiding organisations in evaluating dataset quality and bias to ensure regulatory adherence.

Kelly and others[28] propose a methodological approach to AI Act compliance by extending traditional product quality models to encompass AI-specific regulatory requirements. Their approach systematically maps compliance attributes to quality standards, thereby assisting in structured dataset evaluations for high-risk AI applications.

Chard and others[29] studied an audit framework specifically designed for assessing privacy compliance in AI systems. Their framework includes precise prompts for evaluating privacy practices, enhancing AI technologies' security and trustworthiness. This contribution develops robust data assessment tools that align with regulatory requirements.

There is a relevant area of research in this field that goes beyond academic scholarship, since AI assessment tools represent a promising business. Among the prospective products, it is possible to find tools prepared by law firms, consulting firms, and institutions. For instance, *"Conducting an AI Risk Assessment"* by Bloomberg Law[30] shows the need for a quality management system with written policies, procedures, and instructions, and provides a detailed methodology for AI risk assessments. Similarly, *"Article 43: Conformity Assessment"* by SECURITI.AI[31] focuses on assessing quality management systems and documentation to ensure compliance with the AI Act for high-risk AI systems.

The European Fund and Asset Management Association (EFAMA)'s AI-system Assessment Tool[32] helps firms understand AI regulatory complexities, including compliance with the EU AI Act and the GDPR. This tool also aids in documenting and assessing AI use cases, particularly for high-risk systems.

[25] Edyta Bogucka and others, 'Co-Designing an AI Impact Assessment Report Template with AI Practitioners and AI Compliance Experts' in *AIES '24: Proceedings of the AAAI/ACM Conference on AI, Ethics, and Society*, vol 7 (AAAI Press 2025).

[26] Dotan Ravit and others, 'Evolving AI risk management: A maturity model based on the NIST AI risk management framework' [2024] arXiv:2401.15229.

[27] Delaram Golpayegani and others, 'AIRO: an ontology for representing AI risks based on the proposed EU AI Act and ISO risk management standards' (IOS Press 2022) 51–65

[28] Jessica Kelly and others, 'Navigating the EU AI Act: A Methodological Approach to Compliance for Safety-Critical Products' in *2024 IEEE Conference on Artificial Intelligence (CAI)* (IEEE 2024) <https://doi.org/10.1109/CAI59869.2024.00179> accessed 15 September 2025.

[29] Simon Chard, Brent Johnson and Daniel Lewis, 'Auditing Large Language Models for Privacy Compliance with Specially Crafted Prompts' [2024] OSF Preprint <https://osf.io/preprints/osf/8tgkx_v1> accessed 11 September 2025.

[30] Arsen Kourinian and Mayer Brown, 'Conducting an AI Risk Assessment' (*Bloomberg Law*, January 2024) <www.bloomberglaw.com/external/document/X3D03D2K000000/data-collection-management-overview-conducting-an-ai-risk-assess> accessed 28 February 2025.

[31] SECURITI.AI, 'Article 43: Conformity Assessment' (2024) <https://securiti.ai/eu-ai-act/article-43/> accessed 28 February 2025.

[32] EFAMA, 'EFAMA's AI-system Assessment Tool' (5 February 2025) <https://www.efama.org/newsroom/news/efama-s-ai-system-assessment-tool> accessed 28 February 2025.

PwC offers an AI Compliance Tool[33] to guide organisations through the AI Act's requirements. It supports risk assessment, classification, and compliance documentation across technical, business, and compliance teams.

Hogan Lovells' AI Act Applicability Assessment[34] and AI HR Systems Compliance are two questionnaires that are available after registration on the website and designed to help organisations verify the AI Act's applicability to concrete use cases and relevant obligations, offering a preliminary view of the impact of the AI Act.

The European AI Scanner[35] is a RegTech tool designed to ensure compliance with the EU AI Act by standardising AI project workflows. It covers data ingestion, model development, deployment, and lifecycle management, providing a comprehensive solution for firms to comply with AI regulations, especially the AI Act.

3 The need for dataset assessment tools

Data is used in AI training through a process known as machine learning, where algorithms learn patterns, correlations, and decision-making rules from large volumes of structured or unstructured data. During training, an AI model based on machine learning is exposed to a dataset comprising examples relevant to the task at hand so that it can identify statistical relationships within that data. For instance, in supervised learning, a model is trained on labeled datasets, where each input (e.g., a medical image) is paired with a correct output (e.g., a diagnosis). The algorithm adjusts its internal parameters iteratively to minimise the difference between its predictions and the correct outputs, a process guided by optimisation techniques, such as gradient descent.

In unsupervised learning, the AI is given unlabeled data and learns to detect hidden patterns or groupings, such as when patients with similar symptoms are clustered. Reinforcement learning, another approach, involves learning optimal behaviours through trial and error, based on feedback from its environment.

Regardless of which method is used, the quality, quantity, and diversity of the training data are critical: biased, incomplete, or imbalanced data can lead the model to learn inaccurate or discriminatory patterns[36]. Thus, data in AI training is not only a technical input, but also a determinant of ethical and operational outcomes, which needs to be curated and evaluated throughout the AI lifecycle.

Datasets are the foundational building blocks of artificial intelligence, shaping the behavior, accuracy, and decision-making capacity of AI systems. Every algorithm learns

[33] PwC, 'AI Compliance Tool' (PwC, 2025) <www.pwc.com/cz/en/sluzby/technologie-a-data/ai-act/ai-compliance-tool.html> accessed 28 February 2025.
[34] Hogan Lovells, 'AI Act Applicability Assessment' (Digital Client Solutions) <https://digital-client-solutions.hoganlovells.com/ai-act-applicability-assessment?utm> accessed 28 February 2025.
[35] European Commission, 'European AI Scanner - RegTech Tool for EU AI Act Compliance' (1 August 2023) <https://futurium.ec.europa.eu/en/european-ai-alliance/best-practices/european-ai-scanner-regtech-tool-eu-ai-act-compliance> accessed 28 February 2025.
[36] Rispoli and others (n 14).

patterns, associations, and predictive models from the data it is exposed to; thus, the quality, scope, and structure of datasets directly influence how an AI system understands and interacts with the world. Data serves not merely as input, but also as a lens through which AI systems interpret social, economic, and medical realities. For example, in healthcare, datasets containing patient histories, clinical notes, and diagnostic images allow AI to detect diseases or recommend treatments. However, if these datasets are incomplete, biased, or unrepresentative of diverse populations, the AI system may generate misleading or harmful outputs. As such, datasets are not neutral artifacts, for they reflect the social and institutional contexts in which they are produced[37]. Recognising this, it is vital to approach data as a site of ethical, technical, and political concern, requiring deliberate curation, validation, and evaluation to ensure that AI systems are trained equitably and reliably across different populations and environments.

The use of data for AI training is classified as a secondary use (commonly referred to as "reuse"): the data is primarily collected for the so-called primary use, and only later is it employed for AI (see Fig 1 below for an overview of the data lifecycle and related biases).

[37] See, among others: Abeba Paullada and others, 'Data and its (dis)contents: A survey of dataset development' (2021) 2(11) Patterns 100357; Emily Denton, Brent Hecht and Lauren Wilcox, 'On the genealogy of machine learning datasets: A critical history of ImageNet' (2021) 8(2) Big Data & Society <https://journals.sagepub.com/doi/full/10.1177/20539517211035955> accessed 15 September 2025; Alexandra Sasha Luccioni and others, 'Position: Measure Dataset Diversity, Don't Just Claim It' [2024] arXiv preprint arXiv:2407.08188; Milagros Miceli, Julian Posada and Tianling Yang, 'Studying Up Machine Learning Data: Why Talk About Bias When We Mean Power?' (2022) 6 Proceedings of the ACM on Human-Computer Interaction 1; Rodrigo R Gameiro and others, 'The Data Artifacts Glossary: a community-based repository for bias on health datasets' (2025) 32(14) Journal of Biomedical Science 1; Shamik Bose Santy and others, 'NLPositionality: Characterizing Design Biases of Datasets and Models' [2023] arXiv preprint arXiv:2306.01943.

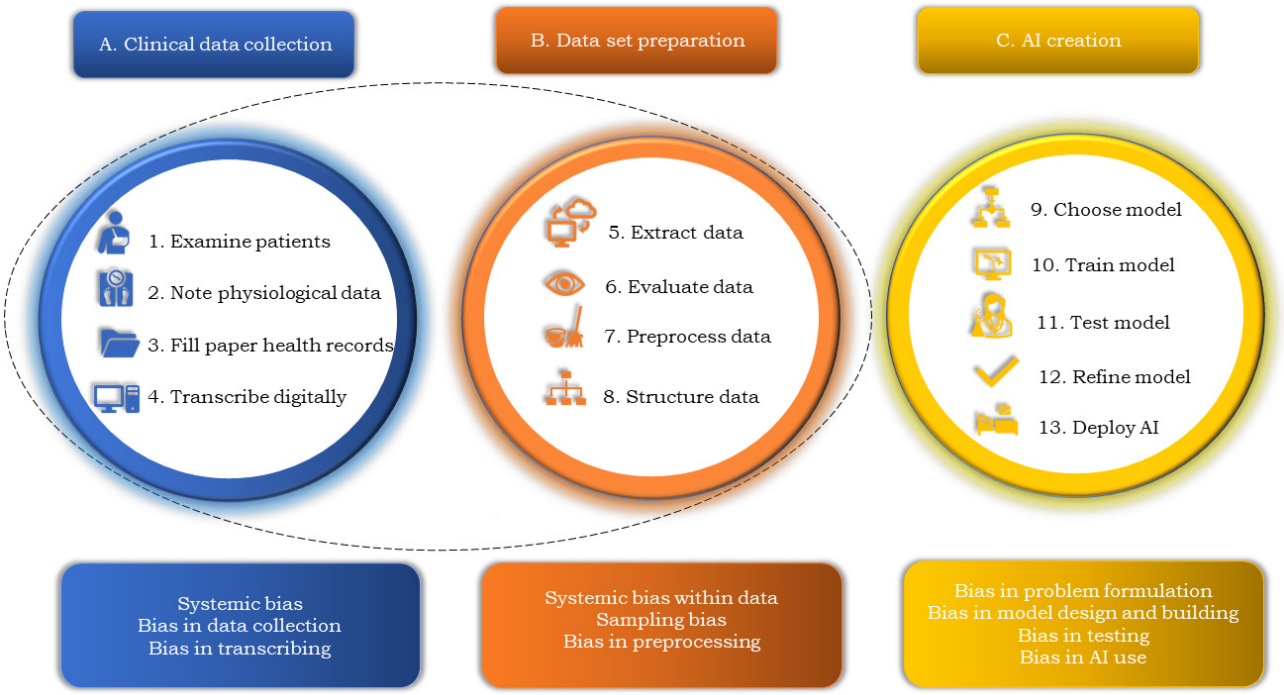

Figure 1 - AI lifecycle and related biases

For instance, in clinical practice, data collection is often performed by subjects with no professional AI knowledge (nurses, MD students, doctors) primarily for a medical purpose (i.e., to deliver healthcare services or to perform clinical trials, though not to create an AI dataset),[38] in a non-standardised way (each hospital has different processes, practices, and IT systems),[39] and not optimised for AI training (data is mostly unstructured, not machine-readable, and often even on paper). The information collected ("raw data") is relevant for primary use but may not be of sufficient quality for proper secondary use.

When data is transcribed in the electronic patient record (EPR) systems and extracted for AI use, there might be additional quality loss and errors[40]. When medical experts are involved in data labelling, other types of bias occur. On the other hand, AI trainers are not usually experts in healthcare, and they often feed the model with the only data available, pre-processing it solely to boost its performance, without considering if the

[38] Giovanni Tripepi and others, 'Selection Bias and Information Bias in Clinical Research' (2010) 115(2) Nephron Clinical Practice 94-99 <https://doi.org/10.1159/000312871> accessed 15 September 2025.
[39] Derek Kyte and others, 'Systematic Evaluation of the Patient-Reported Outcome (PRO) Content of Clinical Trial Protocols' (2014) 9(10) PLoS ONE e110229 <https://doi.org/10.1371/journal.pone.0110229> accessed 15 September 2025.
[40] Abimbola A Ayorinde and others, 'Publication and Related Biases in Health Services Research: A Systematic Review of Empirical Evidence' (2020) 20(1) BMC Medical Research Methodology 137 <https://doi.org/10.1186/s12874-020-01010-1> accessed 15 September 2025; Augustus A White and others, 'Self-Awareness and Cultural Identity as an Effort to Reduce Bias in Medicine' (2018) 5 Journal of Racial and Ethnic Health Disparities 34.

dataset is appropriate, if the quality is good enough, if expert knowledge is missing, or if biases are present.[41]

Additionally, patients and other stakeholders are not involved in the dataset creation phase, and their opinions are not heard despite the efforts to develop inclusive technology.[42] Because of this, it is possible that some biases are overlooked: for example, if women are systemically misdiagnosed, women's data in the datasets will be wrong.[43]

Many errors, biases, unevenness in data, and missing information thus occur when such data is employed. However, to date the main actors involved in AI creation have no guidance on bias mitigation and the concrete application of the GDPR and other Union laws adopted within the Digital Single Market Strategy, being completely unprepared to face the European Data Health Space (EDHS)[44] and the AI Act, among others. As detailed in the literature and in our previous research,[45] clinical datasets might, in the end, be unfair and have poor quality, for they may reflect societal or individual biases, due to having too few examples to represent the target population, missing values in rows or columns, or transcription errors, data loss, and so forth.

Several studies have addressed the pervasive problem of biases in artificial intelligence[46], highlighting how both explicit and implicit biases can significantly impact outcomes in domains such as healthcare.[47] A seminal 2019 study revealed that racial bias embedded in clinical algorithms led to diminished care for patients of colour, demonstrating how such systems can perpetuate systemic disparities.[48] These biases often originate from AI systems trained on data that reflects historically constructed gender and racial hierarchies, thus amplifying inequalities when applied to real-world clinical

[41] SN Stuckless, PS Parfrey and MO Woods, 'The Impact of Misclassification Bias on the Estimation of Relative Effect in Stratified Case-Control Studies: A Simulation Study' (2014) 14 BMC Medical Research Methodology 105.
[42] Rebecca Featherston and others, 'Decision Making Biases in the Allied Health Professions: A Systematic Scoping Review' (2020) 15(10) PLoS One e0240716 <https://doi.org/10.1371/journal.pone.0240716> accessed 15 September 2025.
[43] Lorena Alcalde-Rubio and others, 'Gender Disparities in Clinical Practice: Are There Any Solutions? Scoping Review of Interventions to Overcome or Reduce Gender Bias in Clinical Practice' (2020) 19(1) International Journal for Equity in Health 166 <https://doi.org/10.1186/s12939-020-01283-4> accessed 15 September 2025.
[44] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847.
[45] C Sessa and others, 'Identifying Bias in Data Collection: A Case Study on Drugs Distribution' (2024) International Joint Conference on Neural Networks (IJCNN) 1; C Jones and others, 'A Causal Perspective on Dataset Bias in Machine Learning for Medical Imaging' (2024) 6(2) Nature Machine Intelligence 138; J Vaughn and others, 'Dataset Bias in Diagnostic AI Systems: Guidelines for Dataset Collection and Usage' (2020) Proceedings of the ACM Conference on Health, Inference and Learning 2; R Daneshjou and others, 'Lack of Transparency and Potential Bias in Artificial Intelligence Data Sets and Algorithms: A Scoping Review' (2021) 157(11) JAMA Dermatology 1362.
[46] Reva Schwartz and others, 'Towards a Standard for Identifying and Managing Bias in Artificial Intelligence' [2022] NIST Special Publication 1270 <https://doi.org/10.6028/NIST.SP.1270> accessed 25 September 2025; Eduard Fosch-Villaronga and Adam Poulsen, 'Diversity and Inclusion in Artificial Intelligence' in Bart Custers and Eduard Fosch-Villaronga (eds), *Law and Artificial Intelligence: Regulating AI and Applying AI in Legal Practice* (Springer 2022).
[47] Leo Anthony Celi and others, 'Sources of Bias in Artificial Intelligence that Perpetuate Healthcare Disparities—A Global Review' (2022) 1(3) PLOS Digital Health e0000022 <https://doi.org/10.1371/journal.pdig.0000022> accessed 15 September 2025.
[48] Ziad Obermeyer and others, 'Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations' (2019) 366(6464) Science 447.

settings. The global deployment of AI technologies, frequently developed in the United States or Europe, and then used in Africa, Asia (with the exception of China, which is a major AI producer and exporter), and Latin America, urgently calls for more inclusive data practices.

There is tension in the field of fair ML between two opposing views on AI fairness. On one side, it is argued that "debiasing"[49] and correcting data and models can address rights violations by ensuring AI systems reflect real-world conditions fairly.[50] The EU's policy, for instance, adheres to this view in the AI Act by mandating that AI datasets must be "relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose" (AI Act, art 10) to minimise bias.

However, critics counter that the problem lies not in biased models but in using certain AI systems to solve some specific problems in the first place, which – according to them – is an inherently inequitable practice.[51] They argue that debiasing data may reinforce these inequities by reflecting a world that is already structurally biased against marginalised communities. The real issue, as these critics argue, is that some AI systems amplify and perpetuate existing forms of structural discrimination rather than eliminate them. As such, focusing on debiasing AI models or datasets is seen as insufficient or even counterproductive, as it distracts from addressing the root cause of the issue: structural

[49] According to the EDRi Report by Balayn and Gürses (n 5), «Debiasing refers to the application of select methods to address bias by achieving certain forms of statistical parity (e.g. making sure that the accuracy of a recidivism prediction system is similar for Black and White people by rebalancing a training dataset and re-training a machine learning model)».

[50] Anna Leschanowsky, Birgit Popp and Nils Peters, 'Debiasing Strategies for Conversational AI: Improving Privacy and Security Decision-Making' (2023) 2 Digital Society 34; Nicholas Meade, Elinor Poole-Dayan and Siva Reddy, 'An Empirical Survey of the Effectiveness of Debiasing Techniques for Pre-Trained Language Models' [2021] arXiv:2110.08527 <https://doi.org/10.48550/arXiv.2110.08527> accessed 11 September 2025; Otávio Parraga and others, 'Debiasing Methods for Fairer Neural Models in Vision and Language Research: A Survey' [2022] arXiv:2211.05617 <https://doi.org/10.1145/3637549> accessed 15 September 2025; Marcus Tomalin and others, 'The Practical Ethics of Bias Reduction in Machine Translation: Why Domain Adaptation Is Better than Data Debiasing' (2021) 23 Ethics and Information Technology 419; Andrés Domínguez Hernández and Vassilis Galanos, 'A Toolkit of Dilemmas: Beyond Debiasing and Fairness Formulas for Responsible AI/ML' in *2022 IEEE International Symposium on Technology and Society (ISTAS)* vol 1 (IEEE 2022); Puspita Majumdar, Richa Singh and Mayank Vatsa, 'Attention Aware Debiasing for Unbiased Model Prediction' in *Proceedings of the IEEE/CVF International Conference on Computer Vision* (IEEE 2021) <https://doi.org/10.1109/ISTAS55053.2022.10227133>; Yasaman Yousefi, 'Data Sharing as a Debiasing Measure for AI Systems in Healthcare: New Legal Basis' in *Proceedings of the 15th International Conference on Theory and Practice of Electronic Governance* (ACM 2022); Marta Marchiori Manerba and Riccardo Guidotti, 'Investigating Debiasing Effects on Classification and Explainability' in *Proceedings of the 2022 AAAI/ACM Conference on AI, Ethics, and Society* (ACM 2022); Clarice Wang and others, 'Do Humans Prefer Debiased AI Algorithms? A Case Study in Career Recommendation' in *27th International Conference on Intelligent User Interfaces* (ACM 2022); Ricards Marcinkevics, Ece Ozkan and Julia Vogt, 'Debiasing Deep Chest X-Ray Classifiers Using Intra- and Post-Processing Methods' (2022) 182 PMLR 504; Carlo Alberto Barbano, Enzo Tartaglione and Marco Grangetto, 'Bridging the Gap between Debiasing and Privacy for Deep Learning' in *Proceedings of the IEEE/CVF International Conference on Computer Vision* (IEEE 2021); Ramon Correra and others, 'A Robust Two-Step Adversarial Debiasing with Partial Learning: Medical Image Case-Studies' in *Medical Imaging 2023: Imaging Informatics for Healthcare, Research, and Applications*, vol 12469 (SPIE 2023); Emma AM Stanley, Matthias Wilms and Nils D Forkert, 'Disproportionate Subgroup Impacts and Other Challenges of Fairness in Artificial Intelligence for Medical Image Analysis' in John SH Baxter and others (eds), *Ethical and Philosophical Issues in Medical Imaging, Multimodal Learning and Fusion Across Scales for Clinical Decision Support, and Topological Data Analysis for Biomedical Imaging* (Springer 2022).

[51] Balayn and Gürses (n 5).

injustice. According to this view, debiasing AI cannot overcome societal inequities when the broader system it operates within is fundamentally unequal.

However, despite the efforts of the ML fairness community, Valdivia and others argue that "literature partially fails to show that datafication reinforces racial profiling beyond the creation of racial categories as features" and that "[a] growing scholarship has discussed how datafication is grounded on algorithmic discrimination. However, these debates only marginally address how racialised classification or race categories are enforced through quantification and neglect its political and historical conceptualisation".[52] In addition, some of the arguments in the ML fairness community can be applied to any technology, not just AI. For example, inequalities in medical technology access in wealthy insurance-based countries remain present not only with regard to AI systems but also to basic medical instruments, such as X-rays, RMN, TC, and ultrasound scans. By funding both a new RMN machine and an AI-based diagnostic tool in a wealthy neighbourhood as a reward system for good performance and low surgery error rate, the decision-makers are increasing the gap against disadvantaged citizens. Therefore, in the absence of a political decision to reallocate resources, the only effective solution to fully eliminate inequalities between those who can access healthcare and those who cannot would be eliminating technology from everyday life *tout court*, so that nobody has an unfair advantage. This solution is not what this article argues, nor is it within its scope to focus on the solution to this issue.

