STUDY

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Artificial Intelligence and Civil Liability

A European Perspective

Policy Department for Justice, Civil Liberties and Institutional Affairs
Directorate-General for Citizens' Rights, Justice and Institutional Affairs
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Artificial Intelligence and Civil Liability

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Abstract

This study, commissioned by the European Parliament's Policy Department for Justice, Civil Liberties and Institutional Affairs at the request of the Committee on Legal Affairs, critically analyses the EU's evolving approach to regulating civil liability for artificial intelligence systems. In order to avoid regulatory fragmentation between Member States, the study advocates for a strict liability regime targeting high-risk systems, structured around a single responsible operator and grounded in legal certainty, efficiency, and harmonisation.

This document was requested by the European Parliament's Committee on Legal Affairs.

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LIST OF ABBREVIATIONS

AI	Artificial Intelligence
AIA	Artificial Intelligence Act
AI HLEG	High-Level Expert Group on Artificial Intelligence
AILD	AI Liability Directive
AIS	Artificial Intelligence System
ALTAI	Assessment List for Trustworthy AI
EC	European Commission
EP	European Parliament
EPRS	European Parliamentary Research Service
h-AIS	high risk Artificial Intelligence System
IMCO	European Parliament's Committee on the Internal Market and Consumer Protection
JURI	European Parliament's Committee on Legal Affairs
MS	Member State
NTF	Expert Group on Liability and New Technologies – New Technologies Formation
PLD	Product Liability Directive
PLDr	Product Liability Directive reformed
RLAI	Proposal for a Regulation on a civil liability regime for artificial intelligence
RMA	Risk-Management Approach
SMEs	small-medium enterprises

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EXECUTIVE SUMMARY

A European approach to technology regulation, and its reversal

The European Union's regulatory architecture on civil liability for artificial intelligence (AI) finds itself at a crucial juncture. What had begun as a coordinated effort to harmonise liability standards across Member States has undergone a remarkable shift in strategic focus. Originally, civil liability reform stood at the centre of European AI governance. However, this normative primacy has since been eclipsed by an *ex ante* risk-based compliance model, institutionalised by the AI Act. The possible withdrawal in 2025 of the proposal for an AI Liability Directive (AILD) has confirmed this regulatory inversion. It has also cast doubt on the Union's ability to prevent fragmentation in the application of liability norms across jurisdictions.

Legal gaps and general liability rules: false dichotomy

Throughout the debate, legal gaps have often been cited as either necessitating or negating new regulation. This binary framing is misleading. The mere absence of dedicated rules does not mean that victims are unprotected, as general tort and contract norms are, in theory, flexible enough to accommodate novel harms. However, this legal adaptability comes at the cost of predictability, efficiency, and harmonisation. Conversely, the presence of general rules is not sufficient to dismiss the need for dedicated regulation, particularly where high levels of ex ante uncertainty and ex post divergence undermine market integration and legal coherence. Ultimately, the desirability of regulation depends not on the presence or absence of legal norms, but on whether intervention can deliver improved efficiency, foreseeability, and access to justice.

The strategic risk of legal fragmentation

In the absence of a uniform European approach, Member States are increasingly likely to develop divergent regulatory frameworks for AI liability. This risk is not theoretical. Germany has already enacted legislation on automated driving, and Italy is currently examining a draft bill on AI. Such national initiatives not only complicate compliance for cross-border operators but also generate path dependencies that could entrench fragmentation. The worst case scenario is a piecemeal legal landscape that undermines the internal market and disincentivises innovation by increasing regulatory overhead.

Efficient regulation is the only way to avoid over-regulation

In the absence of a uniform solution at EU level, national tort regimes will reassert themselves, raising significant concerns about legal coherence, judicial efficiency and over-regulation. The latter in particular is the by-product of the combined effect of European and national legislation. The absence of EU-wide rules will lead to a proliferation of national solutions and normative interventions, multiplying the legal regimes with which businesses must comply and preventing uniform protection of European citizens with respect to identical technological products and services. Ultimately, the only way to avoid excessive regulatory burdens is to adopt efficient legal norms. In the area of civil liability, these should primarily aim at ensuring compensation for victims, limiting litigation and its associated costs, promoting legal certainty and ex ante predictability of outcomes, and encouraging the

internalization and management of these costs by companies and professionals that benefit from the diffusion of AI-based services and products.

The legacy of the PLD and Its Limitations

The original Product Liability Directive (PLD), adopted in 1985, represented the main body of European norms theoretically applicable to AIS, despite the notion of product did not directly encompass software. The overall debate about technology regulation thus took into account the adequacy of the framework provided by this directive in its original formulation, also considering the caselaw it generated across MS over a few decades of application. The directive was designed to establish a strict, no-fault liability regime for defective products. Its underlying objective was twofold: to ensure effective compensation for consumers and to harmonise divergent national tort systems. Yet, there is no evidence of product liability increasing ex ante safety investments, as opposed to product safety legislation and market mechanisms such as reputation, that play, indeed, a relevant role. At the same time, the PLD did not prove effective in ensuring victim compensation, as it is witnessed by the limited number of cases litigated, the even smaller number of cases where claimants were successful, and the persistent application of other—non dedicated general tort or contract law—norms, to ensure victim's satisfaction. The directive's doctrinal foundations—particularly its reliance on the notion of "defect" and the "development risk defence"—undermined its purported objectivity. These provisions effectively reintroduced fault-based logic under the guise of strict liability. More fundamentally, the burden-of-proof regime embedded in art. 4 PLD placed a heavy evidentiary load on claimants. All such concerns are destined to be worsened by the advent of AI systems characterised by complexity, opacity, and learning capabilities.

Technological Complexity and the Inadequacy of General Rules

The characteristics of AI, as well as the increased human-machine collaboration that automation brings, challenge traditional principles of tort law. On the one hand, despite safety investments and careful design, harm may occur whose economic consequences should not be left to the injured party. Put another way, the rationale of cost internalization should be preferred to the idea of individual blame; the former is typical of strict liability rules, the latter of fault-based ones. At the same time, the opacity of AIS and the increasing human-machine collaboration in the performance of tasks lead to layered and complex causality that is difficult and costly to disentangle in order to determine what ultimately caused the damage. In addition, because multiple parties are involved, as many liability rules may apply and thus overlap. Determining who should be held responsible and under what conditions therefore becomes an extremely complex task, requiring costly litigation and inevitably leading to a high degree of uncertainty about the outcome. This, in turn, discourages both the development of technologically advanced products and services and their adoption by users who fear that they will not be able to obtain redress in the event of harm.

The PLDr: Procedural Amendments without Structural Reform

In 2024, the European Parliament and the Council adopted a revised Product Liability Directive (PLDr), which aimed to modernise the original text to accommodate digital technologies. The PLDr introduced several procedural mechanisms, including broadened definitions of "product" to include software, and

thence AI, new rules on evidence disclosure, and presumptions of defect and causation. However, these changes did not alter the directive's fundamental structure. The notion of "defect" remained tied to consumer safety rather than system performance, and the development-risk defence was retained. Moreover, the scope of recoverable damages continued to exclude harm to the defective product itself—an exclusion that severely curtails litigation in AI-related incidents where the most substantial loss may be to the autonomous system itself. In sum, while the PLDr appears procedurally innovative, it leaves intact the substantive limitations that rendered the PLD largely ineffective in the first place. In particular, the PLDr like its predecessor, is conceived as a rule that completes the legal system, but of limited application, leaving to other tort law rules a primacy to govern damage compensation. Said otherwise, lack of safety in product design and manufacturing is expected to be a rare circumstance, especially in a modern and heavily regulated economy. However, in the absence of other specific norms, no other rule seems capable of tracing the damage caused by increasingly autonomous machines back to those who designed them and profit from their proliferation. Nevertheless, the PLDr has not been transformed into a strict liability rule that adheres to a risk management perspective; instead, the focus on the lack of safety has been maintained. This is consistent with the original policy intent to address civil liability arising from the use of AI through two separate pieces of legislation, the latter being the AILD. However, the Commission is currently considering withdrawing its second proposal.

The AILD, theoretical complexity and the risk of practical irrelevance

The AILD sought to complement national fault-based liability regimes by introducing harmonized procedural tools–in particular, disclosure requirements and rebuttable presumptions of causation and fault. While the proposal sought to maintain a minimalist approach, preserving the primacy of Member States' fault-based rules in ensuring compensation for damage caused by AIS, it created the possibility of potential interference with those very rules. Indeed, the objective notion of "fault"–as a violation of AI-specific obligations–is difficult to reconcile with those liability rules that require a specific evaluation of the agent's behavior (e.g., medical malpractice). At the same time, the benefits of an artificially divided presumption of causation are limited, especially when compared to the elements that the plaintiff must prove to benefit from it. This complex legal architecture, which places excessive discretion in the hands of national courts and requires problematic coordination with numerous and very different fault-based rules of the Member States, risks exacerbating rather than reducing legal uncertainty and fragmentation. Moreover, given the limited benefits for claimants, it is likely that national courts will soon learn to rely on other provisions, in particular strict liability rules, to facilitate victim compensation, leading to a substantial disapplication of the AILD. Finally, its adoption is unlikely to prevent the proliferation of alternative regulatory paradigms at Member State level, which is precisely the form of over-regulation that a European initiative in this area should primarily avoid.

A Functional and Coherent Strict Liability Model

In light of these deficiencies, the study advocates for the creation of a new, standalone strict liability regime for high-risk AI systems (h-AIS). Such a framework should abandon the notion of fault altogether and instead impose liability on a single operator—defined as the entity that controls the AI system and benefits economically from its use. This notion – taken from the 2020 European Parliament's proposal for a Regulation on Civil Liability and Artificial Intelligence (RLAI) – could also be

replaced through reference to both the provider and the deployer, as defined by art. 3 AIA, for reasons of internal coherence of the European regulatory framework on AI. This "one-stop-shop" model would eliminate the problems of causal uncertainty and overlapping liabilities, allowing risks to be internalised and costs to be managed through insurance and price mechanisms. A strict liability regime would also render procedural tools such as disclosure and rebuttable presumptions largely redundant, by replacing them with clear, substantive obligations that enhance predictability for victims and operators alike.

Policy Options

Four distinct policy options are presented, each evaluated with respect to the effect on the relationship between European and MS law, their awaited efficiency, and impact on innovation.

The first option envisages the plain withdrawal of the AILD. This would likely result in regulatory fragmentation, as MS would adopt divergent solutions through existing tort law or ad hoc legislation. Such a development is expected to generate path-dependencies, elevate legal uncertainty, and foster overregulation through a proliferation of inconsistent national approaches. The study emphasizes that this would not only impede legal harmonization but also discourage technological uptake due to unpredictable liabilities and increased litigation costs.

The second option, retaining the AILD in its current form, is found to be even more problematic. The directive's limited procedural innovations would fail to overcome the underlying diversity of MS fault-based regimes. The resulting regulatory framework would mirror the drawbacks of non-intervention while simultaneously obstructing the possibility of future legislative improvements. Courts would likely revert to applying more familiar and effective national rules, leading to a fragmented and inefficient outcome institutionalized at the European level.

The third policy option, maintaining the AILD while revising it to incorporate a specific fault-based liability rule for high-risk AI systems (h-AIS), is a preferable alternative, addressing many of the shortcomings of the existing proposal. By clearly defining the scope of application and liability conditions—mirroring the approach previously proposed in the European Parliament's RIA—the revised directive could enhance legal certainty, promote uniform interpretation, and reduce litigation costs. Moreover, the objective notion of fault and the alignment with the AIA would ensure consistency across the EU regulatory landscape.

The fourth policy option involves modifying the AILD by transforming it into strict liability for h-AIS. The analysis draws on broad expert consensus and support from the European Parliament in concluding that a strict liability rule—ideally framed within a regulation—would deliver the highest degree of harmonization, efficiency, and user protection. Such a rule would facilitate ex ante risk internalization by providers and deployers, minimize administrative and litigation costs, and offer clear, uniform standards conducive to innovation and cross-border scalability. The ability to apportion costs across the value chain would further enhance its practical effectiveness.

In conclusion, the necessity of a coherent European liability requires rejecting both Policy Option 1 and 2, the latter not only because of its inefficacy but also due to its potential to obstruct better future regulatory alternatives. While Option 4 is the optimal solution, Option 3 could still represent a commendable improvement over the status quo, since both are viable strategies to support legal

coherence, technological innovation, and effective user protection within the evolving European AI ecosystem.

1. WHY REGULATE CIVIL LIABILITY IN THE AREA OF ARTIFICIAL INTELLIGENCE?

KEY FINDINGS

1. **The "Great Reversal" in EU Regulatory Logic**

The European Union has undergone a fundamental transformation in its approach to regulating artificial intelligence. Initially centred on establishing hard-law civil liability rules, the EU progressively shifted to prioritising binding ex ante compliance obligations through the AI Act.

2. Original Centrality of Civil Liability in AI Governance

The European Parliament's 2017 Resolution on Civil Law Rules on Robotics diagnosed a structural misalignment between existing tort law and the challenges posed by autonomous AI systems. It advocated for strict or risk-based operator liability, mandatory insurance, and a compensation fund, emphasising liability as the core regulatory tool complemented by ethical soft law instruments.

3. Expert Consensus on Operator Liability and PLD Modernisation

Expert groups advising the Commission in 2019 strongly supported the modernisation of the Product Liability Directive (PLD) to include software. They also proposed introducing a strict liability rule burdening the "operator" in addition to the producer. They rejected the notion of electronic personhood for AI.

4. Withdrawal of the AI Liability Directive (AILD)

The Commission is considering withdrawing the AILD proposal, citing lack of political consensus and fear of legal fragmentation across Member States. This move definitively confirmes the prioritisation of risk-based ex ante regulation over liability harmonisation.

5. Legal Gaps Do Not Justify or Preclude Regulation

The absence of dedicated legal norms neither proves a lack of protection nor rules out the desirability of new regulation. General tort and contract law ensure adaptability, but they may lead to ex ante uncertainty and ex post fragmentation. Regulatory intervention is justified if it enhances efficiency, predictability, and harmonization.

6. Fragmentation as a Strategic Regulatory Risk

Legal divergence across Member States, exacerbated by directives rather than regulations, poses a significant threat to the internal market. National liability regimes—such as Germany's law on automated driving or Italy's AI legislative proposal—may create path dependencies that hinder future EU-wide harmonisation.

7. Efficiency as Primary Justification for Civil Liability Reform

Regulatory intervention should be assessed primarily through an efficiency lens. Norms should reduce litigation and administrative costs, provide legal certainty, and promote early technology adoption. The revised PLD (PLDr) must be monitored over time to verify if it delivers on these objectives without causing excessive complexity.

8. Clear Liability Rules Improve Compensation and Risk Allocation

The ideal liability framework should maximise victim compensation, minimise uncertainty, and transform uncertain risk into insurable and transferable costs. This fosters trust, reduces transaction costs, and aligns legal risk with technological design and deployment decisions.

9. Overregulation Arises from Fragmented or Inadequate Norms

The proliferation of national alternative liability regimes in the absence of a EU-wide solution, represents a form of over-regulation, as concerning as the adoption of inefficient norms. Uniform, well-defined liability rules reduce compliance burdens and enhance industrial competitiveness, while poorly conceived norms risk entrenching fragmentation and deterring innovation.