This article's arguments fully consider the possible harmful conceptualizations of the AI system's scope: for example, we would consider it to be acceptable to have a correctly trained AI system that recognises malicious cells, but not a tool that would suggest if the patient needed to be treated with chemotherapy, as this decision might be influenced by institutional racism (even in the absence of an AI system). In addition, as shown by our previous research, we adhere to Cynthia Rudin's and other authors' positions,[53] according to which black boxes should not be used in medicine, and we advocate for a "right to technical interpretability".[54] When white boxes are involved, many problematic issues of AI described in the EDRi report are eliminated or mitigated.

This article takes, however, the above-mentioned stream of research very much into consideration. We argue that, while a correct, statistically sound, and fair dataset should be the prerequisite for any AI application in healthcare, it is a condition necessary but not sufficient – alone – to eliminate biases worldwide, especially in countries rooted in a colonialist past. For this reason, the article does not aim to promote debiasing in AI but

[52] Ana Valdivia and Martina Tazzioli, 'Datafication Genealogies beyond Algorithmic Fairness: Making up Racialised Subjects' in *FAccT '23: Proceedings of the 2023 ACM Conference on Fairness, Accountability, and Transparency* (ACM 2023).
[53] Chiara Gallese, 'The AI Act Proposal: A New Right to Technical Interpretability?' in Paulina Kowalicka (ed), *Internet Law and Digital Society: An International Overview* (Milano University Press 2025).
[54] Elena Falletti and Chiara Gallese, 'Credit Scoring Judicial Review between the Court of Justice of the European Union and Comparative Case Law' (2024) 3 Media Laws 92.

rather to incorporate critical studies in the epistemology of datafication of patients, advancing the debate on structural injustice in the use of AI.

In recent years, the notion that only the use of data is political has been challenged: the way data is collected and processed represents a political choice.[55] The apparatus of dataset production needs to be studied, as noted in the literature.[56] To do so, we do not rely on a model/system-centric view but take a socio-technical approach to the issue, considering power relations along with technical issues.

Addressing these issues necessitates a structural shift in how datasets are conceived and validated. Drawing on Michel Foucault's theories[57] and Kitchin and Lauriault's notion of "data assemblages",[58] AI datasets must be recognized not merely as technical constructs but as socio-political products embedded in power relations. The datafication process, shaped by unequal access to care and resources, reinforces marginalisation by encoding and legitimising hierarchical distinctions through algorithmic design. Inadequate representation in datasets compromises diagnostic accuracy and patient safety, threatening public trust in AI systems. Thus, ethical AI development demands a critical examination of the data infrastructures that shape clinical intelligence, with greater transparency, accountability, and participatory input from diverse and vulnerable communities.

Given the critical role that datasets play in shaping AI outcomes, the development and implementation of robust data assessment tools is essential. These are necessary to systematically evaluate the provenance, composition, and representativeness of data used to train AI systems. Without standardised mechanisms for auditing datasets, biased or incomplete data can go undetected, embedding structural inequalities into algorithmic outputs.

Data assessment tools help identify gaps in demographic representation, highlight potential sources of skewed labelling or annotation practices, and assess the contextual relevance of data across different populations and regions. Especially in high-stakes fields like healthcare, where flawed data can result in misdiagnoses or inappropriate treatments, such tools serve as a critical checkpoint to safeguard patient welfare.

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[55] Chiara Gallese, 'Redefining Anonymization: Legal Challenges and Emerging Threats in the Era of EHDS' in *Enabling and Safeguarding Personalized Medicine* (Springer 2025).

[56] Remi Denton and others, 'Bringing the People Back in: Contesting Benchmark Machine Learning Datasets' [2020] arXiv:2007.07399 <https://doi.org/10.48550/arXiv.2007.07399> accessed 15 September 2025; Eun Seo Jo and Timnit Gebru, 'Lessons from Archives: Strategies for Collecting Sociocultural Data in Machine Learning' in *FAT* '20: Proceedings of the 2020 Conference on Fairness, Accountability, and Transparency* (ACM 2020); Michael Katell and others, 'Toward Situated Interventions for Algorithmic Equity: Lessons from the Field' in *FAT* '20: Proceedings of the 2020 Conference on Fairness, Accountability, and Transparency* (ACM 2020); Os Keyes, 'The Misgendering Machines: Trans/HCI Implications of Automatic Gender Recognition' (2018) 2 (CSCW) Proceedings of the ACM on Human-Computer Interaction 88.

[57] Michel Foucault, Michel Senellart (ed), *The Birth of Biopolitics: Lectures at the Collège de France, 1978-1979* (Palgrave Macmillan 2008).

[58] Rob Kitchin and Tracey P Lauriault, 'Towards Critical Data Studies: Charting and Unpacking Data Assemblages and Their Work' in Jim Eckert, Andrew Shears and Josef Thatcher (eds), *Thinking Big Data in Geography: New Regimes, New Research* (University of Nebraska Press 2018).

Moreover, as AI technologies increasingly cross jurisdictional boundaries, transparent and interoperable assessment frameworks ensure that ethical standards are upheld globally, not just in the regions where the AI was developed.

4 The FAnFAIR tool

This tool develops a semi-automated framework to evaluate the fairness of datasets employed in machine learning applications, especially in sensitive domains such as healthcare. The method integrates statistical indicators with normative and legal considerations to generate a composite fairness score, thereby enabling principled decision-making regarding data use. Recognizing the legal implications of biased or non-compliant data, the framework draws from EU data protection law, principles of algorithmic fairness as drawn in the relevant literature, and established ethical guidelines to operationalise fairness assessment.

FAnFAIR evaluates datasets across six core dimensions: balance (distribution of target classes), numerosity (ratio of data points to features), unevenness (presence of statistical outliers), compliance (conformity with legal and ethical standards), quality (domain expert assessment), and incompleteness (extent of missing data). Each dimension is formalised as a linguistic variable within a fuzzy logic (FL) system, which permits reasoning under uncertainty and vagueness, conditions often encountered in legal and data governance contexts. Fuzzy logic is applied using a Takagi–Sugeno inference model,[59] implemented through the Python-based Simpful library.[60] Each variable is evaluated through membership functions and mapped to fairness-related rules structured in a fuzzy rule base.

The compliance dimension uniquely captures multi-jurisdictional legal concerns, including conformity with the GDPR, copyright law, medical and bioethical standards, and non-discrimination law. Because compliance involves jurisdiction-specific legal obligations, it is not automatically derived from the data; instead, it must be manually set by the user based on a detailed legal checklist encompassing lawful basis, consent, anonymization, data minimisation, and stakeholder accountability, among others.

The resulting fairness score, expressed on a 0–100 scale, synthesises the output of all fuzzy rules and reflects both technical data characteristics and legal-ethical considerations. In our first work, the tool was applied to two public datasets from the UCI Machine Learning Repository to illustrate its functionality and generate preliminary insights. These applications demonstrate the viability of FAnFAIR as a transparency-

[59] Tomohiro Takagi and Michio Sugeno, 'Fuzzy Identification of Systems and Its Applications to Modeling and Control' (1985) 15(1) IEEE Transactions on Systems, Man, and Cybernetics 116.
[60] Simone Spolaor and others, 'Simpful: A User-Friendly Python Library for Fuzzy Logic' (2020) 13 International Journal of Computational Intelligence Systems 1687.

enhancing instrument to assess data fairness prior to AI deployment, aligning technological design with both ethical principles and legal requirements.

Fuzzy Logic (FL) represents a form of many-valued logic specifically developed to manage imprecision and uncertainty, characteristics often inherent in complex real-world systems. Unlike classical binary logic, which permits only strict true/false evaluations, FL enables decision-making based on degrees of truth. At its core is the *fuzzy set*, an extension of traditional set theory that allows an element to possess a *membership degree* between 0 and 1. This approach permits partial inclusion in multiple sets simultaneously, thereby capturing nuances that conventional logic systems overlook.

To quantify these membership degrees, *membership functions* (MFs) are employed. A commonly used MF is the triangular function, which offers intuitive modelling of gradual transitions between fuzzy categories. In our study, we adopt normalised triangular fuzzy sets, ensuring that the cumulative membership values across the defined domain equal one. This normalisation supports a coherent assessment of input variables while retaining the capacity for refinement through more sophisticated functions if required.

Fuzzy sets are used to define *linguistic variables*, that is, variables articulated through natural language expressions such as "low", "moderate", or "high." For instance, a variable like "room temperature" may be described by the linguistic terms "cold" or "warm," each corresponding to its own fuzzy set. A specific temperature value, like 25°C, may then belong simultaneously to both sets with varying degrees of membership, for example, minimally to "cold" and significantly to "warm."

These linguistic variables serve as the foundation for *fuzzy rules*, which operate in the form of conditional logic, typically expressed as:

IF *X* is *a* **THEN** *Y* is *b*,

where *X* and *Y* are linguistic variables, and *a* and *b* are associated linguistic terms. Such rules permit partial satisfaction; each rule is evaluated on a scale from 0 (not satisfied) to 1 (fully satisfied). A typical fuzzy inference system contains multiple such rules to address different conditions and nuances in the data.

In our implementation, we employed a 0-order *Takagi-Sugeno* inference system,[61] which synthesises the outcome of all applicable rules through weighted averaging. The output is computed using the formula:

$$output = \frac{\sum_{i=1}^{N} w_i z_i}{\sum_{i=1}^{N} w_i},$$

where N is the number of rules, w_i denotes the degree of satisfaction of the i-th rule, and z_i is the output value associated with that rule. The rule-based system was constructed

[61] Takagi and Sugeno (n 60).

using the *Simpful* Python library, a specialised tool designed to streamline the development of fuzzy inference models. Simpful supports natural-language rule encoding and allows for flexible and complex membership functions. For the purposes of this research, we configured the library to use the 0-order Takagi-Sugeno model, aligning with our need for interpretability and precision in fairness assessments of data sets.

4.1 Statistical considerations

We identified the following statistical features that we consider important in a dataset: balance, unevenness, and incompleteness.

A dataset may be considered *balanced* when all relevant classes or categories are proportionately represented across its entries. This concept is of central importance in both technical and legal discussions surrounding algorithmic fairness, as a lack of balance can lead to systemic bias in AI outputs.[62] Specifically, when one class is significantly underrepresented, machine learning models may exhibit skewed behaviour, undermining their generalisability and accuracy. Such an imbalance has been empirically linked to prejudicial outcomes, including disparities in error rates and misclassification - issues that disproportionately affect marginalised groups and may give rise to legal and ethical concerns under anti-discrimination and data protection regimes.

To illustrate, consider a medical dataset used to train an AI model to classify patients as either "healthy" or "non-healthy." If the dataset includes a vast majority of diseased cases but only a few examples of healthy individuals, the resulting model is likely to exhibit diminished accuracy in identifying healthy patients. This not only compromises clinical reliability but may also infringe upon the rights of individuals by perpetuating unequal treatment, especially if protected characteristics correlate with underrepresented classes.

To quantify balance in formal terms, we calculate a *normalised balance score*. First, the frequency of each class is determined and divided by the total number of instances to generate a class ratio vector. The standard deviation of this vector, denoted by σ, reflects the extent of distributional disparity. A perfectly balanced dataset would have a standard deviation of zero. Conversely, in the worst-case scenario, where all data points belong to a single class, the standard deviation reaches a maximum value, denoted σ*. The balance score is therefore defined as:

$$\text{Balance} = 1 - \sigma / \sigma*$$

This metric ranges from 0 (complete imbalance) to 1 (perfect balance) and provides a foundational basis for assessing the representational fairness of a dataset. In contexts where algorithmic decisions affect fundamental rights, such as healthcare access,

[62] Natalia Criado and Jose M Such, 'Digital Discrimination' in Karen Yeung and Martin Lodge (eds), *Algorithmic Regulation* (OUP 2019); Philippe Burlina and others, 'Addressing Artificial Intelligence Bias in Retinal Diagnostics' (2021) 10(2) Translational Vision Science & Technology 13; Taeuk Jang, Feng Zheng and Xiaoqian Wang, 'Constructing a Fair Classifier with Generated Fair Data' (2021) 35(9) Proceedings of the AAAI Conference on Artificial Intelligence 7908.

employment, or criminal justice, this measure may serve as a preliminary but crucial safeguard against discriminatory data practices.

Numerosity, in the context of dataset evaluation, refers to the quantity of data instances relative to the number of features, formally expressed as the ratio $\alpha = S / D$, where S denotes the number of instances and D the number of features. This ratio is critically important for ensuring that machine learning models trained on a dataset can produce valid and generalizable inferences. A dataset with insufficient numerosity may lead to overfitting, where the model captures noise rather than meaningful patterns, resulting in outputs that are statistically misleading and potentially harmful, especially in contexts involving high-stakes decision-making.

To illustrate, consider a dataset in which the input features bear no real relationship to the target outputs. Ideally, a machine learning model would not perform well on such data, reflecting the lack of substantive correlation. However, if the number of features exceeds the number of instances, it becomes statistically possible, even trivial, for an algorithm to perfectly "fit" the data through random associations. Empirical studies confirm that linear systems of equations, when overparameterised in this way, can be solved with probability one, even if based on entirely random inputs. This mathematical phenomenon allows for the appearance of model accuracy where none exists, undermining trust and violating principles of scientific validity and procedural fairness. In legal and ethical terms, deploying such a model could be interpreted as negligent, or even discriminatory, if it systematically fails to generalise across different populations or contexts, especially if those populations are protected by anti-discrimination laws. To guard against such risks, best practices in statistical modelling recommend that datasets maintain a minimum threshold of numerosity, commonly approximated as $S \geq 10 \times D$.[63] This guideline provides a safeguard against learning from coincidental or spurious patterns that are not representative of the real-world phenomena the model seeks to capture.

Although more advanced assessments of dataset sufficiency can be performed using the Vapnik–Chervonenkis (VC) dimension, which relates to the complexity of the hypothesis space, this requires prior knowledge of the model architecture, an assumption that is often impractical at the data collection stage. Consequently, the simplified numerosity ratio α serves as a pragmatic and legally prudent proxy for evaluating whether a dataset is sufficiently robust to support ethical and lawful AI development.

For computational purposes, this feature is defined over the universe of discourse [0, 10], and the numerosity score is calculated as:

$$\text{Numerosity} = \min(10, \alpha)$$

where a value of $\alpha \geq 10$ reflects an optimally sized dataset suitable for model training. This threshold contributes to the overall fairness assessment of a dataset and supports compliance with emerging regulatory standards for trustworthy and non-discriminatory AI.

[63] FE Harrell, *Regression Modeling Strategies* (2nd edn, Springer 2015).

Incompleteness refers to the presence of missing values, also referred to as “holes”, within a dataset, particularly with respect to relevant attributes or variables. This phenomenon is common in real-world data collection, especially in high-stakes domains such as healthcare, where individual patients may lack information for specific physiological parameters.

The presence of such gaps presents both statistical and legal challenges. From a modelling standpoint, missing data can reduce accuracy, impair generalisability, and lead to erroneous outputs. From a legal and ethical perspective, it may compromise the integrity of informed decision-making, skew representation across demographic groups, and violate principles of fairness and due diligence under data governance laws.

Depending on the extent and distribution of missing values, researchers may choose to apply imputation techniques (e.g., statistical estimation of missing values) or to exclude affected cases entirely. The choice between these approaches must be made carefully, balancing statistical robustness with respect for individual dignity and data minimisation principles enshrined in data protection regimes such as the GDPR.

In practice, three common types of incompleteness can be observed:

1. Variable-level incompleteness – where certain columns (features) contain missing values. This typically occurs when certain tests or measurements are not universally administered across all individuals.
2. Instance-level incompleteness – where specific rows (individuals) lack multiple values, often due to medical fragility or procedural limitations.
3. Randomly distributed incompleteness – where missing values appear without systematic pattern across the entire dataset.

For purposes of computational simplicity, this study assumes the third form of incompleteness. The degree of incompleteness is assessed by calculating the ratio of missing to total values across the dataset. We define a binary matrix I ∈ {0,1}^{S × D}, where S is the number of samples and D the number of features. Each element i_{d,s} is defined as:

i_{d,s} =
1 if the value is missing (NaN),
0 otherwise

The incompleteness score is then calculated as the proportion of missing entries:

$$incompleteness = \frac{\sum_{d=1}^{D} \sum_{s=1}^{S} i_{s,d}}{S \times D}.$$

This metric yields a normalised score ranging from 0 (indicating a complete dataset) to 1 (indicating that all values are missing). As with other fairness-related dimensions, high levels of incompleteness may signal the need for closer scrutiny of data collection protocols, legal compliance, and potential adverse impacts on underrepresented or vulnerable populations.

4.2 Qualitative Considerations

We identified two qualitative features that we consider essential for a dataset to be fair: quality and compliance.

Quality refers to the substantive reliability and interpretability of the data, as assessed by a qualified domain expert. This variable is particularly salient in fields such as medicine, where input data may consist of images, physiological signals, or clinical annotations that require expert interpretation to determine their usability and clarity. For instance, the recognisability of a radiographic image or the audibility of a recorded voice sample is critical in determining whether the data can support accurate and ethically sound AI inferences.

The quality of data is inherently context-sensitive and cannot be automatically measured using computational methods alone. Instead, domain experts must evaluate the dataset in accordance with the latest standards of their field, factoring in both scientific rigour and practical relevance. This expert-driven evaluation is crucial because data collection processes are frequently decentralised or inconsistent, involving individuals with varying levels of expertise, such as medical trainees, technicians, or crowdsourced contributors. As a result, data may be incomplete, mislabelled, or poorly annotated, undermining the reliability of any models trained on it.

Data quality also includes the design and execution of the annotation process. Large-scale data labelling, especially through crowdsourcing, poses significant challenges to label accuracy, especially in high-stakes environments like healthcare. In such contexts, systematic quality assurance mechanisms, such as assessing annotator performance and measuring inter-rater reliability, become essential. For example, collaborative initiatives between clinicians and AI researchers have demonstrated the importance of iterative quality control in medical image annotation.[64]

In our study, we adopt a holistic and manual approach to evaluating data quality. The *FAnFAIR* framework includes a set quality method, which allows domain experts to assign a quality score based on a broad array of considerations. These may include the clarity of the annotation scheme, the comprehensiveness of labelling instructions, the interpretability of features, and alignment with professional standards. This approach is conceptually aligned with best practices from fact-checking and media accountability organisations, which similarly rely on expert-driven, context-aware quality metrics.[65]

As with legal compliance, the quality variable is not computable through automated means. Indeed, it requires reflective judgment from those with domain-specific expertise, ensuring that AI systems are trained on datasets that are not only statistically robust but also ethically and professionally sound.

[64] Beverly Freeman and others, 'Iterative Quality Control Strategies for Expert Medical Image Labeling' (2021) 9 Proceedings of the AAAI Conference on Human Computation and Crowdsourcing 60.

[65] 'Website Rating Process and Criteria' (*NewsGuard*) <www.newsguardtech.com/ratings/rating-process-criteria/> accessed 11 September 2025.

Compliance is a feature composed of multiple sub-features. It refers to the conformity of a dataset and its underlying data practices with applicable legal and regulatory frameworks. These include, but are not limited to, data protection laws, intellectual property rights, medical and clinical regulations, and anti-discrimination laws. In this study, our compliance model draws primarily on European Union law and the civil law tradition, although it is adaptable to other jurisdictions and normative systems. We acknowledge that the notion of fairness is culturally contingent and that different societies may place emphasis on varying legal, moral, and social standards.

While legal compliance alone does not exhaust the ethical evaluation of data, it constitutes a foundational threshold. The *lawfulness* criterion is one of the three pillars of *Trustworthy AI* articulated by the European Commission's High-Level Expert Group on Artificial Intelligence (AI HLEG).[66] The use of unlawfully collected or processed data in AI systems violates both legal obligations and ethical norms, rendering such systems fundamentally flawed from the standpoint of legitimacy and fairness[67].

In our framework, we operationalise compliance through five key dimensions, each reflecting essential legal and ethical considerations:

1. **Data Protection Law**: This includes compliance with principles such as anonymization, establishing a lawful basis for data processing, conducting Data Protection Impact Assessments (DPIA), Legitimate Interest Assessments (LIA), Transfer Impact Assessments (TIA), and Re-use Impact Assessments (RIA), as well as adhering to contractual obligations, data minimization principles, data retention limitations, the rights of data subjects, and transparency duties.
2. **Copyright Law**: Ensuring that data collection and utilisation respect applicable intellectual property regimes, licensing terms, and authorial rights.
3. **Medical Law**: Including requirements for informed consent, ethical review by institutional bodies, and adherence to clinical and diagnostic regulations specific to health-related data.
4. **Non-Discrimination Law**: Affirming the principles of equality and non-discrimination and the prohibition of discrimination on grounds such as gender, ethnicity, disability, or socioeconomic status, in accordance with both national and international legal instruments.
5. **Ethics**: Encompassing broader normative standards such as accountability, respect for human dignity and autonomy, traceability of data practices, stakeholder involvement, risk assessment, and evaluation of societal impact.

These dimensions serve as evaluative checkpoints for assessing whether a dataset is fit for ethical and lawful deployment in AI systems. Importantly, while some elements can

[66] High-Level Expert Group on Artificial Intelligence (AI HLEG), 'Ethics Guidelines for Trustworthy AI' (European Commission 2019) 6.
[67] B Buruk, PE Ekmekci and B Arda, 'A Critical Perspective on Guidelines for Responsible and Trustworthy Artificial Intelligence' (2020) 23(3) Medicine, Health Care and Philosophy 387.

be technically validated (e.g., the presence of consent documentation), others require legal or expert judgment tailored to the jurisdiction and context in which the dataset is used.