1.1. Introduction

In order to understand if and how civil liability for damages arising from the use of advanced technologies needs to be regulated, also taking into account the current regulatory framework–primarily the Artificial Intelligence Act (hereafter AIA)–it is necessary to briefly recall how the whole debate started already in 2014 and 2015, first within the European Parliament (hereafter EP).

This brief historical account (see §1.2 below) is intended to demonstrate a complete reversal of perspective by the European institutions, primarily the European Commission (hereafter EC), that needs to be analyzed and discussed. In fact, the original focus of the European institutions was on the adoption of specific civil liability rules for advanced technologies (robotics and AI), leaving all other aspects to soft law (primarily the ethical principles of AI). A major reversal occurred after 2019, when the first von der Leyen Commission took office and initiated a debate that led to the adoption of the AIA.

After analysing this essential change in perspective, a discussion of the reasons for regulation (see §1.3) will take place do determine whether gaps need to be found or fragmentation and/or efficiency considerations made to justify intervention. Then the risk of adopting regulation will be addressed (see §1.4 below) to determine what normative intervention should radically be avoided.

This will represent the starting point to (i) define the regulatory needs that were identified (see Chapter 2), (ii) discuss whether those were actually met by the emergent regulatory framework, taking into account the revised product liability directive, and the proposal for an AI Liability Directive (Chapter 3), and finally (iii) determine what action is needed and could be beneficial (Chapter 4).

1.2. A brief history of technology regulation in Europe: a great reversal

The purpose of this section is to demonstrate the profound inversion in the European Union's regulatory approach to artificial intelligence—a transformation we term "the great reversal". Whereas the original EU blueprint situated civil-liability reform at the core of technology regulation and confined broader governance questions to soft-law instruments, the current framework under President von der Leyen places detailed, binding ex ante obligations at the centre and defers comprehensive liability harmonization. To trace this evolution, we proceed chronologically through the principal milestones—from the European Parliament's 2017 resolution, via successive Commission communications and expert reports, to the AI Act proposal and the debate around the hereafteral of the AI Liability Directive—presenting each document's institutional origin, adoption context, and detailed content in narrative form. We then synthesize these developments in a comparative table and conclude with an analytical reflection on the reversal in regulatory logic.

1.2.1. European Parliament Resolution on Civil Law Rules on Robotics

In February 2017, the European Parliament's Committee on Legal Affairs (hereafter JURI), led by Rapporteur Mady Delvaux-Stehres, adopted Resolution 2017/2001 (INL) on "Civil Law Rules on

Robotics"[1]. This resolution opened by diagnosing a fundamental mismatch between traditional fault-based tort law—designed for human decision-makers—and the novel challenges posed by autonomous, learning machines. It identified three core deficiencies: (1) the inability of victims to obtain redress when no human actor's negligence could be established; (2) the misfit of the "producer" model of liability for software-driven systems that evolve post-deployment; and (3) the burdensome evidentiary requirements under existing procedural rules.

To address these gaps, the resolution proposed a hard-law overhaul of civil liability. Operators or owners—defined as those who control and benefit from robotic systems—would be subject to strict or risk-based liability, irrespective of fault, thereby internalizing risks and incentivizing safer design. Mandatory insurance would ensure compensation, and a central compensation fund would cover cases where no liable party could be identified. In parallel, it envisioned a complementary soft-law framework of ethical guidelines, codes of conduct, and voluntary standards to govern transparency, data protection, and human oversight. By delineating civil liability as the primary tool and relegating broader governance to non-binding instruments, the policy sought to harmonize liability across the Single Market while fostering public trust in robotics.

1.2.2. Commission Communication "Artificial Intelligence for Europe"

On 25 April 2018, the European Commission published a communication entitled 'Artificial Intelligence for Europe' (COM (2018) 237). Addressed jointly to Parliament, Council, the Economic and Social Committee, and the Committee of the Regions, this Communication acknowledged the need to devise a human-centric regulatory framework for AI, and announced the creation of the High-Level Expert Group on AI to draft voluntary guidelines, and a series of ethical principles. The hard-law liability reform was maintained on the legislative agenda, and the appointment of an expert group was announced, to determine the adequacy of the current framework and the direction new legislation ought to pursue.

1.2.3. High-Level Expert Group on AI: Ethics Guidelines and ALTAI

In June 2018, the Commission appointed fifty-two independent experts to the High-Level Expert Group on Artificial Intelligence (hereafter AI HLEG)[2], explicitly tasked not with liability reform but with formulating a soft-law framework for "Trustworthy AI." On 8 April 2019, the HLEG published its Ethics Guidelines for Trustworthy AI, resting upon three foundational pillars—legality (ensuring compliance with laws and fundamental rights), ethics (upholding dignity and non-discrimination), and technical robustness (guaranteeing safety and resilience). To operationalize these pillars, the Guidelines defined seven requirements: human agency and oversight; technical robustness and safety; privacy and data governance; transparency; diversity, non-discrimination and fairness; societal and environmental well-being; and accountability.

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1 Committee on Legal Affairs (2017). Report with recommendations to the Commission on Civil Law Rules on Robotics. 2015/2103(INL). Strasbourg, European Parliament. available on EUR-Lex: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52017IP0051.

2 For more details see https://digital-strategy.ec.europa.eu/en/news/commission-appoints-expert-group-ai-and-launches-european-ai-alliance.

After extensive stakeholder piloting, on 8 July 2020 the HLEG released the Assessment List for Trustworthy AI (hereafter ALTAI)[3], a self-assessment tool enabling organizations to benchmark their systems against the seven requirements. ALTAI provides a structured questionnaire and scoring methodology, prompting documentation of design choices, risk-mitigation measures, and governance processes. The HLEG emphasized that both documents were voluntary, intended to foster shared ethical standards without pre-empting the binding liability regime envisaged by earlier legislative proposals.

1.2.4. Expert Report on Liability for AI and Other Emerging Digital Technologies

Concurrent with the HLEG's work, the Commission in 2018–19 convened two expert formations: one to modernize the Product Liability Directive (hereafter PLD)[4] and another—the New Technologies Formation (hereafter NTF)—to explore broader tort adaptations[5]. The Report on Liability for AI and Other Emerging Digital Technologies[6], published July 2019, concluded that the PLD's core strict producer liability remained broadly fit for purpose but required targeted updates: "product" must encompass software and data; "defect" must include algorithmic flaws and inadequate training data; and "producer" should extend to entities deploying or maintaining AI systems (hereafter AIS).

Importantly, the Report advocated a no-fault operator liability regime: operators—those exercising decisive control over and benefiting from an AI system—should bear strict responsibility for harm, thereby internalizing associated costs. To alleviate victims' evidentiary burdens, it proposed rebuttable presumptions of causation when operators failed to implement "logging-by-design" mechanisms or breached mandatory safety and transparency protocols. It also recommended narrowing or abolishing the "development-risk" defence—which currently allows producers to escape liability for unknown hazards—on grounds that AI's dynamic learning processes render unforeseeable risks ascertainable. Finally, it rejected "electronic personhood," insisting liability must remain traceable to human or legal person. By meticulously updating the PLD and layering operator liability, the expert groups reaffirmed civil liability as the EU's foremost hard-law instrument.

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[3] High-Level Expert Group on AI (2020). The Assessment List for Trustworthy Artificial Intelligence (ALTAI) for self assessment. Brussels, European Commission.

[4] Europe, C. o. (1985). Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 7.8.1985: 29-33.