The first and arguably most foundational criterion for evaluating dataset compliance concerns adherence to data protection legislation, especially within the European framework. Instruments such as the GDPR, the Council of Europe's Convention 108+, and relevant national regulations establish binding obligations for the lawful processing of personal data. Importantly, these legal standards may also apply to anonymised datasets, particularly where re-identification risks remain non-negligible or where anonymisation is incomplete.

In alignment with GDPR principles and associated jurisprudence, a dataset intended for AI development must satisfy the following key elements to be deemed compliant:

- **Anonymisation**: Where data anonymisation is undertaken, it must be sufficiently robust to prevent re-identification by any reasonably foreseeable means, including linkage with external datasets.
- **Legal Basis**: The collection and use of personal data must be grounded on a lawful basis as defined under Article 6 GDPR, such as informed consent, contractual necessity, legal obligation, vital interests, public interest, or legitimate interest.
- **Data Protection Impact Assessment (DPIA)**: For data processing operations likely to result in a high risk to individual rights and freedoms, a DPIA must be conducted in accordance with Article 35 GDPR, as further detailed by guidance from the European Data Protection Board and national data protection authorities.
- **Legitimate Interest Assessment (LIA)**: If the processing relies on legitimate interests, a thorough balancing test must confirm that such interests are not overridden by the data subjects' fundamental rights and that the processing is necessary and proportionate to pursue those interests (Article 6(1)(f) GDPR).
- **Transfer Impact Assessment (TIA)**: Where data is transferred outside the European Economic Area, whether for storage or processing, an evaluation of the legal and security implications of the transfer must be carried out to ensure adequacy and compliance with Chapter V of the GDPR.
- **Re-use Impact Assessment (RIA)**: Pursuant to the purpose limitation principle, data can only be reused for purposes compatible with the original collection context. Compatibility assessments are necessary to confirm lawful secondary use.
- **Contracts**: In cases involving joint controllership or outsourcing (e.g., through processors), data sharing must be formalised through appropriate legal agreements that clearly define roles and responsibilities, as required by Article 28 GDPR.
- **Data Minimisation**: Only data strictly necessary for the specified processing purposes may be collected or retained (Article 5(1)(c) GDPR);
- **Data Retention**: Personal data must be retained only for the duration necessary to fulfil its intended purpose and must be securely deleted thereafter (Article 5(1)(e) GDPR).

- **Data Subjects' Rights**: Data subjects must be able to exercise their rights effectively, including rights of access, rectification, erasure, restriction, objection, and data portability, as set out in Articles 12–22 GDPR.
- **Transparency Obligations**: The principles of transparency and accountability require clear, accessible, and comprehensive disclosures about data processing practices, including through privacy notices and consent mechanisms.

Compliance with these requirements is not only a legal mandate but a foundational condition for ethical AI. Failure to address them may result in legal liability, reputational harm, and violations of individual rights, especially in AI applications involving vulnerable populations or sensitive data categories.

The second compliance criterion pertains to intellectual property law, particularly copyright and licensing. The legal status of a dataset, including its collection, use, and distribution, is governed by national and international IP laws. The specific legal provisions applicable to a dataset depend on several factors, including the jurisdiction in which the data was created, the intended purposes of use (e.g., research, commercial deployment), and any contractual agreements governing rights and limitations between the data owner (or creator) and the data user. For the data to be lawfully processed and repurposed, both its initial collection and its downstream use must conform to applicable licensing terms and copyright restrictions. Failure to do so may constitute a breach of statutory rights or contractual obligations, exposing parties to legal liability and rendering the AI outputs ethically and legally tainted.

The third criterion addresses compliance with medical and health law, which varies substantially across jurisdictions. Key requirements include obtaining valid informed consent, respecting age-of-consent thresholds, complying with national ethical review standards, and observing rules concerning the reuse of medical data. Some legal systems impose specific conditions on the handling of data relating to deceased individuals, such as restrictions on post-mortem research or continued privacy protections. The heterogeneity of national frameworks means that any cross-border or transnational use of medical data must be accompanied by a careful legal compatibility assessment, especially when such data is fed into AI systems used in clinical decision-making.

The fourth criterion pertains to non-discrimination law and the broader legal obligation to safeguard the fundamental rights and freedoms of data subjects, particularly those belonging to marginalised or vulnerable populations. Systemic inequities in data collection practices, such as the underrepresentation or misclassification of women, ethnic minorities, persons with disabilities, or neurodivergent individuals, can lead to datasets that reinforce structural bias and perpetuate disparate outcomes. For example, inconsistent documentation of medical symptoms across racial or gender lines can result in biased AI models that offer inferior diagnostic performance for these groups. The fairness of AI systems, especially in healthcare, must therefore be evaluated not only at the modelling stage, but also from the very inception of the data lifecycle. Legal and

ethical safeguards must be embedded from the point of collection to ensure that marginalised communities are not disproportionately harmed or excluded.

The fifth and final compliance criterion concerns a set of overarching ethical principles that should guide data practices from the earliest stages of collection. While certain ethical duties are codified in law, such as Article 5(2) GDPR's accountability obligation, many go beyond statutory requirements, offering normative guidance for responsible data governance, even in contexts where personal data or specific legal protections may not apply. These principles are essential to fostering trust, legitimacy, and fairness in the deployment of AI systems, and include:

- **Accountability**: Rooted in both legal frameworks and ethical theory, accountability entails that a clearly designated individual or entity is responsible for decisions, actions, and outcomes arising from data collection and usage. This responsibility applies irrespective of whether personal data is involved.
- **Dignity and Self-Determination**: Respect for human dignity requires that individuals have meaningful control over how their data is used, even where legal consent has been obtained. For example, in the case of deceased persons, their previously expressed wishes should be honoured to the extent possible.
- **Traceability**: Ethical assessments must be documented in a transparent and auditable manner. It should be possible to ascertain when, how, and by whom key ethical decisions were made throughout the data lifecycle.
- **Stakeholder Involvement**: Affected individuals and communities, especially those who bear the highest risks of AI deployment, should be engaged in the development process. Their perspectives must be solicited, considered, and reflected in the design and governance of data systems.
- **Risk Assessment**: Ethical review should include a forward-looking evaluation of the potential harms and injustices that may result from the use of the dataset. These assessments should be conducted proactively, rather than reactively.
- **Societal Impact**: The broader societal consequences of data usage, including its effects on public trust, inequality, and systemic discrimination, must be carefully assessed and addressed through appropriate safeguards and mitigation strategies.

Given the jurisdictional variability and contextual specificity of these considerations, the compliance variable cannot be computed automatically. Instead, users of the FAnFAIR framework are required to manually assign compliance values via the set compliance method. This method takes a dictionary object in which each of the five compliance categories—data protection law, intellectual property law, medical law, non-discrimination law, and ethics—is assigned a Boolean value indicating whether the dataset satisfies the relevant criterion. This approach preserves legal fidelity while allowing for contextual flexibility in the assessment of fairness and legality.

In alignment with the regulatory landscape of artificial intelligence in the European Union, Fundamental Rights Impact Assessments (FRIAs) have emerged as a central

requirement under Article 27 of the AI Act.[68] For AI systems classified as *high-risk*, including those used in healthcare, education, law enforcement, and employment, the AI Act mandates that providers conduct an assessment of the system's impact on fundamental rights prior to placing the system on the market or putting it into service. This obligation is grounded in the EU Charter of Fundamental Rights[69] and aims to ensure that AI does not infringe upon rights such as dignity, non-discrimination, privacy, freedom of expression, and access to justice.

A FRIA requires not only the identification of potential harms to individual rights but also a proactive evaluation of systemic and structural risks, including how algorithmic processes might perpetuate inequality, obscure accountability, or undermine democratic oversight. It must include meaningful stakeholder consultation, clear documentation of risk mitigation strategies, and integration with broader governance and accountability mechanisms. Importantly, the FRIA must be maintained as a living document and updated throughout the AI system's lifecycle. In the context of dataset evaluation, the FRIA is aligned with lawful data collection, ethical curation, and fairness-aware design, particularly when datasets include information about vulnerable or historically marginalised populations. The inclusion of FRIA procedures within the FAnFAIR framework thus represents a necessary evolution toward aligning technical practices with constitutional values and legal obligations under EU law.

Table 1 shows how our tool helps comply with the AI Act.

FAnFAIR Dimension	AI Act Article	How FAnFAIR ensures compliance
Balance	Art. 10(3)(a)	Ensures statistical representativeness in training, validation, and testing datasets to prevent or mitigate bias.
Compliance	Art. 10(4) and (5)	Embeds checks for Fundamental Rights Impact Assessment and ensures adherence to legal frameworks like GDPR, non-discrimination law, and other relevant legal instruments.
Numerosity	Art. 10(1)(c) and (e)	Ensures that training, validation and testing data sets is subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system, including data enrichment and an assessment of the availability, quantity and suitability of the data sets.
Unevenness	Art. 10(1)(e)	Ensures that training, validation and testing data sets is subject to data governance and management practices appropriate for the

[68] Alessandro Mantelero, 'The Fundamental Rights Impact Assessment (FRIA) in the AI Act: Roots, Legal Obligations and Key Elements for a Model Template' (2024) 54 Computer Law & Security Review 106020.
[69] Andrea Cosentini and others, 'Assessing the Impact of Artificial Intelligence Systems on Fundamental Rights' [2025] SSRN https://dx.doi.org/10.2139/ssrn.5168579 accessed 15 september 2025.

		intended purpose of the high-risk AI system, including an assessment of the availability, quantity and suitability of the data sets.
Quality	Art. 10(1)	Ensures that training, validation and testing data sets meet the quality criteria of paragraphs 2 to 5.

Table 2 shows how our tool compares with model cards and data sheets.

Function	**Model Cards**	**Data Sheets**	**FAnFAIR**
Model description	Must include this information	Data Sheets only consider data, not the model	Our tool is agnostic towards the model
Intended use	Must include this information	Data Sheets only consider data, not the model	This is part of the compliance assessment
Features used in the model	Must include this information	Data Sheets only consider data, not the model	Our tool only addresses the dataset, not the model
Metrics	Must include this information	Data Sheets only consider data, not the model	Our tool only addresses the dataset, not the model
Data used for training & evaluation	Must include this information	Must include this information	Must include this information
Limitations	Must include this information	Not included	Not included
Ethical Considerations	Must include this information	Not included	Must include this information
Dataset overview & example of data points	Not included	Must include this information	Must include this information
Data source collection, validation, transformations and sampling methods	Not included	Must include this information	Included in the compliance feature
Sensitive attributes	Not included	Must include this information	Included in the new version
Training and evaluation methods	Not included	Must include this information	Our tool only addresses the dataset, not the model
Intended and extended use of data	Not included	Must include this information	Must include this information

5 Conclusions

The increasing legal, ethical, and technical scrutiny placed on artificial intelligence by the European Union's AI Act calls for the creation of robust dataset assessment tools. Assessing datasets for fairness is essential to promoting equity and social justice, above all for marginalised groups who are often underrepresented, misrepresented, or systematically excluded from data collection and technological design.

In many AI systems, biased datasets serve as the foundation upon which models are trained, thereby encoding and amplifying existing social inequalities. If these datasets do not reflect the lived experiences, linguistic variations, health conditions, or socioeconomic realities of marginalized populations, such as racial and ethnic minorities, women, people with disabilities, LGBTQ+ individuals, or economically disadvantaged communities, then the resulting AI outputs risk perpetuating harm. These harms may include misdiagnosis in healthcare, exclusion from financial services, biased hiring practices, or surveillance and policing disparities.

Dataset fairness assessment ensures that such groups are not only included but also accurately represented in AI systems, mitigating the risk of discrimination and enabling equitable access to benefits like improved healthcare, education, and public services. Beyond individual impact, fair datasets strengthen public trust in AI by aligning technological development with principles of democracy, transparency, and human rights. They also promote innovation by ensuring that AI models are robust, generalizable, and ethically sustainable across diverse populations. Ultimately, fairness in datasets is an acknowledgement that data, as a reflection of human systems, must be assessed and evaluated to ensure it does not reinforce injustice but instead advances inclusion and equality.

As demonstrated throughout this article, the FAnFAIR framework provides a concrete, semi-automated solution for evaluating the fairness and regulatory compliance of datasets used in AI development. By combining fuzzy logic with domain expertise and legal criteria, FAnFAIR operationalises abstract regulatory requirements into a transparent, reproducible methodology for dataset governance. Importantly, the framework is not limited to statistical metrics but incorporates qualitative judgments regarding data quality and compliance with legal obligations under data protection, intellectual property, medical, and anti-discrimination laws. It also integrates ethical principles such as dignity, accountability, and stakeholder inclusion, and aligns with the AI Act’s requirement for Fundamental Rights Impact Assessments.

Rather than presenting debiasing as a silver bullet, this paper advocates for a broader epistemological and structural critique of data practices, situated within postcolonial and feminist theoretical frameworks. Our contribution thus expands the conversation from compliance to justice, highlighting how datasets are shaped by power relations and institutional asymmetries. By offering both theoretical reflection and a practical tool, this

work aims to support developers, regulators, and scholars in designing AI systems that are not only lawful, but also fair, inclusive, and socially responsible.

In addition, we want to highlight that discarding a dataset when it is found to be biased is a critical safeguard in the development of ethical and legally compliant AI systems. A biased dataset that reflects historical discrimination, underrepresents certain populations, or encodes structural inequalities, can lead to harmful and unjust outcomes when used to train machine learning models. These harms may include misdiagnoses in healthcare, unfair allocation of resources, discriminatory treatment in employment or credit scoring, or the reinforcement of societal stereotypes. In high-risk AI systems, such as those governed by the EU AI Act, the use of a flawed dataset may not only undermine the fairness and accuracy of the system, but also breach fundamental rights and legal obligations, including those related to data protection, non-discrimination, and human rights.

Continuing to use a dataset despite evidence of significant bias, especially when that bias cannot be adequately mitigated through rebalancing, imputation, or filtering, risks legitimising and perpetuating structural injustices. Additionally, it may expose developers, deployers, and regulators to legal liability and reputational damage. In such cases, discarding the dataset is not a failure of innovation but a responsible and necessary decision aligned with ethical design principles and regulatory compliance. It reflects a commitment to harm prevention, respect for affected individuals and communities, and integrity in the deployment of AI technologies. Choosing not to proceed with a dataset that fails fairness thresholds ultimately protects both societal interests and AI systems developers.

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GENERAL SECTION

ADAPTING ILO OCCUPATIONAL SAFETY AND HEALTH STANDARDS TO NEW CHALLENGES: REMOTE WORK AND HYBRID EMPLOYMENT MODELS

Abstract

The spread of remote and hybrid employment models, intensified by digitalisation and the COVID-19 pandemic, has reshaped labour relations and raised new challenges for occupational safety and health. Existing ILO standards and EU directives were primarily designed for centralised workplaces and therefore require adaptation to decentralised and digital forms of work. The aim of this study is to evaluate the effectiveness of current ILO OSH standards in the context of remote and hybrid work, identify emerging risks, and propose recommendations for updating international and regional frameworks. The research applied philosophical, dialectical, analytical, and inductive methods to examine the relevance of ILO conventions, EU directives, and collective agreements. Findings show that while ILO Conventions No. 155 and 187 provide a strong foundation, they lack clarity for home-based environments. EU Directives 89/391/EEC and 90/270/EEC remain relevant but insufficiently address psychosocial risks. Trade unions increasingly fill these gaps through provisions on equipment, working time, and psychological support. The study concludes that adapting OSH standards requires clarifying employer obligations, integrating digital and psychosocial risks, and fostering social dialogue to ensure safe and sustainable remote and hybrid employment.

JEL CLASSIFICATION: J81, J28, J21

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10.13135/2785-7867/12841

SUMMARY

1 Introduction

The transformation of labour relations has accelerated in recent years due to technological progress, the COVID-19 pandemic, and growing demand for flexible employment. Remote and hybrid working models have become a permanent feature of the labour market. While they offer advantages such as flexibility and autonomy, they also create new challenges in the area of occupational safety and health (OSH). Remote work encompasses various models, including telework, hybrid work and smart working. Definitions vary depending on the jurisdiction. The ILO and the EU distinguish between telework (the use of ICT outside the employer's premises), remote work (a broader category) and hybrid models (a combination of office and home). National frameworks also introduce nuances[1]. Classification criteria include place of work, technological dependence and degree of flexibility. That is why remote work and various variants of hybrid labour have become dominant in the labour sphere.

Remote work provides certain benefits for employees, such as flexible working hours, saving time on commuting to and from the office, and finding the desired work-life balance, but it also brings with it certain difficulties and challenges[2]. In general, these issues relate to occupational safety and health and stem from the fact that traditional standards were developed for centralised workplaces[3]. However, risks become more difficult to regulate in decentralised environments[4].

The International Labour Organisation (ILO) plays a central role in shaping global labour standards[5]. Over many years of practice, it has become clear that ILO standards generally apply to traditional work environments where risks are mitigated through managerial

[1] J Oakman, N Kinsman, R Stuckey, M Graham and V Weale, 'A Rapid Review of Mental and Physical Health Effects of Working at Home: How Do We Optimise Health?' (2020) 20 BMC Public Health 1825 <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-09875-z> accessed 31 October 2025.

[2] Y Roquelaure, Hybrid Work: New Opportunities and Challenges for Occupational Safety and Health (European Agency for Safety and Health at Work 2023).

[3] International Labour Organization and World Health Organization, 'Healthy and Safe Telework: Technical Brief' (2021) <https://www.ilo.org/global/publications/books/WCMS_836250/lang--en/index.htm> accessed 30 October 2025.

[4] International Labour Organization, 'Working from Home: From Invisibility to Decent Work' (2021) <https://www.ilo.org/sites/default/files/wcmsp5/groups/public/@ed_protect/@protrav/@travail/documents/publication/wcms_765806.pdf> accessed 30 October 2025.

[5] European Agency for Safety and Health at Work, 'Remote and Hybrid Work: Managing Safety and Health Anywhere' (2024) <https://osha.europa.eu/sites/default/files/documents/Remote_Hybrid_work-infosheet-EN.pdf> accessed 30 October 2025.

oversight and institutionalised safety practices[6]. However, remote working and hybrid working models have become a kind of breach of established workplace safety practices, as employees' homes often fall outside the scope of traditional health and safety regulations[7]. This is often also linked to an increase in workload due to flexible working hours. Therefore, the cause-and-effect relationship is quite logical since ILO standards need to be updated to reflect current labour market trends.

Changes in the labour market will continue to occur. Therefore, it remains important for the international community and national authorities to respond to these changes in a timely manner, prioritising the welfare and safety of workers[8]. Remote and hybrid working models create a variety of new risks that cannot be adequately addressed by traditional approaches to occupational health and safety. By adapting ILO standards to these new realities, it can be ensured that in the future, work remains not only productive and flexible, but also safe and sustainable for all workers, regardless of where they perform their duties.

In this regard, this research is based on the ILO core labour standards (in particular, Conventions No. 155 and No. 187), relevant EU directives, and the ILO's latest policy document on the challenges of digitalisation and its impact on work. The aim of this study is to assess the effectiveness of existing ILO standards in the context of remote and hybrid employment models, identify new challenges in the field of occupational safety and health, and provide recommendations for updating international standards in line with current labour market trends.

2 Methodological Framework

A set of additional research methods was used in this study. The general philosophical method served as a comprehensive approach that guided the analysis of labour standards, ensuring a consistent understanding of their conceptual foundations and practical significance. The systematic analysis method made it possible to examine the effectiveness of current ILO standards on occupational safety and health in the context of remote and hybrid employment models. This approach provided a holistic view of the problem, allowed for an assessment of the pandemic's impact on the labour market, and helped identify gaps in the existing regulatory framework. The synthesis method complemented the systematic analysis by integrating individual findings into a comprehensive picture. It was useful for assessing how changes in the labour market affect the perception of new forms of employment by workers and employers. The dialectical method was used to identify the dynamics of the legal framework and its evolution in

[6] J Vleeshouwers and others, 'The Relationship Between Telework from Home and the Psychosocial Work Environment: A Systematic Review' (2022) 95(10) International Archives of Occupational and Environmental Health 2025.
[7] M Udalamaththa, 'Does Remote Work Distance Labour Rights?' (Research Society of International Law, 2023) <https://rsilpak.org/2024/does-remote-work-distance-human-rights/> accessed 30 October 2025.
[8] Ibid.

response to new challenges, while the methods of deduction and induction contributed to the formulation of conclusions: from general principles of occupational safety to specific recommendations, and from observed practical cases to broader theoretical generalisations. These methods provided a balanced methodological framework for assessing the adequacy of existing ILO standards and for developing proposals for their adaptation to the realities of remote and hybrid work.

3 Results and Discussion

3.1 Definition and classification of remote, hybrid and smart working

The transformation of modern labour relations over the past two decades is marked by the institutionalisation of remote, hybrid, and smart working models. The ILO (2020) defines remote work as any work carried out away from the employer's premises, while telework is a subcategory that relies systematically on information and communication technologies. Hybrid work combines remote and on-site work within a single employment relationship, allowing flexibility in location. Smart work, introduced in Italian and Spanish labour law, emphasises autonomy and flexibility in time and space, often mediated by digital platforms). These distinctions, though conceptually related, vary significantly across jurisdictions, leading to ambiguity in the application of occupational safety and health (OSH) standards[9].

Remote work is generally considered the broadest category. It covers all forms of employment performed outside the employer's premises, regardless of whether digital technologies are involved. This can include not only ICT-driven office tasks, but also other types of decentralised working arrangements. Within this broad category, the ILO and the EU distinguish a narrower form known as telework. Telework is characterised by the systematic use of information and communication technologies (ICT) to perform work duties outside the employer's premises. Its defining feature is regularity: the worker habitually relies on ICT tools such as computers and digital platforms to perform tasks and interact with colleagues or managers. Hence, telework is a subcategory of remote work, although it has specific regulatory implications given its reliance on digital technologies and its prevalence in knowledge-intensive sectors[10].

Hybrid work is another option that combines elements of office and remote working. Unlike remote working, which is usually done exclusively outside the employer's premises, hybrid work involves alternating between two environments. This duality creates both

[9] R Katsande, N Farhana and A Devi, 'Hybrid Models for Remote Work Practices in the Post Pandemic Era: Prospects and Challenges' (2022) 12(11) International Journal of Academic Research in Business and Social Sciences 437.

[10] 'The Impact of Remote Work on Occupational Health and Safety' (*Vorecol*, 2024) <https://psico-smart.com/en/blogs/blog-the-impact-of-remote-work-on-occupational-health-and-safety-179206> accessed 30 October 2025.

opportunities and risks. On the one hand, employees benefit from flexibility and reduced commuting time while retaining the collaborative and social aspects of the office environment. On the other hand, moving between different workplaces makes it difficult to implement consistent OSH measures. Thus, employers are faced with the challenge of ensuring compliance with safety standards not only in a centralised office environment, but also in home or co-working spaces used by employees. This makes hybrid work particularly challenging from a regulatory perspective[11].

Smart work is the newest and developing category, which is widely discussed in European political debates and national legislation, particularly in Italy and Spain. Smart work expands the principles of remote work, emphasising autonomy and flexibility in time and space. It allows employees to choose their place of work and their working hours, provided that tasks and productivity targets are met. Smart work is inherently based on ICT and reflects the digitalisation of business, the growth of platform work and the increasing demand for working conditions that combine professional and personal commitments[12]. From a regulatory perspective, smart work challenges traditional OSH systems even more profoundly than remote or hybrid work, as it disperses the centre of control over working conditions and blurs the boundaries of employer responsibility[13].

A key problem in contemporary academic and regulatory debates is that these terms are often used interchangeably, creating confusion and undermining legal certainty. For example, in some national frameworks, remote work and telework are considered synonymous, while in others they are distinguished by their degree of technological dependence. Similarly, hybrid work is sometimes considered merely a practical measure rather than a separate legal category. Moreover, the lack of conceptual clarity directly affects the applicability of existing ILO conventions and EU directives, which were developed at a time when centralised office work prevailed. Therefore, establishing a clear taxonomy of employment models is important for assessing the extent to which international standards remain relevant or need to be updated[14].

When studying the relationship between these models, a hierarchy emerges. Remote work serves as a general criterion that includes telework, hybrid work, and smart work (Table 1). Telework is defined primarily by technological dependence, hybrid work by spatial alternation between the office and home, and smart work by autonomy in choosing the time and place of work. Each model has specific implications for OSH. Thus, remote work compromises physical safety by decentralising the workplace and adds risks associated with digital technologies, such as screen fatigue or cybersecurity issues; hybrid

[11] S Manning, 'Work Migration: The Rise of Remote Working and You' (*Forbes*, 30 January 2024) <https://www.forbes.com/councils/forbesbusinesscouncil/2024/01/30/work-migration-the-rise-of-remote-working-and-you/> accessed 30 October 2025.
[12] Wells and others, 'A Systematic Review of the Impact of Remote Working on Health and Well-being' (2023) 71 (11) International Journal of Environmental Research and Public Health 507 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10612377/> accessed 31 October 2025.
[13] ibid.
[14] ibid.

work complicates monitoring and enforcement; and smart working increases psychosocial risks due to blurred boundaries between professional and personal life[15].

Table 1. Classification of working forms

Working forms	Definition	Key features	Regulation	Examples of regulation
Telework	Performing work using ICT outside the office on a regular basis	Technological dependence; regularity	ILO, EU directives	- ILO Convention No. 177 on Home Work (1996); - EU Framework Agreement on Telework (2002, implemented via Directive 89/391/EEC); - *France*: Labour Code Art. L1222-9 (amended 2012, 2017); - *Poland*: Labour Code, Chapter IIc (amended 2023); - *Ukraine*: Law No. 1213-IX "On amendments to certain legislative acts on remote and home work" (2020).
Remote work	A broader category covering any work outside the employer's premises	Does not always involve ICT; various models	National legislation	- ILO (2022) *Working from Home: From Invisibility to Decent Work*; - *Spain*: Royal Decree-Law 28/2020 "On Remote Work"; - *Germany*: Homeoffice Regulation (2021) under ArbSchG §3; - *Ukraine*: Labour Code (Art. 60^2, as amended 2021).
Hybrid work	Combining remote and office work	Flexibility, but double control by the employer	Partially regulated	- *European Commission* (2022) "Report on the impact of telework and hybrid work on OSH"; - *Italy*: Law No. 81/2017 (Articles 18–24) introducing "lavoro agile"; - *Finland*: Working Hours Act (872/2019); - *Ukraine*: Collective agreements (sectoral level, 2022–2023) including hybrid work clauses.

[15] TR Daviau, 'The Rise of Remote and Hybrid Work Models: Investigating How Remote and Hybrid Work Are Reshaping Company Cultures and Employee Expectations' (*LinkedIn*, 2024) <https://www.linkedin.com/pulse/rise-remote-hybrid-work-models-investigating-how-reshaping-daviau-58ztc> accessed 30 October 2025.

Smart work	Flexible format that allows workers to choose one's own place and time to work using ICT	Maximum employee autonomy	New trend, mainly at EU and enterprise level	- *Italy*: Law No. 81/2017 "Misure per la tutela del lavoro autonomo e lavoro agile"; - *Spain*: Law 10/2021 "on remote work"; - *OECD* (2020) *Productivity gains from teleworking in the post-COVID-19 era*; - *France*: National Interprofessional Agreement on Telework (2020).

The inclusion of national examples demonstrates that while the ILO and EU provide the overarching legal framework, practical regulation of remote, telework, hybrid, and smart work is largely determined at the national level. For instance, Italy's Law No 81/2017 introduced lavoro agile as a distinct legal category, Spain's Royal Decree-Law 28/2020 established specific employer obligations for remote workplaces, and Ukraine's 2020 amendments to the Labour Code defined both remote and home-based work for the first time. These examples highlight the diversity of national approaches and the need for harmonisation through updated ILO standards and EU directives.

This classification is relevant for two reasons. Firstly, it allows international standards, such as ILO conventions and EU directives, to be more accurately reflected in modern forms of employment. Secondly, it highlights areas where current regulations are insufficient. For example, although Convention No. 155 on occupational safety and health establishes general obligations for employers, its practical application in the context of smart work remains largely unresolved. Similarly, EU Directive 90/270 on display screen equipment covers the ergonomic risks of remote work but does not address the psychosocial risks of blurred boundaries characteristic of smart work. In conclusion, the classification of remote, distance, hybrid and smart work provides the conceptual clarity needed to assess the applicability of international labour standards[16].

Remote work represents a broad foundation, remote work defines the technological dimension, hybrid work concerns spatial alternation, and smart work takes flexibility to the extreme by decentralising both time and space[17]. Each of these models has different implications for the OSH and requires tailored regulatory measures. This classification provides a basis for further analysis of ILO conventions and EU directives, which now need

[16] 2022 Report on 'Global Hybrid and Remote Work Trends' (*Coolpo*, 2022) <https://www.coolpo.io/eu/resources/2022-report-on-global-hybrid-and-remote-work-trends> accessed 30 October 2025.

[17] F Koh, 'Companies Grapple with New Normal of Hybrid Work Arrangements' (*CNA*, 2022) <https://www.channelnewsasia.com/asia/companies-pandemic-covid-19-new-normal-hybrid-work-arrangements-employees-employers-3050036> accessed 30 October 2025.

to be assessed for their ability to regulate decentralised and digitalised forms of employment[18].

3.2 ILO conventions and recommendations relating to remote and hybrid work

Various international and regional documents regulate OSH in the context of remote and hybrid work (Table 2). These documents outline fundamental responsibilities, preventive frameworks, and specific provisions that address both traditional and emerging risks, ensuring the protection of workers outside conventional workplaces.

Table 2. Key international and regional documents on OSH (application to remote work)

Document	Year	Essence	Significance for remote/hybrid work
ILO Convention No. 155	1981	General employer responsibilities for safety and health	Fundamentally applicable, but needs clarification for home workplaces
ILO Convention No. 187	2006	The framework of preventive culture in OSH	Flexibly applies to new risks, including remote ones
ILO Convention No. 192	2001	Occupational safety in agriculture	An example of extending standards to decentralised work
ILO Recommendation No. 209	2019	Combating violence and harassment at work	Important for cyber risks and psychosocial factors of remote work
EU Directive 89/391/EEC	1989	Framework Directive on occupational safety and health	Allows for remote work, but depends on national implementation
EU Directive 90/270/EEC	1990	Requirements for display equipment	Directly relevant to remote workers, but needs modernisation
ILO Report "Revolutionizing health and safety: The role of AI and digitalization at work"	2025	The impact of digitalisation on occupational safety	Identifies new cyber risks, monitoring and ethical issues
Collective agreements (EU, Ukraine)	2016-2023	Equipment compensation, right to disconnect, psychological support	Ensure the practical implementation of the rights of remote workers

The ILO provided a global regulatory framework for OSH. Its conventions and recommendations form the basis of labour legislation in various jurisdictions and shape national workplace safety legislation. The international labour standards established by the ILO are guidelines aimed at improving working conditions, which can become

[18] 'The Impact of Remote Work on Occupational Health and Safety' (*Vorecol*, 2024) <https://psico-smart.com/en/blogs/blog-the-impact-of-remote-work-on-occupational-health-and-safety-179206> accessed 30 October 2025.

mandatory once integrated into national legislation[19]. However, most of these documents were developed in an era dominated by centralised, office-based or factory employment. The expansion of remote, hybrid, and smart work exposes the limitations of these standards, while demonstrating their enduring relevance[20].

Since the 110th International Labour Conference in 2022, OSH have been recognised as part of the ILO Fundamental Principles and Rights at Work. Accordingly, the Occupational Safety and Health Convention, 1981 (No 155) and the Framework Convention on Occupational Safety and Health, 2006 (No 187) were given the status of fundamental conventions. This means that even in cases where these conventions are not formally ratified, member states are still obliged to respect, promote, and implement the fundamental right to a safe and healthy working environment[21].

Convention No. 155 on Occupational Safety and Health (1981) remains the cornerstone of international OSH regulation[22]. It requires Member States to develop, implement, and review a coordinated national policy on workplace safety. Moreover, it places a duty on employers to ensure, as far as reasonably practicable, that workplaces, equipment, and processes under their control are safe and do not pose a risk to health. Although originally designed with physical, centralised workplaces in mind, its principles are broad enough to be extended to remote and hybrid working. For example, an employer's duty to provide a safe working environment could be interpreted as covering support for ergonomic home workplaces, digital safety training or advice on preventing screen fatigue. However, the lack of direct control by employers over workers' homes complicates enforcement. Without clear legal mechanisms for monitoring remote workplaces, the application of Convention No. 155 risks being ambitious. Thus, the Convention needs additional guidance or revision to ensure that employers can fulfil their obligations in a decentralised environment[23].

Convention No. 187 Concerning the Promotion of Occupational Safety and Health represents a more modern and preventive approach[24]. Rather than focusing solely on compliance with specific safety standards, it emphasises the creation of a national culture of prevention, continuous improvement, and employee participation. This perspective is valuable for remote and hybrid work, where risks are more diffuse and often psychosocial. A preventive culture involves physical safety measures, mental health support, digital literacy, and stress management policies. For example, the Convention's call for

[19] ibid.
[20] TR Daviau, 'The Rise of Remote and Hybrid Work Models: Investigating How Remote and Hybrid Work Are Reshaping Company Cultures and Employee Expectations' (*Linkedin*, 2024) <https://www.linkedin.com/pulse/rise-remote-hybrid-work-models-investigating-how-reshaping-daviau-58ztc> accessed 30 October 2025.
[21] RF Syed, 'Labor Standards, Labor Policy, and Compliance Mechanism: A Case Study in Bangladesh' (2023) 65(2) Labor History 256 <https://doi.org/10.1080/0023656X.2023.2272124> accessed 30 October 2025.
[22] ibid 22.
[23] International Labour Organization, Convention No 155 on Occupational Safety and Health and the Working Environment (1981).
[24] ibid.

continuous OSH programmes can be applied to initiatives such as online training modules, remote risk self-assessment or virtual consultations with OSH specialists[25]. By raising workers' awareness and empowering them to manage risks, Convention No 187 provides a flexible framework that is well suited to decentralised working patterns. Nevertheless, its general nature highlights the need for more specific tools addressing the hazards specific to remote work. Although it promotes a preventive culture of safety and health at work, Convention No 187 remains a valuable guide to providing workers with knowledge and resources to manage their safety in remote environments.

Although Convention No. 192 on Safety and Health in Agriculture is designed for agricultural work, where work is often performed outside centralised premises and supervision is limited, it demonstrates how OSH standards can be extended beyond the traditional factory or office. It obliges employers to provide protective measures even in dispersed and informal settings[26]. In this case, the analogy with remote work is obvious. If protection can be ensured in agriculture, it can also be adapted to digital employment, where control is also fragmented. However, since Convention No. 192 is limited to one sector, its wider application requires rethinking or inclusion in more general documents.

Recommendation No 209 on Violence and Harassment in the World of Work expands the scope of occupational safety and health regulation to include psychosocial risks[27]. It recognises that the present-day working environment exposes workers not only to physical hazards, but also to stress, intimidation, cyberbullying and blurred boundaries between professional and personal life. For remote workers, who are heavily dependent on digital communication, the risks of online harassment and invasive surveillance are significant. Thus, Recommendation No. 209 is one of the first international instruments to address issues structurally embedded in remote and hybrid work directly[28]. Although the recommendations are not legally binding, they guide national policy and emphasise the urgent need to consider psychosocial well-being as an integral part of OSH.

Hence, these ILO documents offer opportunities and limitations. Conventions No 155 and No. 187 provide broad principles and a preventive framework that can be applied to decentralised work[29]. However, they lack operational clarity for the home environment. Although Convention No 192 illustrates how protective standards can be extended to dispersed workplaces, its sectoral focus limits its applicability. Recommendation No 209 covers the psychosocial dimension of remote work, but as a non-binding document, it

[25] H Katsapaos, 'What Are International Labour Law and Standards, and How Do They Affect Companies Doing Business Abroad?' (*Mauve Group*, 2023) <https://mauvegroup.com/innovation-hub/blog/international-labour-law-what-is-it-standards> accessed 30 October 2025.

[26] International Labour Organization, Convention No 187 "On Promotional Framework for Occupational Safety and Health" (2006) <https://zakononline.com.ua/documents/show/267608___267673> accessed 30 October 2025.

[27] A Joy, 'The Future of Work: Remote Work, Hybrid Models, and the Evolving Workplace' (*Linkedin*, 2024) <https://www.linkedin.com/pulse/future-work-remote-hybrid-models-evolving-workplace-allen-joy-rsloe> accessed 30 October 2025.

[28] International Labour Organization, Convention No 192 on Safety and Health in Agriculture (2001).

[29] MS Wütschert and others, 'A Systematic Review of Working Conditions and Occupational Health in Home Office' (2022) 72(3) Work 839.

requires stronger institutional oversight. Therefore, while existing ILO standards provide a solid normative framework, they need either interpretation or formal revision to remain fit for purpose. Having analysed these documents, it is possible to claim that remote and hybrid work cannot be regulated adequately by traditional OSH instruments without targeted adaptation. Consequently, the ILO system must evolve, integrating ergonomic, digital, and psychosocial risks into its mandatory conventions. Such an evolution would allow employers and governments to reconcile the decentralisation of work with the fundamental right to a safe and healthy working environment.

3.3 EU directives on occupational health and safety and their relevance to remote working

It is important to consider how regional frameworks, particularly EU directives, address remote and hybrid work and what lessons they offer for updating ILO standards[30]. The EU developed one of the most comprehensive OHS regional frameworks. Its directives are binding on Member States and have a significant impact on global labour legislation. Unlike ILO conventions, which establish broad principles, EU directives contain more detailed and operational standards. They offer a practical understanding of how legal obligations can be applied in decentralised environments[31]. Directive 89/391/EEC (Framework Directive) and Directive 90/270/EEC on display screen equipment are particularly relevant for assessing the adequacy of regulation in the context of remote employment.

Directive 89/391/EEC (Framework Directive) is the basis of EU legislation on occupational health and safety[32]. It establishes a general obligation for employers to ensure the safety and health of workers in every aspect related to work. This broad wording allows the directive to remain relevant despite technological changes. It obliges employers to assess risks, implement preventive measures, and provide workers with information and training. A key innovation is its preventive logic. In other words, risks must be anticipated and eliminated at source wherever possible. Applied to remote and hybrid work, this means that employers are responsible for assessing not only the hazards in the office, but also the risks associated with home workplaces, dependence on ICT, and irregular working hours. The directive does not explicitly mention remote working, but its general nature ensures its applicability. National authorities in several EU Member States relied on this directive to require employers to provide ergonomic advice, reimburse the cost of equipment or set rules on availability outside working hours. However, its broad obligations require transposition into national law. In this regard, not all Member States have adapted their legislation to the realities of remote working. In practice, this leads

[30] International Labour Organization, Recommendation No 209 on Violence and Harassment in the World of Work (2019)
[31] Y Roquelaure, 'Hybrid Work: New Opportunities and Challenges for Occupational Safety and Health' (European Agency for Safety and Health at Work 2023).
[32] Council of Europe, Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (1989).

to uneven protection, i.e., while some countries require ergonomic assessments of home offices, others leave the issue to individual agreements between employers and employees. Thus, although Directive 89/391 establishes the principle that employer responsibility extends to remote work, its practical implementation remains inconsistent.

Directive 90/270/EEC sets out more specific obligations that are particularly relevant to remote workers[33]. It requires employers to assess and minimise the risks associated with prolonged use of computers, including ergonomic factors such as screen height, lighting, seating, and posture. It also provides for regular breaks or changes of activity to prevent fatigue and visual strain. For office workers, these obligations have long been standard practice, but extending them to remote work is necessary. In fact, the overwhelming reliance on digital devices in remote settings makes Directive 90/270 even more relevant today than when it was adopted. Nevertheless, new challenges arise in applying this directive to remote environments. Employers often do not have direct access to employees' homes to assess workstations. In response, some Member States introduced self-assessment checklists or virtual inspections as a compromise between employee privacy and employer responsibility. Another difficulty lies in monitoring compliance with requirements for breaks and screen time, which largely depend on individual discipline in remote settings. This demonstrates that while Directive 90/270 provides a solid regulatory framework, its mechanisms need to be modernised to take account of decentralisation and digitalisation.

The analysis of Directives 89/391 and 90/270 illustrates the strengths and weaknesses of the EU approach. On the one hand, the EU created a preventive culture and detailed obligations that are flexible enough to apply to remote work. On the other hand, the lack of clear provisions on decentralised employment creates gaps in interpretation, leading to uneven implementation across Member States. Moreover, psychosocial risks such as isolation, burnout or digital harassment are not directly covered by these directives, even though they are central issues in remote work. The EU indirectly addressed these issues through soft law instruments and agreements with social partners, but binding legislation remains limited.

From a comparative perspective, EU directives demonstrate how broad principles (as in Directive 89/391) and specific technical obligations (as in Directive 90/270) can complement each other. They show that remote and hybrid work can be regulated within the existing framework, provided that the interpretation and implementation mechanisms are developed and adapted. They also illustrate the importance of compliance tools such as self-assessment, virtual training and recommendations from national labour inspectorates, which can bridge the gap between centralised and decentralised workplaces.

[33] Council of Europe, Council Directive 90/270/EEC of 29 May 1990 on the minimum safety and health requirements for work with display screen equipment (fifth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (1990).

Hence, the EU experience offers two key lessons. First, combining general preventive obligations with specific ergonomic requirements can effectively address many of the risks of remote working. Second, without clear recognition of remote and hybrid models in binding legislation, uneven implementation is inevitable. For this reason, EU directives should be updated to explicitly include decentralised work and to integrate psychosocial risks, which are increasingly recognised by both the ILO and the EU itself. This reinforces the argument that international and regional standards must evolve to ensure the universality of the right to safe and healthy working conditions, regardless of where the work is performed.

3.4 EU directives on occupational health and safety: a framework for reporting information

The European Union play a leading role in shaping OSH standards at the regional level. Among the most influential pieces of legislation are Directive 89/391/EEC[34], known as the Framework Directive, and Directive 90/270/EEC on display screen equipment. Both remain directly relevant in the context of remote and hybrid working, despite having been adopted decades before digitalisation became central to labour markets.

Directive 89/391/EEC establishes a general obligation for employers to ensure the safety of workers in every aspect related to work[35]. Its preventive focus requires employers to anticipate risks, eliminate hazards at source, and adapt work to each worker. The broad wording makes this directive adaptable to remote work, as employers are equally obliged to assess risks in home offices or co-working spaces. Although not designed specifically for decentralised work, the directive provides a legal basis for extending OSH obligations beyond traditional workplaces. Micro conclusion: the framework nature of the directive allows remote work to be included in the scope of occupational health and safety, but practical implementation depends on the national level.

Directive 90/270/EEC, adopted in 1990, focuses specifically on the risks associated with the use of display screen equipment. It requires employers to ensure ergonomic conditions, including adequate lighting, screen positioning, seating arrangements and mandatory breaks[36]. These provisions are important for remote workers whose work is almost entirely screen-based. However, practical application in the home environment is challenging, as employers are often unable to directly inspect private workspaces. As a result, some countries introduced self-assessment checklists or virtual audits to reconcile

[34] Interpretative Document of the Implementation of Council Directive 89/391/EEC in relation to Mental Health in the Workplace (1989). <https://ec.europa.eu/social/BlobServlet?docId=13880&langId=en> accessed 30 October 2025.
[35] Council of Europe, Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (1989).
[36] Council of Europe, Council Directive 90/270/EEC of 29 May 1990 on the minimum safety and health requirements for work with display screen equipment (fifth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (1990).

privacy with compliance[37]. Both directives are silent on psychosocial risks such as isolation, stress or blurred boundaries between work and private life. However, they define issues of remote working. To address this gap, EU institutions encourage soft law instruments, including agreements with social partners, although mandatory provisions remain limited.