[5] European Commission (2018). Commission Staff Working Document. Liability for emerging digital technologies. Accompanying the document 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 Artificial intelligence for Europe. SWD(2018) 137 final. Brussels, European Commission. available at the following link: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018SC0137.

[6] Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission. and for a comment see Bertolini, A. and F. Episcopo (2021). "The Expert Group's Report on Liability for Artificial Intelligence and Other Emerging Digital Technologies: a critical assessment." European Journal of Risk Regulation 12(3): 644-659.1 ff.

1.2.5. The European Parliament's call for experts on AI and civil liability

In response to the work of experts nominated by the EC, the EP has commissioned research and interdisciplinary studies through Policy Departments[7]. Among these latter, some authors[8] have raised some criticism on the matter.

One such study highlighted the inadequacy of the European legal framework, in particular the PLD, due to high litigation costs, the ambiguity of concepts such as "defectiveness" and the less than strict nature of the liability regime. The study also noted how such a limitation could be exacerbated by complex AI systems, which make the assessment of causation more complex and uncertain, ultimately preventing technological uptake. Since these norms seemed to be a viable solution only for high-value claims (e.g., pharmaceuticals), but not for low-value litigation dependent on automation, the expert suggested adopting a special liability rule that adheres to a risk management approach (hereafter RMA). A strict liability regime should prima facie burden a single party that is best placed to identify, control and manage, including through insurance mechanisms, the risks associated with the diffusion of certain categories of advanced technological products and services. The main rationale is to ensure compensation for victims rather than to deter bad behaviour, which would force the internalization of costs, reduce litigation, promote access to justice and ultimately increase public confidence in new technologies.

1.2.6. European Parliament Proposal for a Regulation on Civil Liability for AI

Building on the NTF's work, in October 2020 the European Parliament's Committee on Legal Affairs tabled a resolution with recommendations on a civil liability regime for AI, for which Mr Axel Voss (EPP, Germany) was the rapporteur, endorsed in plenary November 2020[9] (RLAI). The draft mirrored the expert Report's recommendations, establishing a dual liability regime: strict liability for "high-risk" AI systems (hereafter h-AIS)–as defined by the AI Act–and a rebuttable presumption of fault for all others, with compulsory insurance for the operators of h-AIS.

The strict liability of the operator of a h-AIS was grounded in the principle that the operator exercises a degree of control over the risks associated with the functioning of the system. Liability applied to

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[7] Policy departments function as the Parliament's in-house centres of expertise, offering analytical and advisory services to support legislative and oversight work—particularly for committees. They deliver independent, specialised, and current information through both internally conducted and externally commissioned studies. Their analytical output comes in various forms, tailored largely to the needs of committees or parliamentary delegations. The database features a wide spectrum of material—from comprehensive studies and thematic analyses to succinct issue-focused briefings. These deliverables are used to inform committee debates, contribute to legislative processes, or support Members of the European Parliament (MEPs) during official missions. For more details see https://www.europarl.europa.eu/committees/en/juri/supporting-analyses/supporting-analyses-presentation.

[8] Bertolini, A. (2020). Artificial Intelligence and Civil Liability. Bruxelles, European Parliament - Committee on Legal Affairs: 1-132. 9-15; Karner, E., B. A. Koch and M. A. Geistfeld (2020). Comparative Law Study on Civil Liability for Artificial Intelligence. Luxemburg, Publications Office of the European Union.

[9] European Parliament (2020). Civil liability regime for artificial intelligence. European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL)). Brussels, European Parliament. available at the following link: https://www.europarl.europa.eu/doceo/document/TA-9-2020-0276_EN.html.

both the front-end and the back-end operator. In such cases, the operator could only escape liability on grounds of force majeure.

Instead, operators of a non-h-AIS was held liable unless they could demonstrate that they took all reasonable and necessary measures to prevent the harm. This included, for example, selecting an appropriate AIS for the intended task, operating it correctly, monitoring its activities, and installing all available software updates. Here too, the operator could not invoke the system's autonomous functioning as a defence.

In order to facilitate the compensation of victims, it provided for the joint and several liability of all operators. This proposal was overtaken by two parallel initiatives in 2022: a proposal for a targeted reform of the Product Liability Directive[10] (hereafter PLDr) and for an AI Liability Directive (hereafter AILD)[11].

1.2.7. Proposal for an AI Act

Upon taking office in December 2019, President von der Leyen prioritized a risk-based regulatory paradigm. On 21 April 2021, the Commission presented its Proposal for a Regulation on a European approach for Artificial Intelligence[12]. Departing from a liability-first approach, the AI Act categorizes AI systems into prohibited practices, high-risk applications, limited and minimal-risk applications. High-risk systems are subject to binding ex ante obligations—conformity assessments, fundamental-rights impact analyses, technical documentation, post-market monitoring—while limited-risk applications face only transparency requirements.

Notably, the AIA covers many of the issues identified by the AI HLEG, thereby establishing an *ex ante* regulatory compliance model[13]. Moreover, it contains no harmonized civil-liability provisions, deferring liability reform to a separate legislative initiative. Furthermore, it can be viewed as a new form of product safety legislation for two main reasons[14]. On the one hand, it belongs to that domain because its core provisions (articles No. 5-6 and 40–49) establish a regulatory scheme grounded in risk

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[10] Commission, E. (2022). Proposal for a directive of the European Parliament and of the Council on liability for defective products, COM(2022) 495 final.. For the timeline of the initiative see https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Product-Liability-Directive-Adapting-liability-rules-to-the-digital-age-circular-economy-and-global-value-chains_en. For a comment, please refer to ELI (2023). "European Commission's Proposal for a Revised Product Liability Directive, Feedback of the European Law Institute."
https://europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/ELI_Feedback_on_the_EC_Proposal_for_a_Revised_Product_Liability_Directive.pdf.

[11] Commission, E. (2022). Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive), COM(2022) 496 final.

[12] Commission, E. (Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, COM(2021) 206 final). available at the following link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0206.

[13] High-Level Expert Group on Artificial Intelligence (2019). Ethics Guidelines for Trustworthy AI. Brussels, European Commission.

[14] In this sense, see Marco Almada and Nicolas Petit, 'The EU AI Act: A Medley of Product Safety and Fundamental Rights?' (Social Science Research Network, 18 October 2023) and Philipp Hacker, 'AI Regulation in Europe: From the AI Act to Future Regulatory Challenges' (arXiv, 6 October 2023) <http://arxiv.org/abs/2310.04072>.

management and certification through conformity assessment. On the other hand, the AIA is only an initial—neither definitive nor exhaustive—step toward regulating AI systems. Its horizontal, cross-sector design underscores this provisional character and leaves space for future, more vertical measures that may address particular technologies (e.g., autonomous vehicles) or specific issues (such as civil liability)[15].

1.2.8. Proposal for reform of the PLD and proposal for an AILD

The EC put forward its proposal for an AILD on 28 September 2022[16] establishing rules on disclosure obligations and rebuttable presumptions to be used in combination with MS's fault-based rules.

In parallel, the Commission also presented a proposal to overhaul the PLD so that producer no-fault liability for defective products is updated considering technological change. On this proposal, the European Economic and Social Committee delivered its opinion on 25 January 2023[17], while the European Data Protection Supervisor followed suit on 11 October 2023[18].

Parliamentary deliberations were paused until the passage of the linked AIA but restarted after the Commission circulated an updated text in July 2024 to align terminology with that act. At JURI's request, the European Parliamentary Research Service (hereafter EPRS) published a complementary impact-assessment study on 19 September 2024[19]. The study suggested broadening the directive's scope to encompass general-purpose and other "high-impact" AI systems, extending coverage to software, and moving toward a hybrid regime that blends fault-based and strict liability. It even proposed replacing the directive with a directly applicable Software Liability Regulation to avoid market fragmentation and ensure legal clarity across the Union.