3.5 Digitalisation and occupational safety and health: analysis of the ILO report (2025)

In 2025, the ILO published a policy report "Revolutionizing health and safety: The role of AI and digitalization at work"[38]. This document is the most comprehensive attempt to date to analyse how digital technologies are changing OSH. It highlights opportunities and new risks, demonstrating the urgent need to integrate digitalisation into occupational safety and health strategies. One of the central themes of the report is the emergence of new cyber risks. As remote working relies on ICT, workers face an increased risk of data leaks, phishing and digital surveillance. Thus, cybersecurity is no longer purely a technical issue; instead, it is directly linked to OSH, as breaches can cause psychological stress, job insecurity or reputational damage.

The report also discusses remote monitoring of safety conditions. Digital tools such as wearable devices, apps and virtual monitoring platforms allow employers to track ergonomics, working hours, and stress levels. Although these tools can improve preventive measures, they also raise concerns about privacy and surveillance. Therefore, striking a balance between monitoring and respecting workers' rights is presented as one of the main challenges. Another key aspect concerns the use of artificial intelligence and big data in occupational safety management. Predictive analytics can identify potential risks, predict burnout, and optimise workload distribution. However, the algorithms can reproduce biases, leading to unfair treatment of employees[39]. The report calls for an ethical framework to regulate the use of artificial intelligence in occupational safety and health.

The document also discusses the role of digital platforms in changing employment. Platform workers often operate outside traditional employer-employee relationships, leaving them vulnerable to safety risks without adequate protection. For example, remote work can lack ergonomic or psychosocial safeguards. Thus, the 2022 ILO report emphasises that digitalisation is both a driver of innovation in occupational safety and a source of unprecedented risks. It advocates for the integration of cybersecurity, psychosocial well-being, and the ethical use of digital tools into future ILO standards.

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[37] 'Managing Remote Work Policies Across Borders: Compliance, Culture, and Connection' <https://us.anteagroup.com/news-events/blog/managing-remote-work-policies-across-borders-compliance-culture-and-connection?utm_source> accessed 30 October 2025.

[38] ILO, 'Revolutionizing health and safety: The role of AI and digitalization at work' (2025). <https://www.ilo.org/publications/revolutionizing-health-and-safety-role-ai-and-digitalization-work > accessed 30 October 2025.

[39] ibid.

4 The role of trade unions in regulating remote work

Alongside international standards and EU legislation, trade unions play a crucial role in shaping the practical regulation of remote working. Through collective bargaining and social dialogue, trade unions are able to fill gaps left by formal legal frameworks, in areas such as compensation for equipment, flexible working hours, and psychosocial support.

In several EU countries, collective agreements include provisions requiring employers to cover the costs of remote working equipment such as chairs, tables, and digital devices. For example, agreements in Italy and Spain provide for reimbursement for ergonomic equipment, reflecting the principle that the employer's responsibility extends to the home office. Trade unions also insist on flexible working hours and the right to disconnect. In Luxembourg, the financial sector has an industry-wide collective agreement (2020–2023) that regulates remote working (introduced in response to the pandemic)[40]. In France, collective agreements inspired legislative reforms that guarantee employees the right to ignore work messages outside working hours. French car giant Renault agreed clear terms for remote working with trade unions[41]. In Germany, pilot agreements in the metalworking industry allow employees to adapt their daily work schedule from home. These initiatives are aimed at addressing the psychosocial risks of blurred boundaries between work and personal life. Similar practices are emerging in Ukraine, where collective agreements include provisions for covering internet costs and partial reimbursement of electricity bills.

Another new area is psychological support for remote workers. Some collective agreements in Scandinavian countries include access to counselling services and stress management programmes, recognising that isolation and digital overload have a tangible impact on health. Ukrainian trade unions have begun to make similar demands, especially during wartime when remote working is a widespread necessity. Overall, the role of trade unions highlights the importance of social dialogue in bridging the gap between regulatory frameworks and realities. While ILO conventions and EU directives establish general principles, collective agreements translate them into binding commitments tailored to specific workplaces.

4.1 Recommendations on adapting labour standards to remote and hybrid work

Due to the disparity between present ILO standards and evolving labour market developments, it is critical that new labour standards adequately reflect the reality of hybrid and remote work arrangements. In this regard, the establishment of clear physical

[40] Birte Dedden, Stan De Spiegelaere and Maureen Hick. Remote work: ensuring trade union and workers' rights through collective bargaining. <https://www.etui.org/sites/default/files/2023-05/Chapter7-The%20future%20of%20remote%20work_2023.pdf?utm_source> accessed 30 October 2025.
[41] Renault agrees conditions for remote working. <https://www.etuc.org/en/renault-agrees-conditions-remote-working utm_source> accessed 30 October 2025.

and ergonomic safety standards for remote work should be considered a priority. It is critical that these guidelines define the ergonomic requirements for home workplaces, including recommendations for equipment, furniture, lighting, and screen. Employers should be obliged to either provide the necessary equipment or compensate employees financially for such expenditures. Therefore, the employer's duty to ensure worker safety must be clearly stated. This involves conducting virtual or self-assessment audits of employees' home offices, as well as developing adaptable rules and practices for ensuring ergonomic compliance[42].

Furthermore, it is imperative to consider on the psychosocial risks associated with remote and hybrid working. These types of employment increase the risk of burnout, stress, and a blurring of the lines between personal and professional realms. As a result, there is a compelling case for ILO safety standards to include mental health support within occupational safety frameworks. Employers should be required to enable access to psychological therapy, stress management services, and mental health screenings for their employees. Furthermore, the implementation of legally obligatory guidelines for work-life balance is necessary, including clear definitions of rest intervals, required breaks, screen time restrictions, and prohibitions on after-hours discussion about work-related issues. It would be necessary to conduct regular surveys and evaluations of stress and burnout levels in order to guarantee the effectiveness of such measures and enable the prompt modification of working procedures[43].

Regulations of working hours should be modified at the regulatory level to take into account the characteristics of remote and hybrid employment. In addition to making sure that workers are assured that their working hours will not be surpassed, it is critical to stress the value of maintaining flexibility in the workforce. It is advised that internal job descriptions support employees in creating their own timetables while making sure that sufficient time is set up for breaks and rest. From the standpoint of the employer, the incorporation of digital technologies, including login and logout systems, may be used as a way to monitor compliance with designated working hours and help avoid overwork[44].

Another significant development is the promotion of digital technologies to enhance OSH. In this regard, the ILO regulations should encourage the use of real-time monitoring systems and require that safety training be modified for remote work settings using digital platforms. This strategy would guarantee that training materials are distributed to staff members regardless of where they are located. Furthermore, there is necessary to establish a clearer definition of employer accountability within the context of hybrid and remote working. Thus, it is the duty of employers to ensure the security of home offices by providing financial resources for the purchase of ergonomic equipment or by offering

[42] J Reznik and others, 'Home-Based Work and Ergonomics: Physical and Psychosocial Considerations' (2022) 43(10) Issues in Mental Health Nursing 975.
[43] ibid.
[44] ibid 22.

expert advice on how to create a secure and effective remote work environment. In order to ensure that standards are maintained in both the home and the workplace, it is crucial that the ILO criteria be used to govern the continuity of safety measures in a hybrid work paradigm[45].

Given how the labour market dynamics, it is advised to establish a dedicated ILO task force on remote and hybrid work. Such a body would be tasked with monitoring ongoing trends, analysing emerging risks, and issuing timely recommendations for updating safety standards[46]. Regular reviews of existing protocols, with active consideration of feedback from both employers and employees, would help to ensure that standards remain relevant, flexible and effective in addressing the evolving challenges of remote and hybrid employment.

4.2 Towards a European framework for psychosocial risks: lessons from ILO and case law

Although the European Union provides a robust regulatory base for occupational safety and health (OSH), there is currently no unified European model addressing the psychosocial risks associated with remote and hybrid work. The fragmentation of national approaches has resulted in uneven protection and inconsistent guidance for employers and trade unions. In this context, the ILO Report "Revolutionizing Health and Safety: The Role of AI and Digitalization at Work"[47] provides a valuable conceptual and methodological reference. It underscores that digitalisation has redefined occupational risks, extending OSH to include mental health, digital surveillance, and algorithmic management.

Building upon this framework, it becomes evident that psychosocial risks such as burnout, cyberbullying, and stress induced by constant connectivity must be addressed through a combination of legal regulation and collective bargaining. The ILO recommends integrating AI ethics, data protection, and digital well-being into OSH strategies, thus aligning occupational safety with the emerging principles of decent digital work.

From a European perspective, several national court decisions already offer guidance that could inform a more coherent model. In France, the Court of Cassation[48] recognised employer liability for "digital overexposure" leading to burnout, reinforcing the legal importance of the right to disconnect. In Spain, the National High Court[49] held that the employer must prevent online harassment in remote settings under Law 10/2021 on

[45] B Loef, SH van Oostrom, E Bosma and KI Proper, 'The mediating role of physical activity and sedentary behavior in the association between working from home and musculoskeletal pain during the COVID-19 pandemi'c' (2022) 10 Frontiers in Public Health 1072030.
[46] C McKee and A Hedge, 'Ergonomic Lighting Considerations for the Home Office Workplace' (2022) 71(2) Work 335.
[47] International Labour Organization, 'Revolutionizing health and safety: The role of AI and digitalization at work' (Geneva: ILO 2025).
[48] Cassation Court of France (Chambre sociale). (2021). *Arrêt n°19-13.856 du 17 février 2021.*
[49] Audiencia Nacional (Spain). (2022). *Judgment on remote work and digital harassment, Law 10/2021.*

remote work. In Italy, the Milan Court[50] extended protection against cybermobbing to smart workers, applying the principles of Law No. 81/2017 on lavoro agile. These cases collectively illustrate a growing judicial awareness that psychosocial well-being is an integral component of occupational safety.

A growing body of judicial practice further confirms the need to adapt OSH standards to remote and hybrid work. For example, the French Court of Cassation has repeatedly affirmed employer liability in cases of psychosocial harm caused by digital overload and inadequate risk prevention in remote settings[51]. Similarly, the Spanish National High Court has interpreted the employer's duty of care under Law 10/2021[52] on remote work as extending to the prevention of online harassment and the provision of adequate digital tools. These cases illustrate how national courts are responding to the decentralisation of work by expanding traditional OSH obligations into the digital environment. As case law increasingly recognises psychosocial and digital risks as integral to occupational safety, it provides important empirical support for the argument that ILO and EU standards must be renewed to reflect the realities of remote and hybrid work.

Based on this emerging jurisprudence, companies and trade unions can develop practical instruments for prevention and redress:

1. Psychosocial risk assessment protocols, including indicators for stress, digital overload, and burnout;
2. Collective agreements that incorporate clauses on the right to disconnect, mental health support, and anti-harassment policies;
3. AI ethics charters ensuring transparency and fairness in digital monitoring and workload distribution;
4. Joint training programmes on digital resilience, covering both managers and employees.

Such mechanisms can help translate abstract international principles into operational standards within enterprises. They also reflect a preventive and participatory approach consistent with both ILO Convention No. 187 and EU Directive 89/391/EEC. Therefore, developing a European framework for psychosocial risks—inspired by the ILO's 2025 vision—should be prioritised to harmonise protection levels, integrate case law insights, and foster social dialogue across Member States.

5 Conclusion

The analysis of international and European standards show that a number of ILO documents remain highly relevant for regulating remote and hybrid working conditions. In particular, Convention No. 155 establishes basic employer obligations regarding occupational safety, while Convention No. 187 promotes a culture of prevention that can

[50] Tribunale di Milano (Italy). (2023). *Decisione in materia di cybermobbing e lavoro agile*.
[51] Cour de cassation (France), chambre sociale, 17 February 2021, No 19-13.316.
[52] Audiencia Nacional (Spain), Law 10/2021 on remote work, decision of 22 March 2022.

be extended to the digital environment. At the same time, their practical application in remote conditions requires clarification of control mechanisms, especially with regard to psychosocial risks and the organisation of workspaces outside the office.

EU directives provide a valuable example of how general principles and technical standards can be integrated into a single regulatory system. Thus, the Framework Directive 89/391/EEC creates a universal basis for extending employer obligations to remote forms of work, while Directive 90/270/EEC sets out specific requirements for working with display screen equipment, which directly affects remote workers. However, both documents display limitations in the area of psychosocial risks, being a key challenge today.

The new ILO report "Revolutionizing health and safety: The role of AI and digitalization at work" highlights the impact of digitalisation on OSH. It demonstrates new risks from cyber threats to remote monitoring and the use of algorithms in labour management. This proves the need to integrate digital factors into the ILO classic system of standards, which previously focused primarily on physical working conditions. Moreover, trade unions remain an important actor in filling gaps in international and regional regulation. Their collective agreements and negotiations provide real guarantees for remote workers such as compensation for equipment, flexible schedules, the right to disconnect, and psychological support. This demonstrates the growing role of social dialogue in adapting legal norms to the digital economy.

As a result, in order to update international and national standards of OSH, it is advisable to follow several recommendations, namely: integrate digital risks (cybersecurity, remote monitoring, algorithmic management) into ILO conventions and EU directives; clarify the mechanisms of employer's responsibility for organising safe working conditions in remote environments, through reimbursement of equipment costs and the creation of standards for remote workplaces; include psychosocial factors (stress, isolation, work-life balance) in mandatory standards, rather than leaving them at the level of recommendations; promote the development of collective agreements that specify international standards and ensure their practical application at workplace; create a unified international approach to regulating remote and hybrid work that combines universal ILO principles, detailed EU directives, and national social dialogue practices. Thus, modern challenges require a qualitative update of the legal framework that takes into account the realities of digital transformation and new models of work organisation.

Juan David Vinasco Marin[*]

GENERAL SECTION

EU DUAL-USE ITEMS EXPORT CONTROLS REGIME AND BIOTECHNOLOGIES

Challenges and opportunities for the EU-Andean Community trade relations

Abstract

The subject of Dual-use Research and Innovation (R&I) is a matter of current debate within the European Union (EU). Debated issues include research collaboration with third countries and qualification as a Dual-use technology as covered under the Export Controls Regulation (EU) 2021/821 and its Annex I. On one hand, it is important for the EU's security interests to restrict Transfer of Technologies in these sensitive fields, while on the other, it is also important to collaborate with other States that share the same interests and promote the Transfer of Technology. One of the examples where this situation can be found is the Trade Agreement signed between the EU and the Andean Community countries in 2012 (Colombia and Peru) and 2016 (Ecuador), where the protocol of accession was recently concluded under the Council Decision (EU) 2024/2728 of 14 October 2024. Interestingly, Article 255 of the Intellectual Property Title of this Agreement mentions that the Transfer of Technology between the parties shall consider the Dual-use Export Controls regime. This consideration may be understood as a tension between the competing objectives of restricting sensitive technologies and promoting their transfer. Considered this provision of the Trade Agreement, the question arises as to whether robust Export Controls regulations are compatible with treaty-based trade relations. In addressing this question, this paper will assess the compatibility of the EU Export Control regime with relevant World Trade Organization (WTO) law, mainly the General Agreement on Tariffs and Trade (GATT) and the Trade Related Aspects on Intellectual Property Rights (TRIPS) Agreement. This analysis will be done on both the sides of the Trade Agreement. Section 1 provides an overall introduction to the issue. Section 2 then mentions the main legal issues in the EU legal framework and the EU–Andean Community Trade Agreement. In Section 3, the concepts of Critical Technologies, Dual-use technologies and Dual-use R&I are discussed. Section 4, then focuses on the relevance of Transfer of Technology and Biotechnology, as well as Intellectual Property (IP) and TRIPS Agreement. In Section 5, the possible intersections and clashes between these different legal instruments and issues is discussed. Finally, conclusions are drawn in Section 6.

JEL CLASSIFICATION: K33, F13, O32, O34

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10.13135/2785-7867/12842

SUMMARY

1 Introduction

This paper aims to address the question of whether robust Export Control regulations are compatible with treaty-based trade relations through a selective analysis, focusing on EU Dual-use Research and Innovation (R&I) cooperation, the EU–Andean Community Trade Agreement, as well as other relevant instruments in international law.

This is an important issue to research as both the liberalisation of international trade and promoting the security interests of trading partners are important policy issues for all parties to any Trade Agreement. However, these two objectives may be in tension, thus requiring an interpretation of international trade law to clarify the permissible regulatory scope of a party. It is also important as compatibility of Export Controls on Dual-Use technologies with international trade law principles, can have far-reaching implications for international security, the link between technological innovation and global peace, and the effectiveness of a trade agreement in promoting the Transfer of Technologies. At the same time however, while international trade aims at creating the conditions for economic development and global prosperity, the same can be said for measures for cooperation in preventing the proliferation of Weapons of Massive Destruction (WMD). There is thus a sort of trade-off between sharing scientific and technological information that promotes innovation and development and restricting the sharing of such information where it might be used to undermine global peace through creating WMD.

This article proceeds as follows. Section 2 will draw the relevant legal issues concerning the Dual-use Export Controls in the EU-Andean Community Trade Agreement. It will begin with a background on how the Trade Agreement was adopted in accordance with EU international trade policy. The Agreement is considered to be a 'mixed agreement' with a clause of non-proliferation of Weapons of Mass Destruction (WMD) and a commitment for the States to establish effective trade controls according to the United Nations Security Council Resolution 1540 of 28 April 2004 (UNSCR 1540). Furthermore, this Section will also explain how the Export Control provisions relate to the Transfer of Technology, as mentioned in Article 255 of the Agreement. It will also discuss the legal framework of the Export Controls Regulation (EU) 2021/821 of the EU, the legal provisions at the

international level, and the related set of rules within the Andean Countries party to the Agreement.

Section 3 provides clarifications and explanations of the terms 'Critical Technologies' and 'Dual-use technologies', as well as the concept of 'Dual-use Research and Innovation (R&I)' within the EU. This discussion is within the context of the EU's international cooperation with third countries, namely Andean Community Countries, in fields related with Dual-use technologies, and how these technologies fall under the purview of the Regulation (EU) 2021/821 thus creating implications for research institutions in the party countries.

Subsequently, Section 4 addresses the tensions that can arise between promoting the Transfer of Technology and restricting Dual-use technologies, using Biotechnology as a specific example. It will also stress the relevance of Intellectual Property (IP) and the TRIPS Agreement to highlight the concepts of patents and Trade Secrets (TS) as part of Dual-use R&I. Section 5 critically analyses the intersections of these issues and potential clashes for the parties in light of the EU–Andean Community Trade Agreement. Finally, Section 6 presents the relevant Conclusions.

2 Relevant legal issues pertaining to Dual-use Export Controls for the European Union and the Andean Community Trade Agreement

This Section discusses the legal issues present in the European Union (EU) legal framework and the EU–Andean Community Trade Agreement concerning Dual-use Export Controls. First, it explains the connections between the EU's international trade policy and the Dual-use Export Controls included in the EU–Andean Community Trade Agreement. Second, it mentions the regional and international framework of the Export Controls Regulation (EU)2021/821. Third, it then explains the equivalent Andean Countries' (Colombia, Ecuador and Peru) set of rules. Fourth it then discusses the relationship between Export Controls and the Transfer of Technology.

2.1 Preliminary remarks and basic concepts

A first legal issue that should be mentioned is the connection between European Union (EU) international trade policy and the EU Dual-use Export Controls.[1] Nevertheless this is not a novel matter, as it was presented by *Caponetti* in 2017[2], when several EU Trade Agreements were in the process of modernization, including the EU-Andean Community Agreement, although none of the Andean Countries (Colombia, Ecuador and Peru) were

[1] Lia Caponetti, 'Looking for the correlation between EU international trade policy and its dual-use export controls outreach programme: The WMD clause coherence' in Quentin Michel and Wolfgang Lehofer, *Incentives of Europe for Non-Proliferation Outreach Activities* (European Studies Unit 2017) 127.
[2] Ibid 127. This sub-section is based on the research question presented by Caponetti in her chapter.

part of the Dual-use Export Controls programmes of the EU at the time. These concepts will be explained in the next paragraphs.

For this purpose, this sub-section will begin by describing what the EU-Andean Community Trade Agreement is and then will explain the preliminary concepts of an 'EU mixed agreement', 'WMD (Weapons of Mass Destruction) non-proliferation clause' and 'EU P2P (Partner to Partner) Export Control Programme for Dual-use Goods'. It will also mention the relevant elements of these concepts with an updated focus on EU and Andean Countries trade relations.