Members of the JURI committee exchanged views on the restarted proposal on 5 December 2024[20], revealing divergent opinions about the need for harmonised non-contractual liability rules for AI. A formal hearing, coupled with a presentation of the EPRS study, followed on 30 January 2025[21]. Subsequently, the European Parliament's Committee on the Internal Market and Consumer Protection

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15 For an in-depth analysis, see Bertolini, A., F. Fedorczyk, M. M. Mollicone and G. Migliora (forthcoming, 2025). "The Brussels Sphinx's Riddle. What is a high-risk AI System?" Working Paper.1 ff.

16 On the point, see Wendehorst, C. (2022). AI liability in Europe: anticipating the EU AI Liability Directive, Ada Lovelace Institute. 1-23.

17 European Economic and Social Committee (2023). Opinion: Artificial Intelligence Liability Directive. available at the following official link: https://www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/artificial-intelligence-liability-directive.

18 European Data Protection Supervisor (2023). Opinion 42/2023 on the Proposals for two Directives on AI Liability rules. available at the following official link: https://www.edps.europa.eu/system/files/2023-10/23-10-11_opinion_ai_liability_rules.pdf.

19 EPRS (2024). Proposal for a directive on adapting non-contractual civil liability rules to artificial intelligence: Complementary impact assessment. available at: https://www.europarl.europa.eu/thinktank/en/document/EPRS_STU(2024)762861.

20 See https://www.europarl.europa.eu/legislative-train/theme-a-europe-fit-for-the-digital-age/file-ai-liability-directive.

21 See https://www.europarl.europa.eu/committees/en/hearing-on-adapting-non-contractual-civi/product-details/20250128CHE12883.

(hereafter IMCO) adopted its opinion on 20 May 2025, describing the directive as premature and unnecessary and urging JURI to recommend its rejection[22].

1.2.9. Approval of the revision to the PLD and debate on withdrawal of the AILD

Indeed, in 2025 the Commission formally announced its intention to hereafter the pending AI Liability Directive[23], consigning comprehensive liability reform to future guidance rather than law. President von der Leyen's statements at the AI Action Summit in February 2025[24] lauded the AI Act as a "historic" framework without reference to liability harmonization. Thus, soft-law elements originally conceived as auxiliary have become the core of EU hard-law intervention, while the envisioned liability regime has been indefinitely postponed.

Regarding the reasons why the AILD is considered for withdrawal, in its 2025 Work Programme the EC said that there was "no foreseeable agreement" on the proposal among the Member States[25]. On the point, Henna Virkkunen, the EU Commissioner responsible for tech, criticised that the AILD would not have led to one set of uniform rules across the EU since "With a directive, member states implement the rules in different ways"[26] .

Lawmakers have been divided over the need for the rules. The rapporteur in JURI Axel Voss[27], wanted to keep working on the dossier. On the contrary, his counterpart in IMCO, Kosma Złotowski, said in his draft opinion published in January that the "adoption of an AI Liability Directive at this stage is premature and unnecessary"[28].

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22 IMCO (2025). Draft Opinion of the Committee on the Internal Market and Consumer Protection for the Commitee on Legal Affairs on the proposal for a directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive), (COM(2022)0496 – C9-0320/2022 – 2022/0303(COD)). available here: https://www.europarl.europa.eu/doceo/document/IMCO-PA-768056_EN.pdf?ref=eutechloop.com.

23 In its 2025 Work Programme presented on 11 February 2025, the Commission listed the AI Liability Directive in the withdrawals section due to the lack of agreement on a final text. For more details see https://commission.europa.eu/strategy-and-policy/strategy-documents/commission-work-programme/commission-work-programme-2025_en.

24 For the speech by the President Von der Leyen at the AI Action Summit see https://ec.europa.eu/commission/presscorner/detail/it/speech_25_471.

25 See fn. 22.

26 She added that: "We need to fully implement the AI Act before we propose new rules – in the last years the European Commission has proposed a lot of digital rules and we need to simplify them before presenting something new". See https://www.euronews.com/next/2025/04/09/eu-tech-commissioner-defends-scrapping-of-ai-liability-rules.

27 He said that: "liability rules are needed anyway to create a true digital single market". On the point, see https://multimedia.europarl.europa.eu/en/video/press-conference-by-axel-voss-epp-de-rapporteur-on-the-presentation-of-juri-position-on-ai-act_I222710.

28 IMCO (2025). Draft Opinion of the Committee on the Internal Market and Consumer Protection for the Commitee on Legal Affairs on the proposal for a directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive), (COM(2022)0496 – C9-0320/2022 – 2022/0303(COD)). 1 ff.

Table 1: Comparative Summary of Key Documents

Document	Date	Institution	Hard-Law Measures	Soft-Law Measures
EP Resolution on Civil Law Rules on Robotics	16 Feb 2017	European Parliament (JURI; Delvaux-Stehres)	Strict/risk-based operator liability; insurance; compensation fund	Ethical guidelines; voluntary codes of conduct
Communication from the Commission "Artificial Intelligence for Europe"	25 Apr 2018	European Commission (COM 2018 237)	–	Funding commitments; Necessity to develop a coherent, human-centric framework for AI. Subsequent launch of a call[29] to appoint a High-level Expert Group to elaborate soft law principles to regulate AI and of two Expert groups on civil liability (Product liability and New Technologies formations)
HLEG Ethics Guidelines & ALTAI	8 Apr 2019; 8 Jul 2020	High-Level Expert Group on AI	–	Seven ethical requirements (human agency and oversight; technical robustness and safety; privacy and data governance; transparency; diversity, non-discrimination and fairness; societal and environmental wellbeing; accountability); self-assessment tool ALTAI[30]

[29] For the calls, see respectively https://digital-strategy.ec.europa.eu/en/policies/expert-group-ai and https://ec.europa.eu/newsroom/just/items/615947.

[30] See https://digital-strategy.ec.europa.eu/en/library/assessment-list-trustworthy-artificial-intelligence-altai-self-assessment.

Expert Report on Liability for AI & Other Emerging Digital Technologies	Jul 2019	Commission Expert Groups on PLD & New Technologies	No-fault operator liability; extension of the notion of product to encompass software; identification of procedural constraints in demonstrating defectiveness and the existence of a causal nexus.	–
EP Resolution on Civil Liability for AI (2020/2014(INL))	Oct–Nov 2020	European Parliament (JURI)	Dual regime: strict liability for high-risk AI; rebuttable presumption of fault for others; mandatory insurance	–
Proposal for a Regulation laying down harmonised rules on AI (Artificial Intelligence Act) and amending certain Union legislative acts	April 2021	European Commission (COM 2021 206 final)	Binding ex ante risk-based obligations; conformity assessments and certification requirements; impact analyses; post-market surveillance	–
Proposal for a revised version of the Directive on liability for defective products (PLDr)	September 2022	European Commission (COM 2022 495 final)	Product encompasses software and therefore AI; adoption of solutions elaborated by European case law in particular with respect to the notion of defect and the demonstration of a causal nexus	–

Proposal for a Directive on adapting non-contractual civil liability rules on artificial intelligence (AILD)	September 2022	European Commission (COM 2022 496 final)	Horizontal approach to regulating civil liability for AI; emphasis on procedural rules on disclosure duties and presumptions about causation and fault; preserves the peculiarities of MS's fault-based rules	–
Approval Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence (AIA)	June 2024	European Parliament and the Council	Binding ex ante risk-based obligations; conformity assessments and certification requirements; impact analyses; post-market surveillance	–
Approval Directive (EU) 2024/2853 on liability rules for defective products and repealing Council Directive 85/374/EEC (PLDr)	October 2024	European Parliament and the Council	Strict liability of producers of products, including software; rules on access to evidence and presumptions of defectiveness and causal nexus	–
2025 Work Programme	February 2025	European Commission	Debate on Hereafteral of the AILD	

1.2.10. A Commentary

In critically examining "the great reversal," one observes that the EU's original blueprint—hard-law liability first, soft-law governance second—has been inverted. The 2017 Delvaux-Stehres resolution enshrined civil liability as the primary mechanism to internalize risk and secure compensation, with voluntary ethical instruments as the complement. All subsequent efforts at European level were consistent with this perspective.