The Andean Community ('CAN' in Spanish) is a Free Trade Area (FTA)[3] established on 26 May 1969, formerly known as the Andean Pact, which currently comprises of four countries: Bolivia, Colombia, Ecuador and Perú[4]. However, it was after the Trujillo protocol of 10 March 1996, that the Andean Integration System was created as is known today, which includes the main organisations such as the Andean Presidential Council, the Foreign Relations Ministers Council, the Andean Community Commission, the General Secretariat, the Court of Justice of the Andean Community, and the Parliament.[5] Moreover in general terms, the CAN's objectives are to continue facilitating the exchange of goods and the economic growth in the region, and improving the position of the Andean Countries in the international economic context.[6]

As *Quispe-Remón* mentions, the EU-Andean Community Trade Agreement derived from the negotiations started by Colombia and Peru with the EU in January 2009, to find an exhaustive Agreement compatible with WTO law[7]. Also, as the same author explains, is a multiparty Agreement which establishes an FTA with the goal of liberalizing progressively and gradually, not only the trade of goods and services, but also facilitating trade with the protection of Intellectual Property (IP) and securing cooperation and technical assistance between the parties, including titles such as institutional provisions and general exceptions.[8]

[3] Trade within the group is duty free but members set their own tariffs on imports from non-members. World Trade Organization, 'Glossary' (*The WTO*, 2025) <https://www.wto.org/english/thewto_e/glossary_e/glossary_e.htm> accessed 23 June 2025.
[4] Humberto Zuñiga Schroder, 'Los procesos de integracióneconómica: Área de Libre Comercio, Unión Aduanera, Mercado Común y Unión Económica' [The economic integration processes: Free Trade Area, Customs Union, Common Market and Economic Union] in Hugo Gómez and others (eds), *Tribunal de Justicia de la Comunidad Andina: 1979-2024. 45 años de creación y 40 años al servicio del derecho y la integración, Tomo I* [Court of Justice of the Andean Community: 45 years of creation and 40 years at the service of the law and the integration, Volume I] (1st edn, Editorial Ecuador F.B.T. Cía. Ltda 2024) 44.
[5] Sandra Catalina Charris Rebellón, 'La Comunidad Andina y el Sistema Andino de Integración' [The Andean Community and the Andean Integration System] in Hugo Gómez and others (eds), *Tribunal de Justicia de la Comunidad Andina: 1979-2024. 45 años de creación y 40 años al servicio del derecho y la integración, Tomo I* [Court of Justice of the Andean Community: 45 years of creation and 40 years at the service of the law and the integration, Volume I] (1st edn, Editorial Ecuador F.B.T. Cía. Ltda 2024) 121-122.
[6] Zuñiga Schroder (n 4); Charris Rebellón (n 5).
[7] Florabel Quispe-Remón, 'Relations between the European Union and the Andean Community of Nations Free Trade Agreements' (2020) 9(2) Iberoamerican Journal of Development Studies 110, 123.
[8] ibid 125-126.

In this sense, on 26 June 2012, the EU through the Council Decision 2012/735/EU and its Member States signed the provisional application of a Trade Agreement with Peru and Colombia as Andean Countries[9]. Later, on 11 November 2016, the EU signed the provisional application of the Trade Agreement for Ecuador through the Council Decision (EU) 2016/2369[10], with Ecuador becoming the third Andean Country party to the Agreement. Finally, on 14 October 2024, the Trade Agreement fully entered into force in accordance with Council Decision (EU) 2024/2728[11]. It should be noted that Bolivia has not joined the Trade Agreement yet, although the Agreement is open to its accession.[12]

Agreements of this kind are also called 'EU mixed agreements' because they cover matters under EU exclusive competence (Common Commercial Policy, notably, and other matters such as EU-level competition policy) and elements which are not of EU exclusive competence, notably political cooperation, industrial cooperation, and research and innovation.[13] For its adoption, this type of agreement requires the conclusion by the EU according to Art 218 of the Treaty on the Functioning of the European Union (TFEU), and the ratification by all EU Member States (MS) following their constitutional procedures.[14] As a matter of fact, the EU-Andean Community Trade Agreement was signed by all the EU Member States and the EU, as well as the relevant Andean Countries.

Moreover, 'mixity' is required by the inclusion of the 'Weapons of Mass Destruction (WMD) non-proliferation clause', that is a conditional clause where the parties agree on cooperating with the objective of disarmament and non-proliferation of WMDs.[15] For the EU-Andean Community Trade Agreement this can be found in Article 2, quoting the first two paragraphs as follows:

"Disarmament and non-proliferation of weapons of mass destruction

1. The Parties consider that the proliferation of weapons of mass destruction and their means of delivery, both to States and non-state actors, represents one of the most serious threats to international stability and security.

2. Consequently, the Parties agree to cooperate and contribute to countering the proliferation of weapons of mass destruction and their means of delivery through full compliance with and national implementation of their existing obligations under

[9] 2012/735/EU: Council Decision of 31 May 2012 on the signing, on behalf of the Union, and provisional application of the Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part [2012] OJ L 354.
[10] Council Decision (EU) 2016/2369 of 11 November 2016 on the signing, on behalf of the Union, and provisional application of the Protocol of Accession to the Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part, to take account of the accession of Ecuador [2016] OJ L 356.
[11] Council Decision (EU) 2024/2728 of 14 October 2024 on the conclusion, on behalf of the Union, of the Protocol of Accession to the Trade Agreement between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part, to take account of the accession of Ecuador [2024] OJ L, 2024/2728.
[12] Since is still benefited of the EU's Generalised Scheme of Preferences (GSP), Bolivia is treated as a vulnerable developing country, ratifying a series of international conventions required by the EU. European Union, 'Country info' (*GSP hub*, 31 March 2025) <https://gsphub.eu/country-info/Bolivia> accessed 25 June 2025.
[13] Caponetti (n 1) 128-129.
[14] ibid 129.
[15] Caponetti (n 1) 128-129.

agreements, treaties and other relevant international obligations on matters of disarmament and non-proliferation. (…)".[16]

Also relevant, the EU-Andean Community Trade Agreement was signed after the entry into force of the United Nations Security Council Resolution 1540 of 28 April 2004 (UNSCR 1540) adopted under the Chapter VII of the United Nations Charter. This Resolution requires Member States to *'[E]stablish, develop, review and maintain appropriate effective national export and trans-shipment controls over such items [nuclear, chemical or biological weapons and their means of delivery], including appropriate laws and regulations to control export, transit, trans-shipment and re-export (…)'*.[17] Therefore, after the [entry in force of the] Resolution 1540 it was born [for the States] a sort of international/duty right to establish trade controls.[18]

In the same vein, it should be noted that the EU has adopted the 'EU P2P (Partner to Partner) Export Control Programme for Dual-use Goods', with the objective *to 'enhance capacities on strategic trade controls of dual-use goods through the creation, consolidation and/or updating of effective strategic trade control systems for dual-use goods in partner countries'*.[19] Also called the 'outreach programme', it comprises of three ongoing projects: (i) EU P2P in Central Asia (EU CBRN CoE Project 105); (ii) EU P2P in Middle East (EU CBRN CoE Project 89); and (iii) Global Project (EU CBRN CoE Project 103).[20]

In particular, for the purpose of this present analysis, attention should be paid to Project 103 which was developed by the EU Chemical, Biological, Radiological and Nuclear (CBRN) Centers of Excellence (CoE), for the period December 2023 to December 2026. This Project involves partner countries from different regions, including the following countries from South America: Colombia, Ecuador, and Peru (as well as Chile, Guyana, and Uruguay). Because such a programme is being developed with three Andean Countries, it is worth delving in some of the specific objectives, activities and expected outcomes, as follows:

"[1] Specific objectives: Assist partners in developing sound legal frameworks at national and, if applicable, regional level; (…) Strengthen communities of practice among export control officials, scientists, academia, industry and other stakeholders; [2] Activities: Legal assistance in drafting or updating national legislation; (…) Regional cooperation and best practices exchange events; [3] Expected outcomes: Awareness of EU P2P counterparts and key stakeholders globally with regards to the implementation and challenges of effective dual-use trade control systems and support in drafting or

[16] Consolidated text: Trade Agreement between the European Union and its Member States, of the one part, and Colombia, Peru and Ecuador, of the other part [2022] Document 02012A1221(01)-20221116. Article 2.
[17] S.C. Res. 1540, U.N. SCOR at 495, U.N. Doc. S/RES/1540 (2004), Operative paragraph 3(d).
[18] Caponetti (n 1) 134.
[19] European Union, 'EU P2P Brochure' (*EU P2P export control programme for dual use goods*, 21 February 2024) <https://cbrn-risk-mitigation.network.europa.eu/document/download/f13b694b-c13b-4abc-8d04-8c72817074b7_en?filename=Fact%20Sheet%20P103.pdf> Accessed 1 October 2025.
[20] European Union (n 19).

amending national legal frameworks, including the adoption of national control list(s)".[21] (text underlined by the author)

The fact that the Trade Agreement was signed before the Andean Countries became part of the P2P Programme can be seen as an example of not only how the EU considered these countries as trading partners, but also the third country's willingness to cooperate in the area of Dual-use Export Controls.[22]

However, this leads to a key issue of this analysis: Can the inclusion of the WMD non-proliferation clause and the implementation of trade controls through outreach activities following the goal of prevent the WMD and other related security threats, become an obstacle to the Transfer of Technology[23] to the Andean trading partners, and thus to their prospects for economic growth these countries? For this purpose, is necessary to deepen consideration of the current Export Controls Regulation at the EU level and the Andean Countries' rules.

Furthermore, it should be mentioned that Resolution UNSCR 1540 addresses technology transfers by prescribing Export Controls as the measures to prevent the proliferation of weapons and Dual-use goods.[24] Besides, adding Dual-use items to the traditionally pure military control lists characterised the change in Export Controls after the end of the Cold War.[25] At this point, it is important to highlight the concept "Transfer of Technology" (TT) mentioned in the EU-Andean Community Trade Agreement which is defined as follows: *'(…) TT includes access to and use of technology as well as the process of generation of technology'.*[26] This is part of the Article 255 of the Agreement on TT, which states in paragraph 6 the following:

"Article 255 Transfer of Technology (…)

6. Each Party shall make its best efforts to evaluate the possibilities to facilitate the entry and exit from its territory of data and equipment related to or used in research, innovation and technological development activities by the Parties under the provisions of this Article, pursuant to the legislative and regulatory provisions applicable in the territory of each Party, including the regimes regarding export control of dual use products and its related legislation".[27] *(text underlined by the author)*

This Article can be complemented with the TT definition provided by *Correa and Beneke* in the sense that *'TT is a series of processes aimed at sharing ideas, knowledge, technologies and skills with another individual or institution (e.g. a company, a university or a government agency) and the acquisition by the other party of those ideas,*

[21] ibid.
[22] Caponetti (n 1) 139.
[23] Consolidated text: Trade Agreement (n 16) Article 255 Paragraph 1 (fn 86): For greater clarity, Transfer of Technology includes access to and use of technology as well as the process of generation of technology.
[24] Oliver Meier and Iris Hunger, *Between Control and Cooperation: Dual-Use Technology Transfers and the Non-Proliferation of Weapons of Mass Destruction* (German Foundation for Peace Research – DSF, 2014) 21.
[25] ibid 21.
[26] Consolidated text: Trade Agreement (n 16) Article 255(1) fn 86.
[27] Ibid Article 255(6).

knowledge, technologies and skills'.[28] Hence, at first it seems that the Export Controls lead to the restriction of Dual-use technologies while TT implies the promotion of exchanges in these technologies, meaning that are opposite concepts in the context of the Trade Agreement referred in the same article.

However, the benefit of recognising that restricting Dual-use technologies and promoting TT may not be opposing activities can be stressed, in that it is much easier to push for better TT control systems if a cooperative relationship already exists.[29] This issue will be developed in the next sections of the paper.

2.2 The Regulation (EU) 2021/821 on the Union regime for the control of exports in the framework of EU primary law and GATT rules

Regulation (EU) 2021/821 issued by the European Parliament and the Council of the European Union on May 20th, 2021, is the current EU legal framework for controls on the export, brokering, transit and trans-shipment of Dual-use items, which defines them in Article 2(1)[30] as follows:

"[The] items, including software and technology, which can be used for both civil and military purposes, and includes items which can be used for the design, development, production or use of nuclear, chemical, or biological weapons or their means of delivery, including all items which can be used for both non-explosive uses and assisting in any way the manufacture of nuclear weapons or other nuclear explosive devices."

Besides the obligations derived from the UNSCR 1540 described in the previous subsection, the conventional basis for the Regulation of Dual-use items (as also mentioned in Recital 4 of Regulation 2021/821) is found in three universally applicable international treaties on WMDs control and disarmament, namely the Treaty on the Non-Proliferation of Nuclear Weapons (NPT)[31], the Biological and Toxin Weapons Convention (BTWC)[32], and

[28] Juan Correa and Francisco Beneke, 'International Technology Transfer Regimes in Latin America' (2024) Max Plank Institute for Innovation and Competition Research Paper No. 24-07 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4827321> accessed 6 October 2025, 19.

[29] Meier and Hunger (n 24) 25.

[30] Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items (recast) [2021] OJ L 206, article 2(1).

[31] Entered into force in 1970, NPT objective is to prevent the spread of nuclear weapons technology, to promote cooperation in peaceful of nuclear energy and to further the goal of achieving nuclear disarmament and general and complete disarmament. UN Office for Disarmament Affairs (*NPT*, 2025) <https://disarmament.unoda.org/en/our-work/weapons-mass-destruction/nuclear-weapons/treaty-non-proliferation-nuclear-weapons> accessed 6 October 2025.

[32] Entered into force in 1975 and also known as Biological Weapons Convention (BWC), effectively prohibits the development, production, acquisition, transfer, stockpiling and use of biological and toxin weapons. It was the first multilateral disarmament treaty banning an entire category of WMD. UN Office for Disarmament Affairs (*BWC*, 2025) <https://disarmament.unoda.org/en/our-work/weapons-mass-destruction/biological-weapons/biological-weapons-convention> accessed 6 October 2025.

the Chemical Weapons Convention (CWC)[33].[34] Moreover, these treaties are supplemented by soft-law norms which are non-legally binding guidelines agreed by groups of Dual-use good supplier states organised in Multilateral Export Control Regimes (MECRs). The most relevant of these regimes are the Nuclear Suppliers Group (NSG)[35]; the Australia Group (AG)[36]; the Missile Technology Control Regime (MTCR)[37]; and the Wassenaar Arrangement (WA)[38].[39] One of the main contributions of these MECRs, if not the main, to the international normative framework of dual-use goods, is the control lists.[40] In the case of the EU, the relevant goods are traduced in the Commission Delegated Regulation (EU) 2024/2547[41] which contains the current list of Dual-use items, also known as Annex I of the Regulation 821. This EU list sets out 10 categories from 0 to 9 that are: 0 Nuclear materials, facilities and equipment; 1 Special materials and related equipment; 2 Materials processing; 3 Electronics; 4 Computers; 5 Telecommunications and "information security"; 6 Sensors and lasers; 7 Navigation and avionics; 8 Marine; and 9 Aerospace and propulsion.

It should be added that Export Controls are measures undertaken by governments to ensure that transfers of strategically sensitive items are properly reviewed[42] and in the case of the EU, require an authorisation for the export of the Dual-use items listed in the Annex I of the Regulation 2021/821 as mentioned in Article 3(1). Notwithstanding the foregoing, Member States can also prohibit Dual-use items not listed in Annex I for reasons of public security, including the prevention of acts of terrorism, or for human rights considerations, notifying to the European Commission and the other Member States as provided for in Articles 9(1) and 9(2).

[33] Entered into force in 1997, aims to eliminate an entire category of weapons of mass destruction by prohibiting the development, production, acquisition, stockpiling, retention, transfer or use of chemical weapons by States Parties. Organisation for the Prohibition of Chemical Weapons (*CWC*, 2025) <https://www.opcw.org/chemical-weapons-convention> accessed 6 October 2025.

[34] Quentin Michel, Sylvain Paile-Calvo and Veronica Vella, *Elaborating a Strategic Trade System of Dual-Use Items: Experiences from the European Union, Morocco, the Philippines, Serbia, Singapore and Ukraine* (Publications Office of the European Union 2024) 17.

[35] Group of nuclear supplier countries that seeks to contribute to the non-proliferation nuclear weapons through the implementation of two sets of Guidelines for nuclear exports and nuclear-related exports. About the NSG (*NSG*, 2025) <https://www.nuclearsuppliersgroup.org/index.php/en/about/about-the-nsg> accessed 7 October 2025.

[36] Informal forum of countries which through the harmonisation of export controls seek to ensure that exports do not contribute to the development of chemical or biological weapons. The AG an introduction (*AG*, 2025) <https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/index.html> accessed 7 October 2025.

[37] Informal political understanding among states with the mission of coordinate national export licensing efforts aimed at preventing proliferation of unmanned delivery systems capable of delivering WMD. Missile Technology Control Regime (*MTCR*, 2023) <https://www.mtcr.info/en> accessed 7 October 2025.

[38] MECR established to contribute to regional and international security and stability, by promoting transparency and greater responsibility in transfers of conventional arms and dual-use goods and technologies. The WA (*WA Introduction*, 2024) <https://www.wassenaar.org> accessed 7 October 2025.

[39] Michel, Paile-Calvo and Vella (n 34) 17.

[40] ibid 18.

[41] Commission Delegated Regulation (EU) 2024/2547 of 5 September 2024 amending Regulation (EU) 2021/821 of the European Parliament and of the Council as regards the list of dual-use items [2024] OJ L, 2024/2547.

[42] Wassenaar Arrangement Secretariat, 'Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-Use Goods and Technologies' in World Trade Organization (ed), *International export regulations and controls Navigating the global framework beyond WTO rules* (World Trade Organization 2023) 126.

Moreover, it can be addressed the relevant role of the Court of Justice of the European Union (CJEU) in shaping the Dual-use items discipline at the regional level and its current situation. Briefly, a first input is the inclusion of the Regulation of Export Controls of Dual-use goods (items) as part of the EU's Common Commercial Policy (CCP) due to the nature of these goods, as mentioned in the *Leifer* judgment in 1995.[43]

It is also important to comment here on the *InsTiimi Oy* (2012)[44] Case, where the CJEU interpreted the application of Article 10 of Directive 2004/18/EC[45] in conjunction with Article 296(1)(b) of the Treaty Establishing the European Community (Now Article 346(1)(b) of the Treaty on the Functioning of the European Union), mentioning the latter states[46]:

"*[A]ny Member State may take such measures as it considers necessary for the protection of the essential interests of its security which are connected with the production of or trade in arms, munitions and war material; such measures shall not adversely affect the conditions of competition in the internal market regarding products which are not intended for specifically military purposes*".

The issue in this case was whether certain equipment (tiltable turntable) which the Finnish Defence Forces (contracting authority) intended to use only for military purposes fell in the scope of the Directive 2004/18, although there also existed largely identical technical applications of the equipment in the civilian market.[47] On this matter, the CJEU concluded that the equipment can be considered for military purposes within the terms of Article 296(1)(b) only if it is established that the equipment by virtue of its intrinsic characteristics may be regarded as having been specially designed and developed for such purposes.[48]

As *Bennet*[49] explains, in this case the term 'equipment' refers to 'Dual-use items', which was in fact the concept that the CJEU was dealing with, meaning that Dual-use items are to be treated as 'civilian' assets for the purpose of the Treaty, unless these are specifically designed, developed, and intended to be used for military purposes.[50]

Subsequently, in the case *EllinikaNafpigeia AE v European Commission* (2013)[51] on the application of state aid to shipbuilding, the Court confirmed that Article 346(1)(b) of the

[43] Case C-83/94 *Criminal proceedings against Peter Leifer, Reinhold Otto Krauskopf and Otto Holzer* [1995] ECLI:EU:C:1995:329.
[44] Case C-615/10 *InsinööritoimistoInsTiimi Oy vs Puolustusvoimat*[2012] ECLI:EU:C:2012:324.
[45] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2005 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts [2004] OJ L 134, 30.4.2004 /114. Article 10: "*This Directive shall apply to public contracts awarded by contracting authorities in the field of defence, subject to Article 296 of the Treaty*".
[46] Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C 202, 7.6.2016/1.
[47] *InsinööritoimistoInsTiimi vs Puolustusvoimat* (n 44), paragraph 24.
[48] ibid, paragraph 44.
[49] Charlie J. P. Bennet, 'The Dual-Use Conundrum of the Lisbon Treaty Regarding Space Governance: Solutions Through International Legal Interpretation?' [2025] Global Policy Early View <https://doi.org/10.1111/1758-5899.70029> Accessed 18 September 2025.
[50] ibid 2.
[51] Case C-246/12 P *EllinikaNafpigeia AE v European Commission* [2013] ECLI:EU:C:2013:133

TFEU only covers measures necessary for the protection of the Member State's security interests, and in particular the production of war material, and cannot be invoked for civil activities that are not specifically military, even though these are inseparable. Thus, measures relating to the production of or trade in arms, munitions and war material must not adversely affect the conditions of competition in the internal market regarding other (civil) products, that is to say those not intended for specifically military purposes.[52]

This evidences that the Court brings the security domain more within the ambit of EU law[53], based on the adverse effects of restricting civil products that are not intended specifically for military purposes, narrowing the interpretation of Article 346(1)(b) TFEU for the Member States.

At the same time, there is no formal and universally agreed definition of the notion of 'national security'.[54] For this purpose is relevant Article XXI of the General Agreement on Tariffs and Trade (GATT) on 'Security Exceptions', and particularly its paragraph (b), permits WTO Members to take trade-restrictive measures that have been introduced to protect essential security interests under certain circumstances.[55] A first approach concerning the WTO panel in *Russia-Traffic in Transit* (2019) explains that 'essential security interests' refer to '*those interests relating to the quintessential functions of the state, namely, the protection of its territory and its population from external threats, and the maintenance of law and public order internally*'.[56]

To add to this, *Sevetlicinii and Su* indicate that Article XXI GATT paragraph (b) contains two components: the first, a chapeau which provides that a contracting party is permitted to take any measures 'which it considers necessary' for the purpose of protecting essential security interests; and the second, the circumstances under the countries are allowed to do so.[57]

According to these authors, the WTO panel in *Russia-Traffic in Transit* (2019)[58] limited the term 'essential' in the sense that the 're-labelling' of trade interests as 'essential security interests' represents a misuse of security exceptions[59], and therefore the WTO member must articulate its interests 'sufficiently enough to demonstrate their veracity', satisfying that the invocation is made in good faith and not to circumvent its obligations under WTO agreements[60].[61]

[52] *EllinikaNafpigeia AE v European Commission* (n 51) paragraph 20.
[53] Bennet (n 49) 7.
[54] Michel, Paile-Calvo and Vella (n 34) 25.
[55] Alexander Svetlicinii and Xueji Su, 'The Unsettled Governance of the Dual-Use Items under Article XXI(b)(ii) GATT: A New Battleground for WTO Security Exceptions' (2025) 24(1) World Trade Review 75–100 <https://doi.org/10.1017/S147474562400048X> accessed 19 September 2025, 78, 92.
[56] Michel, Paile-Calvo and Vella (n 34) 25. Authors' footnote 43 on WTO Panel Report, *Russia-Traffic in Transit* (2019).
[57] Svetlicinii and Su (n 55) 86-87.
[58] ibid 87. Authors' footnote 82 on WTO Panel Report, *Russia-Traffic in Transit* (2019).
[59] ibid.
[60] ibid 88.
[61] See also relevant contributions on the WTO Security Exceptions topic among others: Mona Pinchis-Paulsen, 'Let's agree to disagree: A Strategy for Trade-Security' (2022) 25 Journal of International Economic Law 4527-547 <https://doi.org/10.1093/jiel/jgac048> accessed 10 October 2025; Mona Pinchis-Paulsen, Kamal Saggi and Pietros C

2.3 The Andean Countries' set of rules

From the Andean Countries' side, it is not possible to mention a Regulation *per se,* or even an equivalent Act at the regional level that defines or sets out Export Controls for Dual-use items. However, since the three Andean countries of the EU-Andean Community Trade Agreement are part of the international treaties NPT, BTWC and CWC, specific examples at the domestic level can be found where each country has some set of rules that deal with items that can be considered as 'Dual-use goods'.

In Peru, although the country does not specifically regulate Dual-use goods, the rules for customs transit and transhipment are governed by the general provisions that are set forth in the General Customs Law (Legislative Decree 1053 of 27 June 2008), which follows from the regional and international commitments[62] of the country.[63] Article 38 of this Law considers 'Restricted or forbidden goods' as those that require the authorisation of a competent authority for export, including for example, Ammonium Nitrate which can be used as a high-nitrogen fertiliser but also to fabricate explosives.[64] In this case, the competent authority is the National Superintendence for Security Services Controls, Weapons, Ammunitions and Explosives of Civilian Use (SUCAMEC). [65]

Following the example of chemical substances, Ecuador's Law of Weapons, Ammunitions, Explosives and Related Material of November 2024 includes in its Chapter V, 'Chemical substances and controlled biological agents', referring in Article 37 to the scheduled list of toxic chemicals in the Chemical Weapons Convention (CWC)[66] as well as the facilities where these substances are traded. Nevertheless, this provision is only sanctioned under the Criminal Code when applicable in an armed conflict[67], according to

Mavroidis, 'The National Security Exception at the WTO: Should it be a matter of when Members can avail it? What about how?' (2024) 23 (Special issue 3) World Trade Review 271-295 <https://doi.org/10.1017/S1474745624000065> accessed 10 October 2025; Ian Allen, 'The War on Trade: Applying WTO Security Exceptions to Economic Security Measures' (2025) 45 (2) Northwestern Journal of International Law & Business 157-212 <https://scholarlycommons.law.northwestern.edu/njilb/vol45/iss2/1> accessed 10 October 2025.

[62] Peru is a Member State of the Chemical Weapons Convention (CWC) and its implementing body the Organisation for the Prohibition of Chemical Weapons (OPCW) which oversees the global endeavour to permanently and verifiably eliminate chemical weapons. OPCW (*Member States*, 2025) <https://www.opcw.org/about-us/member-states> accessed 6 October 2025.

[63] Julio Guadalupe, 'The Americas: Peru' in World Export Controls Review *Dual-Use Export Controls in International Transit and Transhipment* (D.C. Houghton Ltd., 2017) 41-42.

[64] National Superintendence of Customs and Taxes - SUNAT (*Restricted gods*, 2025) <http://www.aduanet.gob.pe/servlet/AI_Mrestri> accessed 6 October 2025. Please note that SUNAT is the webpage administrator, but SUCAMEC is the competent authority due to the nature of the goods.

[65] ibid.

[66] Ecuador is also a Member State of the Chemical Weapons Convention and its implementing body the Organisation for the Prohibition of Chemical Weapons (OPCW) which oversees the global endeavour to permanently and verifiably eliminate chemical weapons. OPCW (*Member States*, 2025) <https://www.opcw.org/about-us/member-states> accessed 6 October 2025.

[67] Código Orgánico Integral Penal de la República del Ecuador [Integral Compiled Criminal Code of the Ecuador Republic] last modification 29 July 2024. Article 113.

the application of International Humanitarian Law, thus remaining silent on potential application when these substances are used during peaceful times outside of conflict.[68]

Regarding Colombia, Articles 358 to 367 of the Criminal Code include sanctioned offenses related to the possession, manufacture, and traffic of dangerous substances and objects, mostly radioactive, nuclear, or chemical considered as under the international treaties ratified by the country.[69]

Moreover, the Law 526 of 1999 and the Decree 1068 of 2015 created and updated the Unit for Research and Financial Analysis ('UIAF'), a procurement agency whose functions include preventing and detecting the 'funding of WMDs', defining such as *'every action that uses funds or financial services (…) for manufacture, acquire, develop, export, (…) transfer, deposit or dual-use for illegitimate purposes against the national laws or international commitments [related with the non-proliferation of WMD] (…)'*.[70] Although the UIAF is in essence a financial procurement agency,[71] Article 2.14.1 of the Decree 1068 also includes the obligation for the other government Superintendencies, and particularly the Colombian Customs Agency ('DIAN'), to inform any suspicious operation related to the UIAF's functions.

Thus, it can be said that the Andean Countries enforce the respective laws and decrees related to Dual-use items through their agencies and institutions mostly based on the international WMD and chemical weapons instruments. Nevertheless 'Dual-use items' is still a concept that is not defined in the same sense that it is in Article 2(1) of the EU's Regulation 2021/821, meaning that an opportunity exists for the EU to prompt regulation this field within the Andean Countries, which in fact is being done through the P2P Programme. Nevertheless, it also means that the parties should be aware of the limitations when implementing the Programme, especially when deciding whether a possible norm can apply in the regional level (Andean Community) or national level within each Andean Country. Furthermore, this also leads to another legal issue, which concerns the TT of the Dual-use technologies as it is envisaged in the EU-Andean Community Trade Agreement.

[68] Karol Mishelle Murillo Montalvo, 'El uso dual de sustancias químicas en Ecuador: un riesgo latent desde la perspectiva del Derecho Internacional Humanitario' [Dual-use chemical substances in Ecuador: A hidden threat from the perspective of the International Humanitarian Law] (*San Francisco de Quito University - International Protection Law Centre*, 2025) <https://www.usfq.edu.ec/es/grupos-de-investigacion/centro-de-derecho-internacional-de-proteccion-usfq/el-uso-dual-de-sustancias-quimicas-en-ecuador-un-riesgo-latente-desde-la-perspectiva-del-derecho-internacional-humanitario> accessed 6 October 2025.

[69] Código Penal Colombiano [Colombian Criminal Code] Law 599 of 2000. See for example: Article 358 Possession, manufacture and traffic of dangerous substances and objects; Article 361 Entrance to the territory with nuclear and toxic wastes; Article 367 Manufacture, import, traffic, possession and use of chemical, biological and nuclear weapons.

[70] UIAF, 'The funding of Weapons of Massive Destruction' (*International affairs*, 2025) <https://www.uiaf.gov.co/financiacion-de-la-proliferacion-de-armas-de-destruccion-masiva> accessed 6 October 2025.

[71] The WMD inclusion is derived from the Ant Money Laundry and Financing Terrorist Risk Management System (SARLAFT in Spanish) implemented by Colombia, following the Financial Action Task Force (FATF) Recommendation 7 under Chapter VII of the UN Charter. For more information see: FATF (2012-2025), *International Standards on Combating Money Laundry and the Financing of Terrorism & Proliferation*, FATF, Paris, France <https://www.fatf-gafi.org/en/publications/Fatfrecommendations/Fatf-recommendations.html> accessed 6 October 2025.

3 Critical Technologies, Dual-use technologies and Research and Innovation

Having discussed the legal issues at the EU and EU-Andean Community Trade Agreement levels, it is now necessary to clarify the term 'Dual-use technologies', since Regulation 2021/821 mentions these as 'Dual-use items', and to some extent, these can also be considered as Critical Technologies (CTs) within the Research and Development (R&D) field. For this purpose, the first part of this section will primarily use EU doctrine to interpret this term, while the second part will use the dynamic field of Biotechnology as an example of Dual-use technology, drawing on elements of the WTO TRIPS Agreement and Intellectual Property (IP) literature.

3.1 Critical Technologies or Dual-use technologies?

To clarify whether the terms 'Critical Technologies' and 'Dual-use technologies' are the same or not, is important to mention the independent expert report on the 'Potential of dual-use Research and Innovation (R&I)' recently published by the European Commission (EC) in June 2025. To summarise this matter, the report first refers to the various dichotomies attributed to the term 'Dual-use' such as civilian and military use, defensive and offensive use, peaceful and non-peaceful use, and constructive and destructive purpose, noting that due to the inherent capabilities of these 'technologies' they can be adapted or repurposed for use in military, security, or human rights violation applications.[72]

Subsequently, it clarifies that this 'inherent dual-use nature of many general-purpose technologies' includes the domains of semiconductors, quantum technologies, biotechnologies, and artificial intelligence, giving them alternative names like emerging technologies or Critical Technologies (CTs); these technologies are 'generic' and can address the needs of both civil and military users.[73] This can be understood as complementary to the previous definitions of CTs given by the EC in the Recommendation 2023/2113.[74]

It is complementary in the sense that it continues the definition of CTs that have an enable and transformative nature with their significant economic impact, providing a second dimension of the now called 'Dual-use technologies' related to their 'potential for civil-defence synergies', thus referencing the first criteria of Recommendation 2023/2113

[72] European Commission Directorate-General for Research and Innovation, *Unlocking the potential of dual-use research and innovation* (Publications Office of the European Union 2025) 30.
[73] European Commission Directorate-General for Research and Innovation (n 72) 30.
[74] Commission Recommendation (EU) 2023/2113 of 3 October 2023 on Critical Technology areas for the EU's economic security for further risk assessment with Member States [2023] OJ L, 2023/2113, recital 8.

concerning the technology's potential and relevance. This is also replicated in the Regulation (EU) 2024/795 that also calls them CTs.[75]

Moreover, it also includes the criteria of civil and military use of Recommendation 2023/2113, while mentioning a third dimension of Dual-use that can refer to the involvement of technologies in research activities that have the potential to be used for both civil and military purposes, giving the narrow understanding of 'Dual-use items' (goods, software and technology) of Regulation 2021/821.[76]

This suggests that 'Dual-use technologies' are part of the Dual-use R&I dimension, and are CTs with economic relevance for certain sectors which can be impacted by the Export Controls of the Regulation 2021/821[77], but not necessarily that CTs can be defined as a uniform concept when it comes to the Dual-use R&I generally. Hence, the next sections will use the term 'Dual-use technologies', considering that the research dimension is inherently included in the TT Article of the EU-Andean Community Trade Agreement.

3.2 Dual-use technologies and Dual-use R&I

As addressed in the independent expert report[78], 'Dual-use R&I' refers to research projects that involve dual-use items, which under the Commission Recommendation (EU) 2021/1700[79] specifically includes 'dual-use items that are used during research or research that results in research output in any possible form meeting the technical specification of a dual-use item in the EU dual-use control list or in a complementary national dual-use list (if any)'.

Thus, it is important for the research institution and the researcher to foresee the end-use of this kind of research, since these institutions operate fundamentally differently than industrial operators who are mainly transferring equipment and material.[80] On the other hand, as is the case for universities, the transfers may be essentially technologies often in an intangible form, consisting for example of data, software, or research findings, to end-users located in a third country.[81]

[75] Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241 [2024] OJ L, 2024/795, article 2(2).
[76] European Commission Directorate-General for Research and Innovation (n 72) 30.
[77] Ibid 30.
[78] Ibid 31.
[79] Commission Recommendation (EU) 2021/1700 of 15 September 2021 on internal compliance programmes for controls of research involving dual-use items under Regulation (EU) 2021/821 of the European Parliament and of the Council setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items [2021] OJ L 338, 23.9.2021.
[80] Quentin Michel, *Trade Control and Dual Use Research: A Difficult Compromise* (ESU Publications 2022) 7.
[81] ibid 7.

At this point, it is also interesting to consider the feedback presented by the European Export Control Association for Research Organizations (EECARO)[82] concerning the European Commission White Paper[83] on options for support for technologies with dual-use potential. The EECARO's arguments focus on concern about the terms 'dual-use as software and technology that has the potential to be used for both civil and military purposes', and 'dual-use potential', both used by the Commission.[84] They argue that neither of these terms makes a direct link to Regulation 2021/821, and remind that the Regulation Annex I items have a direct national security link, but the 'dual-use potential' is much broader.[85] In this sense, they propose the term 'R&D with civil/military synergy potential'[86], which can be understood as based in the second dimension of the term 'Dual-use technologies' mentioned in the previous subsection.

Furthermore, it should be stressed that Intellectual Property (IP) is considered to be one of the risks derived from this context. Specifically, there is risk of exposure of IP to technology leakage and the need to ensure the confidentiality and integrity of sensitive research data.[87] This issue relates to the definition of trade secrets as a form of IP, which will be analysed in the next section.

Moreover, a second matter related with IP is the information used for patent applications, since the General Technology Note of Annex I from the Regulation 2021/821 contains an exemption in the sense that *'this minimum information needed to submit a patent application is (…) exempt for export controls'*.[88] Also called 'de-control', it makes no distinction between national, European, or international patent applications, given the fact that once the patent application is published and becomes part of the public domain, it is no longer subject to Export Controls.[89] Nevertheless, since Regulation 2021/821 does not define what is 'minimum necessary information', it is understood as the information needed to meet the filing requirements as determined by the European Patent Office (EPO), or the patent offices of the EU Member States.[90]

These issues demonstrate how IP and Dual-use technologies are related in the current context, since the R&D field necessitates that they converge, particularly for Trade Secrets (TS) and patents. For this reason, the next section will explain how TS and patents for Biotechnology (as one of the CTs areas that is part of the 'Dual-use technologies') are relevant to understand TT in the EU-Andean Community Trade Agreement, and the provisions on Dual-use R&I included in the IP Title under the Export Controls regimes.

[82] EECARO, 'Feedback on the White Paper on options for enhancing support for research and development involving technologies with dual-use potential' 29 April 2024.
[83] European Commission, 'White Paper of 24 January 2024 on options for enhancing support for research and development involving technologies with dual-use potential' COM(2024) 27 final.
[84] EECARO (n 82) 1.
[85] EECARO (n 82) 1.
[86] EECARO (n 82) 1.
[87] European Commission Directorate-General for Research and Innovation (n 72) 6.
[88] Commission Recommendation (n 79) 20.
[89] Commission Recommendation (n 79) 20.
[90] ibid 20.

4 Transfer of Technology, Dual-use technologies and Biotechnology

To start this section, it must be first mentioned that there is a growing importance of Dual-use technologies for economic and technological development as explained by *Meir and Hunger*.

This is to say that while Export Controls on Dual-use technologies are vital to prevent the proliferation of WMDs (with reference to the NPT, BTWC and CWC treaties), they are also important to improve international cooperation to facilitate peaceful application of Dual-use technologies as part of the non-proliferation bargain.[91] Hence, measures to promote TT and the collaborative research are examples of peaceful application of Dual-use technologies. This is particularly relevant for Biotechnology as an example of a technological field which is developing at an exponential rate, with tools and knowledge widely dispersed, and related research remaining mostly unclassified.[92]

However, in the field of the Biotechnology these authors also mention how both the UNSCR 1540 and the BTWC include the general-purpose criterion (items used for hostile purposes) to restrict items related to bioweapon-enabling technologies, adding to the fact that bioweapons agents exist in nature.[93] This creates a tension between: (i) restricting life science research in order to prevent the misuse for bioweapons development; and (ii) restrictions on the peaceful application of science and technology, thereby hindering broader development.[94] The EU-Andean Community Trade Agreement is not outside this concept, since its Article 255 mentions the case of TT and Dual-use technologies. Within this focus can be placed on the definitions of Biotechnology, using the EU Dual-use R&D context and insights from IP and patent law. Moreover, an assessment can be made of the concept of Trade Secrets (TS) under the current EU legal framework, as well as WTO law as represented in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement[95]. The next sections will also present the Security Exceptions clause as written in the Trade Agreement and its relationship with the TT.

4.1 Biotechnology as a Dual-use technology

To define Biotechnology, specific concepts at the EU level as well as the TRIPS Agreement may be referenced. To start, the EC's Communication COM (2024) 137 uses the

[91] Meier and Hunger (n 24) 10.
[92] ibid 10.
[93] ibid 21.
[94] Meier and Hunger (n 24) 21.
[95] The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the most comprehensive multilateral agreement on intellectual property (IP). World Trade Organization, 'Trade topics' (*Intellectual Property*, 2025) <https://www.wto.org/english/tratop_e/trips_e/trips_e.htm> accessed 21 June 2025.

Organization for the Cooperation and Economic Development (OCDE) definition for Biotechnology[96], which states:

"Biotechnology is defined as the application of science and technology to living organisms, as well as parts, products and models of them, to alter living or non-living materials for the production of knowledge, goods and services. Advanced biotechnologies are geared towards various application areas, being the main ones medical and pharmaceutical ("red" biotechnology), agri-food ("green" biotechnology), and industrial and environmental ("white" biotechnology), with the marine biotechnology (so-called "blue") gaining increased attention".

As *Francioni and Pavoni* note, this definition can be further contextualised by recognising that:

"The form of power [Biotechnology] embodies stems from the human ability to manipulate the structure of life and to develop through bio-engineering techniques, new genetically modified organisms and products, as well as the fact that biotechnology is part of [humanity's] common concern due to its potential far-reaching benefits in the medical, pharmaceutical, environmental and agricultural sectors".[97]

Moreover, as *Herdegen* mentions, *'[T]o discuss the opportunities and risks of [B]iotechnologies, their different fields can be divided according to the application of the biotechnological methods in: "Green", to improve the quality of agricultural products or increase yields; "Red", to be used in diagnostic and therapeutic medicine, pharmacology and health care; "White", that are applied in industrial processes; and "Blue" for the exploitation of marine resources'.*[98] Nevertheless, this author also adds that other fields should be considered as part of Biotechnology, such as *'Biopharmaceutical and biosimilars, to describe pharmaceuticals produced in biotechnological processes using molecular biology methods; Reproductive medicine, particularly In Vitro Fertilization; and "Grey" Biotechnology that covers applications which serve environmental protection'.*[99]

Later, in the Communication (2024) 137[100] the Commission also refers to the identification of Biotechnology as a CT from an economic security perspective, referring to Recommendation 2023/2113, as well as the inclusion as one of the technologies prioritised in Regulation 2024/795. Thus, it can be said that in Recommendation 2023/2113 and in the Communication (2024) 137 this CT has specific features in its characteristics, areas, and sectors at the EU level. However, it is important to add that the definition of Biotechnology provided in the Recital 6 of Regulation 2024/795 is in the

[96] Commission, 'Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 20 March 2024 on building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU' COM(2024) 137 final, 1.
[97] Francesco Francioni and Tulio Scovazzi, *Biotechnology and international law* (Hart Publishing 2006) 6, 33.
[98] Matthias Herdegen, *The international law of biotechnology: human rights, trade, patents, health and the environment* (2ndedn, Edward Elgar Publishing 2023) 5, 11, 17.
[99] ibid 14, 15, 17.
[100] Commission (n 96) 1.

same terms of Communication (2024) 137, and that the subcategories mentioned in that Recital are also included in the Article 2 of the Regulation.

As the Commission also assess, *'IP allows biotech innovators to protect research results and to recover the large upfront capital investments needed (…) [as well as is] a critical asset which emerging biotech start-up companies can offer to secure financing'.*[101] In this sense, reference should be made to Section 5 of the TRIPS Agreement which sets out provisions on patent protection in Articles 27 to 34. Considering the mentioned EU's COM (2024) 137 and the White Paper on R&D on Dual-use, for the Biotechnology field[102] Articles 27 and 28 TRIPS are particularly relevant, as they relate to the patents as an IP asset, the scope of possible patentable subject matter, and the rights conferred under a patent once granted.

Furthermore, important insights can be gained from the analysis done by the Joint Research Centre of the European Commission regarding Biotechnology patent families filed between 2001 and 2020, which produced the following results:

"[The first group of patents] (23.1%) (…) fall under the C12N category, which encompasses "Micro-organisms or enzymes; compositions thereof (…); propagating, preserving, or maintaining micro-organisms; mutation or genetic engineering; culture media (microbiological testing media)" [White biotechnology]

The second most prominent technological group is C12Q, accounting for 12.9% of all biotechnology patents. C12Q refers to "Measuring or testing processes involving enzymes or micro-organisms (immunoassay); compositions or test papers therefor; processes of preparing such compositions; condition-responsive control in microbiological or enzymological processes" [White biotechnology]

The third most patented biotechnology is A61K 38/00, categorized as red biotechnology. It pertains to "Medicinal preparations containing peptides". This category accounts for 11.9% of all biotechnology patents filed [Red biotechnology])".[103]

As explains the Commissions' COM (2024) 137, white biotechnology refers to industrial and environmental technology, while red biotechnology refers to pharmaceutical technology. Overall, we can summarise a comparison between the different conceptions of Biotechnology as a CT and Biotechnology as patent subject matter in Table 1 below.