The first comprehensive statement by the EU Commission, rendered in the form of a Communication on "Artificial Intelligence for Europe" (see §1.2.2), maintained the perspective of developing a human-centric regulatory framework based, primarily, on two pillars: a soft-law set of principles, to be elaborated by a group of experts, and implemented by companies on a voluntary basis (see §1.2.3), and a regulatory framework for civil liability, ideally based on two pillars, the revision of the PLD and the adoption of a set of dedicated norms for advanced technologies (see §1.2.4). The 2020 proposal for a regulation on civil liability and artificial intelligence advanced by the European Parliament (see §1.2.6) very well reflected the consensus reached by experts heard on the matter, including those appointed by the EU Commission to the NTF.

Only with the introduction of the draft proposal of the AIA (see §1.2.7) a radical reversal begun of the original balance between soft-law ex ante compliance principles, and hard-law ex post liability rules. The reversal witnessed an intermediate step with the proposal of two directives, namely the PLDr and AILD, respectively (see §1.2.8), whereby the latter radically departed from the advice rendered by all experts heard by the Commission and Parliament over the years (see §2.2).

The reversal was thence completed with the approval of the AIA and of the PLDr, and the consideration of hereafteral of the AILD (see §1.2.9). Indeed, under President von der Leyen's tenure binding ex ante rules have assumed primacy, and comprehensive liability harmonization has been deferred, risking fragmentation of tort law across Member States and shifting emphasis from post-harm redress to prior compliance. Whether such a regulatory shift goes to the benefit of the European industry, and its competitiveness on the one hand, and of European consumers on the other hand is to be proven.

Figure 1: Timeline

1.3. Three fundamental questions (and three policy reasons)

When discussing the need for regulation at European level, especially – yet not solely – in the field of advanced technologies, three policy arguments are typically formulated, that deserve closer scrutiny,

namely (i) the existence of a legal vacuum or absence of protection (§3.1; §3.2), (ii) the risk of legal fragmentation with different solutions being elaborated at MS level (§3.3), (iii) the need to devise a better, more efficient, regulatory solution (§3.4).

By addressing those claims, the correct perspective to technology regulation clearly emerges.

1.3.1. Legal gaps and the personality of the machine: a critical account

The typical and most frequently recalled argument, also in the theoretical and academic debate, to demand legal reform is the existence of a vacuum in the legal system[31]. In the domain of advanced technologies, and liability rules in particular, this argument was frequently formulated by philosophers and legal scholars alike, despite with different perspectives.

In some cases, the existence of a "responsibility gap" was intended as a way to stress that machines – robots or AI systems alike – either because of their autonomy, or ability to learn and, eventually, modify themselves and their functioning, ought to be treated as more than mere objects, possibly moral agents or subjects of the law, in some cases bearer of rights[32]. In such a perspective, the inadequacy of the current legal system, or its legal gap entailed the failure to recognise this different ontological condition of AIS, accounting for it, by attributing rights and obligations directly to them.

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[31] Commission, E. (2021). Commission Staff Working Document - Impact Assessment Accompanying the Proposal for a Regulation of the European Parliament and of the Council Laying down harmonised rules on AI. 6, where it is said that: "The current EU legal framework does not provide specific rules for AI, which leads to legal uncertainty, fragmentation, and gaps".

[32] See for instance Matthias, A. (2004). "The Responsibility Gap: Ascribing Responsibility for the Actions of Learning Automata." Ethics and Information Technology 6: 175–183.; Floridi, L. and J. W. Sanders (2004). "On the Morality of Artificial Agents." Minds and Machine 14: 349–379., claiming they may be deemed moral agents; Gunkel, D. J. (2020). "Mind the gap: responsible robotics and the problem of responsibility." Ethics and Information Technology 22(4): 307-320.; Santosuosso, A., C. Boscarato and F. Caroleo (2012). "Robot e Diritto: una Prima Ricognizione." La Nuova Giurisprudenza Commentata: 494. Gunkel, D. J. (2012). The Machine Question. Critical Perspectives on AI, Robots, and Ethics, The MIT Press. and Gunkel, D. J. (2018). Robot rights, mit Press. *passim*. In this latter book, Gunkel proposes a conceptual mapping of the main theoretical positions regarding whether and to what extent robots and, more broadly, artificial intelligence systems should be granted moral or legal rights. The model is structured as a two-dimensional matrix based on binary variables: the first (S1) concerns whether robots can have rights; the second (S2) addresses whether they should be granted rights. By crossing these two dimensions, Gunkel identifies four fundamental positions. The first, "Can and Should", includes those who believe that robots can fulfill the requirements of agency or personhood and should therefore be recognized as holders of rights (including authors like Mark Coeckelbergh). The second position, "Can but Should Not", concedes that robots might theoretically possess sufficient attributes to justify rights but argues that, for pragmatic, social, or philosophical reasons, it would be inappropriate to grant them. The third, "Cannot but Should," is more paradoxical: it denies that robots can genuinely hold rights, yet nonetheless advocates treating them as if they did, for symbolic, educational, or indirect protective purposes (as found in some relational approaches). Lastly, the fourth position, "Cannot and Should Not," rejects any attribution of agency or legal status to machines, reaffirming a strictly anthropocentric view that regards robots merely as tools (often inspired by a Kantian perspective). This taxonomy not only clarifies the variety of views on the moral status of machines but also helps elucidate the normative and institutional implications of each stance.

This perspective was, however, clearly dismissed by the policy debate at an early stage[33], and even the proposal, by the European Parliament, of attributing legal personality to machines[34]—under conditions to be specified—was not intended as a recognition of any legal vacuum based on ontological considerations. Instead, it was conceived as a possible solution to technical legal problems, in all respects comparable to the choice made with respect to corporations and other legal subjects[35]. So intended, the radical criticism such a proposal attracted[36], even by those that had originally formulated claims about the possible responsibility of autonomous machines[37], seemed misplaced–as if it entailed recognizing an ontological claim–, for that idea is to be intended as a purely functional, technical-legal expedient. Therefore, its desirability ought to be judged entirely on functional grounds[38], comparing alternative solutions of the kind discussed in this report.

At the same time, however, it is clear that existing and reasonable foreseeable technologies do not seem to require the attribution of legal personality for the purposes of tackling issues of civil liability, because alternative mechanisms[39] (see Chapter 2, 3 and 4) entirely relying on–possibly strict–liability rules, and insurance mechanisms, certainly appear to be preferable and more adequate a solution.

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33 Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission. 38.

34 European Parliament (2017). European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics. 2015/2103(INL), European Parliament. paragraph 59 where it is said that: "Calls on the Commission, when carrying out an impact assessment of its future legislative instrument, to explore, analyse and consider the implications of all possible legal solutions, such as: [...] (f) creating a specific legal status for robots in the long run, so that at least the most sophisticated autonomous robots could be established as having the status of electronic persons responsible for making good any damage they may cause, and possibly applying electronic personality to cases where robots make autonomous decisions or otherwise interact with third parties independently".