[101] Commission (n 96) 7-8.
[102] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L 213, sets the current legal framework for these inventions at the EU level. However, the Directive follows the TRIPS Agreement as states its article 1, being this the reason to continue with the analysis of the Agreement. Moreover, a detailed Exports Report on the development and implications of patent law in the field of biotechnology and genetic engineering was done on May 17, 2016, requested by the EU, available in: https://ec.europa.eu/docsroom/documents/18604/attachments/1/translations/.
[103] European Commission, Joint Research Centre, Nicola Grassano and others, *Exploring the global landscape of biotech innovation: preliminary insights from patent analysis* (Publications Office of the European Union 2024) 12.

Biotechnology Characteristics and Subcategories		
Recommendation 2023/2113 (CT)	**Regulation 2024/795 (CT) Recital (6)**	**Patent doctrine (WIPO, 2017)[104]**
Have a major enabling and transformative nature in areas such as agriculture, environment, healthcare, life science, food chains or biomanufacturing. Some biotechnologies, such as genetic engineering applied to pathogens or harmful compounds produced by genetic modification of microorganisms, can have a security/military dimension, in particular when being misused.	Should be understood to be the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services, including the technologies referred to in the statistical definition of biotechnology of the Organisation for Economic Cooperation and Development, as well as the Union List of Critical Medicines.	Means a technological application that uses biological systems, living organisms, or derivatives thereof, such as plants, animals, seeds and microorganisms, as well as biological material, such as enzymes, proteins and plasmids (which are used in "genetic engineering", processes to modify the genetic composition of living organisms).
— Techniques of genetic modification — New genomic techniques — Gene-drive — Synthetic biology	Article 2.1 (a) (iii): Biotechnologies, including medicinal products on the Union list of critical medicines and their components.	— Processes for the creation or modification of living organisms and biological material — The results of such processes — The use of such results

Table 1: Biotechnology Characteristics and Subcategories

These comparisons will be useful references for the analysis of intersections and potential clashes, in the later presented Section 5.

4.2 Trade Secrets, patents and the TRIPS Agreement

As *Taubman* explains regarding the TRIPS Agreement's relevance, in the practical sense a comprehensive set of trade agreements could only be concluded if recognition of the

[104] WIPO, *Introduction to Intellectual Property. Theory and Practice* (2nd edn, Kluwer Law International B.V 2017).

value and significance of IP in the contemporary international economy was part of the deal.[105] Therefore, obligations for WTO Members under the TRIPS Agreement must comply with Article 3 principle of 'National Treatment' and Article 4 principle of 'Most Favoured Nation (MFN) Treatment'. Accordingly, each Member is obligated to treat the nationals of other Members no less favourably than its own nationals, and any advantage granted to the nationals of any other country shall be accorded to the nationals of all other Members. Notably, Article 8 TRIPS allows Members to adopt measures to protect public health (and public interest in sectors important for economic and technological development) as long as they are consistent with the Agreement.[106]

Furthermore, Article 27.1 of TRIPS Agreement requires that patents are to be available in all fields of technology, without discrimination, provided that they are new, involve an inventive step and are capable of industrial application. The World Intellectual Property Organization (WIPO) provides the following definition of a patent:

"(…) [I]s a document, issued, upon application, by a government office (or a regional office acting for several countries), which describes an invention and creates a legal situation in which the patented invention ["invention" referred to the solution to a specific problem in the field of technology] can normally only be exploited (manufactured, used, sold, imported) with the authorization of the owner of the patent".[107]

Specifically, a patent also gives a gives the owner of the patent the exclusive right to make, use, or sell the invention, excluding third non-authorized parties from its use, in return for the disclosure of the invention, so that others may gain the benefit of the disclosed technical information.[108]

Additionally, Articles 39 (Protection of undisclosed information) and 40 (Control of anti-competitive practices in contractual licences) of the TRIPS Agreement are also important for the EU White Paper on Dual-use options for support, since they are linked with the protection of IP, open science, academic freedom and the safeguards to avoid leakage of sensitive technologies, namely Trade Secrets (TS). At the EU-level, *Rajam* states that *'The definition of trade secrets in the European Directive [(EU) 2016/943] is derived from Article 39 TRIPS Agreement on protection of undisclosed information, which in turn places reliance on principles on unfair competition under Article 10bis of the Paris*

[105] Anthony Taubman, 'How Post-TRIPS Negotiations reframe the 'Trade Related Aspects' of Intellectual Property after TRIPS: The lessons of WTO Accessions' in Alexei Kireyev and Chiedu Osakwe (eds), *Trade multilateralism in the twenty-first century: Building the upper floors of the trading system through WTO accessions* (Cambridge University Press 2017) 274.
[106] WTO and others, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (2nd edn, World Trade Organization, World Health Organization and World Intellectual property Organization 2020) 98.
[107] WIPO (n 104) 157.
[108] ibid 157-158.

Convention'.[109] Following this, the definition of TS in Directive (EU) 2016/943, asset out in its Article 2(1) is as follows:

"'Trade secret' means information which meets all of the following requirements:

(a) it is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) it has commercial value because it is secret;

(c) it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret".[110]

Based on the TRIPS Agreement, the EU IP framework provides for protection of patents and TS that can be relevant for Dual-use technologies, and specific elements that may be reviewed under Preferential Trade Agreements (PTAs).

5 Critical analysis of the EU Export Controls in light of the EU – CAN Trade Agreement

Building on this overview it is possible to understand how EU trade-related practice addresses the different challenges at the intersection of its treaty-based relations and regulation of Dual-use technologies.

5.1 Intersections for the EU – CAN Trade Relations

Starting with WTO law, TT is mentioned in Article 7 Paragraph 2 of the TRIPS Agreement in the sense that, *'The protection and enforcement of Intellectual Property Rights (IPRs) should contribute to the promotion of technological innovation and to the transfer and dissemination of technology (…)'*. This can be complemented with the concept previously set out by *Correa and Beneke* that TT is defined *'as a series of processes of sharing ideas, knowledge, technology, and skills with another individual or institution (e.g. a company, a university, or a government agency) and of acquisition by the other of such ideas (…)'*[111]. In terms of convergence of international trade and IP, TT is further conditioned by TRIPS Article 39 on TS, and Article 27 to 34 on patents, which are reflected in the IP Title of EU-Andean Community Trade Agreement.

[109] Neethu Rajam, 'The impact of trade secrets for publicly funded research collaborations in Europe' in Timo Minssen, Thomas Riis and Jens Schovsbo (eds), *The harmonization and protection of trade secrets in the EU: an appraisal of the EU Directive* (Elgar 2020) 302.
[110] Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (Text with EEA relevance) [2016] OJ L 157.
[111] Correa and Beneke (n 28) 17.

Hence, the Trade Agreement includes a definition for patents in its Article 230, in line with TRIPS Articles 27 and 28.[112] Particularly, Article 27 defines patentable subject matter, requiring that inventions should be new, involve an inventive step, and capable of industrial application, while Article 28 explains the rights conferred to the patent owners, such as the right to assign, transfer and licence.

Moreover, Article 231 of the Trade Agreement refers to the 'Protection of data of certain regulated products' in accordance with Article 39 of the TRIPS Agreement and the domestic legislation of each party. With an emphasis on the protection of 'undisclosed test or other data related to safety and efficacy of pharmaceutical products' (namely TS), clarifying the definition of these products as follows:

"*For Colombia and the EU Party, this protection will include data protection of biological and biotechnology products. For Peru and Ecuador, the protection of the undisclosed information of such products shall be granted against disclosure and the practices that are contrary to honest commercial practices, in accordance with Article 39.2 of the TRIPS Agreement, in absence of specific legislation regarding thereof*".[113]

Subsequently in the Sub-committee on IP of the EU-Andean Community Trade Agreement, the Parties expressed their intention to cooperate on different matters under the scope of the TT. First, in the 9th Sub-committee meeting of October 2022[114], Colombia expressed *'its interest in exploring possible cooperation projects with the European Union with the aim of promoting the development of biotechnology through assets generated from IP, which come from access to genetic resources and their derived products'* to which the EU took note *'with the aim of transferring them to the team in charge of the IPKEY[115] programme'*.

Then, in the 10th Sub-committee on IP meeting in October 2023[116], in the scope of the cooperation initiatives of IP, the EU *'outlined the activities of the IP Key LA programme'*. Among these initiatives was a 'Workshop for Patent Examiners from Latin American IP

[112] Note that through the EU's COM (2024) 137 the Biotechnology is mentioned a patent with application in the health, food security, agriculture, and marine dimensions, following TRIPS Articles 27 and 28.
[113] Consolidated text: Trade Agreement (n 16) Article 231 Paragraph 1 (fn 80).
[114] EU – Andean Community, '9th Sub-committee on Intellectual Property – October 2022 – Minutes' (*Committees and Dialogues Intellectual Property*, 20 April 2023) <https://circabc.europa.eu/ui/group/09242a36-a438-40fd-a7af-fe32e36cbd0e/library/2522a71b-46de-4db1-a160-77c8a73a69f2/details> accessed 29 June 2025.
[115] IP Key Latin America is [a program] directed by the European Commission and implemented by the European Union Intellectual Property Office (EUIPO). It supports increased IP protection and enforcement across the Latin American region, from Mexico to Chile. Through its activities, IP Key Latin America aims to support international firms, especially EU enterprises, doing business in the region, and works collaboratively with its partners to increase awareness of the benefits of intellectual property as a key to growth and job creation. Although finished on March 2025, the EU has expressed its wish to continue with several initiatives of this kind. IP Key, 'Latin America' (*Latest news*, 2025) <https://ipkey.eu/en/latin-america> accessed 29 June 2025.
[116] EU – Andean Community, '10th Sub-committee on Intellectual Property – October 2023 – Minutes' (*Committees and Dialogues Intellectual Property*, 2 October 2024) <https://circabc.europa.eu/ui/group/09242a36-a438-40fd-a7af-fe32e36cbd0e/library/8058d7eb-1b9c-4f50-8857-f3347c9d2479/details> accessed 29 June 2025.

Offices: Pharmaceuticals, Biotechnology and Bioinformatics'[117] implemented in September 2024, one year later.

Further, in the latest meeting of November 2024 during the 11th Sub-committee[118], Colombia brought as a point of interest the *'Cooperation under Art 2[5]5[119] of the EU - Colombia, Ecuador, Peru FTA on the exchange of experiences and information on national and international practices and policies influencing technology transfer'*, to which the EU replied that *'is open to exchange experiences and information on national and international practices and policies influencing technology transfer'*.

Furthermore, Colombia and Ecuador have developed specific policies in this regard. In the case of Colombia, in July 2024 the Ministry of Defence presented the so called 'Innovation Strength' ('Fuerza Innovadora')[120], its new public policy on Science, Technology and Innovation, aimed to promote the creation of advanced and adaptable solutions from Dual-use technologies that contribute to strengthening national security and economic development through open innovation. The structure of this policy reflects certain elements of the EU's White Paper on R&D, starting with the definition and importance of the Dual-use technologies, altogether with the open innovation processes and the collaboration between the civil society and the defence sector.

Moreover, in a recent paper about the challenges and opportunities for Dual-use R&I in Ecuador, explicit mention was made of the lack of TT mechanisms, research centres and specialised programs, which limits the capacity for adaptation of Dual-use technologies.[121] It also stressed that is necessary to create partnerships between universities, technology companies and the defence sector, to support the creation Dual-use goods.[122]

All of this has a coherence with the EUCOM (2024) 137 and the White Paper on R&D for Dual-use technologies, as it can be considered as a case of using existing partnerships with third countries, and at the same aiming to exchange information in the scope of Article 255 on TT as well as implementation of the WTO TRIPS Agreement.

[117] IP Key, 'Latin America' (*Activities*, 2024) <https://ipkey.eu/en/latin-america/activities/workshop-patent-examiners-latin-american-ip-offices-pharmaceuticals> accessed 29 June 2025.
[118] EU – Andean Community, '11th Sub-committee on Intellectual Property – November 2024 – Minutes' (*Committees and Dialogues Intellectual Property*, 1 July 2025) <https://circabc.europa.eu/ui/group/09242a36-a438-40fd-a7af-fe32e36cbd0e/library/5c6434a4-ae20-4e5f-9a60-13a1e300a920/details> accessed 5 July 2025.
[119] The original transcription was referred to Article 225 Protection of Industrial Designs, which then is clarified to Article 255 Transfer of Technology in the same Sub-committee minutes.
[120] Ministry of Defence, 'Min Defensa presentó la iniciativa 'Fuerza Innovación' y la Política de Ciencia, Tecnología e Innovación para el sector' [Ministry of Defence presented the proposal 'Innovation Strength' and the Public Policy of Science, Technology and Innovation for the sector] (*News*, 2024) <https://www.mindefensa.gov.co/site/Sitio-Web-Ministerio-Defensa/prensa/noticia-visualizacion/lanzamiento-hub-de-innovacion-mindefensa> accessed 9 July 2025.
[121] Maria Gabriela Cueva-Jiménez and Julio Maximiliano Bolagray Larrea, 'Evaluation of Military Spending and Its Effects on Technological Innovation in Ecuador: Opportunities and Limitations' (2025) 9 (2) Journal of Economics and Social Sciences 15 <https://doi.org/10.18779/csye.v9i2.995> accessed 9 October 2025.
[122] Ibid 15.

5.2 Clashes for the EU-Andean Community Trade Relations

From the scope of WTO law, Article 40 of the TRIPS Agreement allows WTO Members to adopt appropriate measures to prevent and control licensing practices or conditions on IP rights that may impede the adequate transfer and dissemination of technology. These measures however are typically framed as controls on contractual practices at the national level, rather than measures affecting TT at the international level. Furthermore, the Article XXI GATT provisions on Security Exceptions[123] are also replicated in TRIPS Article 73.

Concerning the EU-Andean Community Trade Agreement, the regimes regarding Export Controls of Dual-Use items are included as part of the legislative and regulatory provisions applicable in the territory of each Party (Article 255 Trade Agreement). These provisions are not references as possible licensing practices that may impede TT but as a measure to adequately disseminate 'data and equipment related to or used in research, innovation and technological development activities', bearing in mind that the EU is the Party that actually has an Export Controls regime. This highlights to the first possible clash in the Trade Agreement, as this combined effect of these measures may either effectuate TT or act as a practice that impedes TT.

Furthermore, Article 295 (b)(iii) of the Trade Agreement includes a Security Exception, which incorporates some elements of Art. XXI (b)(ii) GATT. It however seems even broader in the sense that these measures are 'connected' (not related as the Art. XXI GATT) with the 'production of', 'government procurement of', or 'trade of' (none included in the GATT) related to traffic in other goods and materials, and to the supply of services for the purpose of supplying a military establishment.

There is also a further obligation under Article 295 of informing the Trade Committee about such measures. Thus, although the regulation of the TT of Dual-use items was included as part of the IP Chapter (and hence becomes TRIPS related), the measures taken are trade related. In other words, Article 257 states that the functions of the Sub-committee on IP, which consists of following up on the implementation of the provisions of the IP Title (Title VII), may have a role of in reporting Dual-use measures to the Trade Committee. Nevertheless, concerning TT for Biotechnology products, the information related to safety and efficacy may fall under Dual-use R&I if is related with the Regulation

[123] GATT 1994 Article XXI Security Exceptions. Nothing in this Agreement shall be construed:
(a) to require any contracting party to furnish any information the disclosure of which it considers contrary to its essential security interests; or
(b) to prevent any contracting party from taking any action which it considers necessary for the protection of its essential security interests
(i) relating to fissionable materials or the materials from which they are derived;
(ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;
(iii) taken in time of war or other emergency in international relations; or
(c) to prevent any contracting party from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.

(EU) 2021/821, classifying such as a Dual-use item or better as a Dual-use technology. This leads to the second possible clash of the Trade Agreement, as interventions may be necessary from both the Sub-committee on IP and the Trade Committee when a technology is listed as Dual-use under Article 255 (6) of the Trade Agreement.

Particularly, there are specific issues outlined in the White Paper on R&D opportunities for Dual-use technologies and the Dual-use items Export Controls regime, that concern both EU Member States and third countries trade partners. The first is the situation of EU research institutions and international cooperation with third countries[124] that includes Dual-use technologies requiring Intangible Transfers of Technology (ITT) covered by the EU Export Controls Regime. ITT are considered as transfers of non-physical items, such as knowledge and technical data, that can be transferred by intangible means, for instance in emails or in-person meetings[125]. This may thus possibly involve licensing or co-ownership arrangements for either patents or TS protected in both the EU Member State and the third country. Although there is currently a Council Recommendation on enhancing research security at the EU level, the use of technologies like cloud computing requires new guidelines, especially if the collaboration is done through international research projects that can ultimately benefit the security capability of third countries.[126] Such collaborations may even include projects administered or supported under the framework of agreements like the EU-Andean Community Trade Agreement.

As the European Commission recently stated, collaboration at the international level might be described in three classes of research:

"*i) Research with regards to economic competitiveness: there is a trade-off between the gains from knowledge inflow and the risks from knowledge outflow for both European and international cooperation partners; ii) Security related research: Depending on relations with and geopolitical positioning of the non-EU country, there is high interest in controlling knowledge outflows with mutual restrictions of cooperation. There is also a need to provide guidance for understanding risks and conducting risk assessment of dual-use [Research and Innovation] R&I; and iii) Research aiming at addressing global challenges: There is mutual interest in research cooperation, and no incentives for restrictions of knowledge inflows and outflows, while avoiding foreign R&I interference*".[127]

However, based on the publicly available documents of meetings of the Sub-committee on IP, it is not possible to determine which kind of research practices might be current object of exchange between the Parties of the Trade Agreement. This should be a topic

[124] Lauriane Héau, 'The EU Research Security Initiative: Implications for the Application of Export Controls in Academia and Research Institutes' (2025) 94 Non-proliferation and Disarmament Papers <https://www.sipri.org/publications/2025/eu-non-proliferation-and-disarmament-papers/eu-research-security-initiative-implications-application-export-controls-academia-and-research> accessed 30 June 2025.
[125] ibid 2.
[126] Héau (n 124) 2-3, 10.
[127] European Commission Directorate-General for Research and Innovation, *Making the most of EU Research and Innovation Investments: Rethinking dual use* (Publications Office of the European Union 2025) 16.

of discussion for both the EU and Andean Countries since as the Commission stresses, each category of research classification requires a different risk category to be assessed.[128] Furthermore, it is important to address research security and responsible internationalisation, as the Commission has stated that there is an important role for governments to 'adopt research security frameworks to safeguard critical knowledge, while also promoting responsible internationalisation to ensure that global R&D cooperation remains both open and secure'.[129] In this regard, the Commission suggests IP protection as the first measure to be considered, mentioning how *'Horizon Europe and the European Defence Found have introduced clearer IPRs provisions to protect sensitive results and ensure commercial viability within their respective mandates, [although both programmes are limited to civil and military scope respectively], meaning that currently none of them is designed to support integrated Dual-use R&D projects'*.[130]

6 Conclusions

For the EU, Biotechnology can fall as a Dual-use technology under the Dual-use R&D dimension. The above analysis showed how the EU-Andean Community Trade Agreement permits supporting technology transfer (TT) through this connotation. On the one hand, the Trade Agreement refers to the developments and cooperation under the TRIPS Agreement, and, on the other hand, it allows for a Security Exception as reflected in the GATT Article XXI, replicated in TRIPS Article 73 and Article 295 of the Trade Agreement with possible application to unilateral measures adopted within the EU's Export Controls regime.

Consequently, a preliminary answer to the question as to whether robust Export Control regulations are compatible with treaty-based trade relations must be "yes", at least in the context of EU-Andean Community trade relations. As *Hrynkiv* highlights, it remains in the EU's interest to preserve compatibility between its model and the global trading system and ensure that other States adhere to similar values and rules.[131]

The explicit reference to the Export Controls regulations is part of the IP chapter and TT, meaning that the best efforts required by the parties, if deployed by the EU, will guarantee the compatibility of the Regulation 2021/821 with the EU-Andean Community Trade Agreement. Since it is not included as part of Article 295 of the Trade Agreement, but is rather part of Article 255 on TT, the Andean Countries may be able to work in the development of Dual-use regulations according to their domestic legislation, given the importance of envisaging not only the establishment of a viable technological base but also an updated and compliant legal framework.

[128] ibid 17.
[129] European Commission Directorate-General for Research and Innovation (n 72) 75.
[130] European Commission Directorate-General for Research and Innovation (n 72) 75.
[131] Olga Hrynkiv, 'Export Controls and the Green Agenda in the European Union' (2025) 74 International and Comparative Law Quarterly 205, 212 <https://doi.org/10.1017/S0020589325000119> accessed 9 October 2025.

Nevertheless, since the proposals on Export Controls and R&D for Dual-use technologies are under review by the EU, the results of these possible inputs will have implications for the Andean countries. A more robust Export Controls restrictions framework can impact the possible R&D projects concerning Dual-use technologies that the Parties may develop, restricting resulting TT and intellectual property rights arrangements. Bearing in mind that Biotechnology products are included in the category of pharmaceutical products (Article 231 EU-Andean Community Trade Agreement), this gives a hint that Biotechnology may meet the first dimension to be assessed as a Dual-use technology.

Finally, it is feasible to say that IP, TT, and the EU Dual-use items Export Controls regime should be assessed jointly, especially in the context of the EU-Andean Community Trade Agreement. If the concept of Biotechnology is considered as a CT and therefore a Dual-use technology, it cannot be fully understood without its definition in the context of patent law, which becomes even more relevant when managing the research outputs of EU institutions and the importance of protecting their IP rights. The same is case with TS, and although was not mentioned directly the EU Directive on TS, these are an IP aspect of Dual-use technologies that can be transferred and have a paramount relevance when it comes to the latest ITT practices.

Journal of Law, Market & Innovation

ISSN: 2785-7867

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https://www.ojs.unito.it/index.php/JLMI
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The JLMI is edited as part of the
Open Access online scientific journals of
the University of Turin
Via Verdi 8, 10124
Turin, Italy

Vol. 4 - 3/2025