35 Indeed, the reasons for attributing legal personhood to corporations and other entities are always functional and typically refer to the need to (i) identify the entity, (ii) separate it formally from the persons that participate in its constitution and operation, (iii) separate its assets, (iv) provide for a different tax regime, and other similar considerations. For a detailed discussion on how this could be transposed to AIS, in a policy perspective please allow reference to Bertolini, A. (2024). Intelligenza Artificiale e responsabilità civile. Problema, sistema, funzioni. Bologna, Il Mulino. 130-136. In particular, on the asset-segregating function of legal personality, see also Wagner, G. (2019). "Robot, Inc.: Personhood for Autonomous Systems?" Fordham Law Review 88: 591-612. For further insight on the legal relationship simplification, refer to Bonadio, E. and L. McDonagh (2020). "Artificial intelligence as producer and consumer of copyright works: evaluating the consequences of algorithmic creativity." Intellectual Property Quarterly 2020(2): 112-137.; de Cock Buning, M. (2016). "Autonomous intelligent systems as creative agents under the EU framework for intellectual property." European Journal of Risk Regulation 7(2): 310-322.

36 Cfr. Artificial Intelligence and Robotics Experts (2017) "Open letter to the European Commission artificial intelligence and robotics." http://robotics-openletter.eu..

37 Floridi, L. and M. Taddeo (2018). "Romans would have denied robots legal personhood." Nature 557: 309. It is noteworthy the a.'s former opinion where machines' agency was strongly endorsed. For a more thorough examination of this issue, please refer to Floridi, L. and J. W. Sanders (2004). "On the Morality of Artificial Agents." Minds and Machine 14: 349–379.

38 In the same sense see Wagner, G. (2019). "Robot liability." Liability for artificial intelligence and the Internet of things: 53.

39 The attribution of legal personhood could, instead, be considered to attempt to address other concerns, in specific domains such as capital markets regulation and intellectual property, on this please allow reference to Bertolini, A. (2024). Intelligenza Artificiale e responsabilità civile. Problema, sistema, funzioni. Bologna, Il Mulino., 144-149. For an overview on capital markets issues please refer to Azzutti, A. (2022). "AI trading and the limits of EU law enforcement in deterring market manipulation." Computer Law & Security Review 45: 105690.,16 ff; Azzutti, A., W.-G. Ringe and H. S. Stiehl (2021). "Machine Learning, Market Manipulation, and Collusion on Capital Markets: Why the "Black Box" Matters." University of Pennsylvania Journal of International Law 43: 79-135.; On intellectual property rights, please see Smits, J. and T. Borghuis

1.3.1. Legal gaps and the absence of adequate protection: the need for clarification

Another way of intending the existence of legal gaps has to do with acknowledging the absence of dedicated legal rules, whereby not enough protection would be ensured to users and adopters of advanced technologies, in particular–yet not solely–consumers[40].

Such a claim is often used in the positive to argue in favour of the adoption of new, special–liability rules–as well as in the negative, arguing that all MS possess liability rules that apply to this domain, and therefore no need for regulatory intervention exists[41].

Both statements need to be clarified, for the correct perspective to emerge. On the one hand the absence of dedicated rules does not *per se* suffice in admitting lack of protection for users, adopters and consumers of technological products. Indeed, if the time-machine was invented overnight, and someone using it was injured the next day, the absence of dedicated legal norms for time travel would not impede a judge from applying existing norms–primarily general fault-based liability rules that exist in all MS[42]. Legal gaps are, in fact, typically filled through legal interpretation[43] and the operation of general clauses[44]–both in tort and contract law—ensure the much—needed flexibility and adaptability of the legal system.

On the other hand, the presence of general rules, and clauses that could provide a solution to a legal case that involves advanced technologies, both in the European or MS's legal system does not represent *per se* sufficient an argument to dismiss the need for a dedicated regulatory intervention. Indeed, general rules typically allow for greater flexibility in interpretation by courts, increasing both

(2022). Generative AI and intellectual property rights. Law and artificial intelligence: regulating AI and applying AI in legal practice, Springer: 323-344.; Barbalau, A., A. Cosma, R. T. Ionescu and M. Popescu (2020). "Black-box ripper: Copying black-box models using generative evolutionary algorithms." Advances in Neural Information Processing Systems 33: 20120-20129.; Fui-Hoon Nah, F., R. Zheng, J. Cai, K. Siau and L. Chen (2023). "Generative AI and ChatGPT: Applications, challenges, and AI-human collaboration." Journal of Information Technology Case and Application Research 25(3): 277-304.

40 See European Parliament (2020). Civil liability regime for artificial intelligence. European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL)). Brussels, European Parliament. paragraph 80, where it states: "the Commission should examine the existing legal framework and its application, including the consumer law acquis, product liability legislation, product safety legislation and market surveillance legislation, in order to identify legal gaps, as well as existing regulatory obligations; considers that this is necessary in order to ascertain whether it is able to respond to the new challenges posed by the emergence of artificial intelligence, robotics and related technologies and ensure a high level of consumer protection".

41 See fn. 2228.

42 European Group on Tort Law (2005). Principles of European Tort Law. Text and Commentary. Wien-New York, Springer. as well as Karner, E., B. A. Koch and M. A. Geistfeld (2020). Comparative Law Study on Civil Liability for Artificial Intelligence. Luxemburg, Publications Office of the European Union. where it is confirmed that: "In all EU Member States, general tort law provides for fault-based liability as a basic principle, and this applies also to damage caused by defective products outside of strict product liability regimes".

43 See Guastini, R. (2011). Interpretare e argomentare. Trattato di diritto civile e commerciale. A. Cicu and F. Messineo. Milano, Giuffrè. *passim*; MacCormick, N. (1994). Legal Reasoning and Legal Theory Oxford University Press. *passim*; Alexander, L. and E. Sherwin (2008). "Demystifying legal reasoning."1 ff.

44 See, for instance Wieacker, F. (1956). Zur rechtstheoretischen Präzisierung des § 242 BGB. *passim*, Brownsword, R., N. J. Hird and G. G. Howells (1999). Good Faith in Contract: Concept and Context, Ashgate. *passim*; Zimmermann, R. and S. Whittaker, Eds. (2000). Good faith in European contract law Cambridge, Cambridge University Press. *passim.*

potential *ex ante* uncertainty about how those very norms will be applied in a specific case, as well as discrepancies in outcomes, whereby similar cases are treated differently, especially within different MS.

Ex ante uncertainty, then, disincentives technological uptake, increasing legal risks for producers, developers and adopters of technologies, and subsequently leads to an increase in insurance costs, that most likely will reflect itself on the prices[45] for those very good and services.

Ex post discrepancies in outcomes, instead, lead to market fragmentation, that is most relevant if it occurs at MS level. Divergences in the application of European regulation are often observed at national level, in particular, when a subject matter is regulated through a directive[46].

Overall, dedicated norms are therefore preferable if they provide better incentives and optimize the pre-existing legal systems, simplifying the regulatory framework, diminishing administrative costs, reducing litigation, favouring internalization by those that generate risks and profit from them, eventually also allowing for a distribution of said costs among those that benefit from the technology (see §1.4).

Therefore, whether new and dedicated regulation is needed depends not so much on the existence of gaps and vacuums, nor it is excluded by the presence of norms that are applicable to the new context and emergent technologies. Instead, it depends entirely on considerations of risks of legal fragmentation (see §1.3.2) as well as an assessment of the–greater–efficiency of the proposed alternative (see §1.3.3).

1.3.2. Avoiding legal fragmentation

As per the risks of legal fragmentation, firstly, it is certain that if a subject matter is primarily regulated at MS's level, the risk of divergences in outcomes is greater. The difficulty in reaching a real approximation in European private law is well known and largely debated[47], and efforts to elaborate

[45] Price mechanisms allow to transfer costs from those that theoretically bear it, often *prima facie*, to those that purchase the service or product offered. How much of a given cost or tax is effectively transferred to the final user depends on considerations of elasticity of demand for that very good or service, see Delbono, F. and S. Zamagni (1999). Microeconomia, Il Mulino., 92-93.

[46] Considering the specific domain here analyzed a pertinent case in point is offered by the PLD, whereby its application in Germany –Magnus, U. (2016). Product Liability in Germany. European Product Liability. An Analysis of the State of the Art in the Era of New Technologies. P. Machnikowski. Cambridge, Intersentia: 237-274.—is very different from that in France— see Borghetti, J.-S. Ibid.Product Liability in France: 205-236.— as a mere example, see also Machnikowski, P. (2016). Conclusions. European Product Liability: An Analysis of the State of the Art in the Era of New Technologies (Principles of European Tort Law). P. Machnikowski. Cambridge, Intersentia: 669-705.

[47] Legrand, P. (1997). ""Against a European Civil Code" " Modern Law Review 60(1): 44-63.; Collins, H. (2008). The European civil code: the way forward, Cambridge University Press. *passim*; Schmid, D. (2012). "(Do) We Need a European Civil Code." Annual Survey of International & Comparative Law 18(1): 263. *passim*; Micklitz, H.-W. (2016). Failures or Ideological Preconceptions? Thoughts on Two Grand Projects: The European Constitution and the European Civil Code. The Many Constitutions of Europe, Routledge: 109-140.; Markesinis, B. S. (1997). "Why a code is not the best way to advance the cause of European legal unity." European Review of Private Law: 519-524.; Collins, H. (2013). "Why Europe Needs a Civil Code." Ibid.: 907-922.

general principles of European contract[48] and tort law[49] always remained of primary academic relevance, but with limited practical impact, to some extent also preventing the possibility to extend the influence of EU law, beyond its borders and in international transactions in particular[50].

As per tort law specifically, essential concepts such as fault[51], and causation[52] still present relevant differences in the way they are theoretically conceived by academics and subsequently applied by courts.

Secondly, as far as European law is considered, the use of directives as opposed to regulations certainly does not favour uniformity of outcomes across MS[53], and clear examples of that phenomenon are observed in those domains that are of clear and paramount relevance for the analysis here conducted, namely product liability (see §1.4).

Thirdly, and most specifically, MS have already demonstrated their intention to adopt legislation in the domain of technology regulation, that could lead to the creation of relevant path dependencies that, at a later stage, will be most complex if not impossible to overcome. Examples encompass the German

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48 For instance see Acquis and Group (2009). Contract II. General Provisions, Delivery of Goods, Package Travel and Payment Services. Munich, Sellier. European law publishers. *passim*; Lando, O., H. G. Beale and C. E. C. Law (2000). Principles of European Contract Law: Parts I and II, Springer Netherlands.. For an in-depth analysis of the different efforts to identify common principles for a unique European contract law see Bertolini, A. (2023). European Commercial Contract Law. Bruxelles, European Parliament - Committee on Legal Affairs: 1-103. *passim*.

49 Brüggemeier, G. (2011). Principles of European Tort Law (PETL) 2005. Modernising Civil Liability Law in Europe, China, Brazil and Russia: Texts and Commentaries. Cambridge, Cambridge University Press: 139-148.; Bussani, M. and M. Infantino (2014). Harmonization of Tort Law in Europe. Encyclopedia of Law and Economics. J. Backhaus. New York, Springer 1-16. and European Group on Tort Law (2005). Principles of European Tort Law. Text and Commentary. Wien-New York, Springer. 1-16.

50 Bertolini, A. (2023). European Commercial Contract Law. Bruxelles, European Parliament - Committee on Legal Affairs: 1-103.

51 Beatson, J. and D. Friedman, Eds. (1997). Good Faith and Fault in Contract Law. Oxford Oxford University Press. *passim*; Widmer, P. (2005). Unification of Tort Law: Fault. The Hague/London/New York, Kluwer Law International. *passim*.

52 Ben-Shahar, O. (2009). Causation and foreseeability. Tort Law and Economics. M. Faure. Cheltenham, UK - Northampton, MA, USA, Edward Elgar: 83-108. 83-108; Cvetkovia, M. (2020). "Causal uncertainty: alternative causation in tort law." Teme: 33, Bussani, M., A. J. Sebok, M. Infantino, M. Bussani, A. Sebok and M. Infantino (2022). Causation. Common Law and Civil Law Perspectives on Tort Law, Oxford University Press: 0. 15 ff.

53 This is confirmed by the European Commission (2021). Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain union legislative acts. COM/2021/206 final. Brussels, European Commission. 7, where it is said that: "The choice of a regulation as a legal instrument is justified by the need for a uniform application of the new rules, such as definition of AI [...]. The direct applicability of a Regulation, in accordance with Article 288 TFEU, will reduce legal fragmentation and facilitate the development of a single market for lawful, safe and trustworthy AI systems".

See also Weatherill, S. (2020). The Fundamental Question of Minimum or Maximum Harmonisation. The Internal Market 2.0. Garben S. and I. Govaere, Oxford Hart Publishing. 1-21 and Chiocchetti, P. (2023). "A Quantitative Analysis of Legal Integration and Differentiation in the European Union, 1958-2020." Journal of Common Market Studies: 1-23. This last quantitative study analysed legal integration and differentiation in the EU from 1958 to 2020: the results show that fragmentation is not only theoretical but empirically measurable in European legislation and case law. This highlights the EU's inability to achieve effective convergence in national regulatory structures, even after long efforts to harmonise.

law on automated driving[54], with a very specific and narrow focus, or broader normative texts, such as the Italian proposal for "*Disposizioni e deleghe al Governo in materia di intelligenza artificiale*"[55], currently under scrutiny[56].

While, occasionally, normative interventions at MS's level have shown natural convergences in the solutions reached[57], the risk that, in the absence of a dedicated European normative framework, specific solutions will be implemented at national level, with divergent approaches, is certainly high.

At the same time, liability rules impact product design and functioning as much as ex ante product safety norms, since they profoundly shape the incentives of the parties involved in the research and development process, as well as in the use and adoption of technological solutions[58]. Different liability rules emerging at national level could cause products developed and sold on the respective markets within the EU to be different, displaying different characteristics and capabilities. At the same time, an identical product sold in different MS could give rise to different "liability risks" for both the developers and the users, thence fragmenting the market. This is also largely detrimental for the European industry because a fragmented market increases costs and introduces barriers that limit scalability and growth that are essential to compete globally.

Clear, uniform norms, possibly allowing very narrow space for divergent legal interpretation are thence of the outmost strategic importance in the advanced technologies domain.

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54 Lately, Germany adopted the "*Gesetz zur Änderung des Straßenverkehrsgesetzes und des Pflichtversicherungsgesetzes – Gesetz zum autonomen Fahren*" (Law to Amend the Road Traffic Act and the Compulsory Insurance Act – Law on Autonomous Driving). This law was passed by the German *Bundestag* on 28 May 2021, entered into force in July 2021, and it amended the existing *Straßenverkehrsgesetz (StVG)* to introduce specific provisions on Level 4 automated driving systems (according to the SAE scale).

55 The bill containing provisions and delegations to the Government concerning artificial intelligence (A.C. 2316) was submitted to the Senate of the Republic on 20 May 2024, approved at first reading on 20 March 2025, and subsequently transmitted to the Chamber of Deputies, where it was referred to the joint Committees IX (Transport and Telecommunications) and X (Productive Activities). More specifically, the bill aimed at introducing a national legal framework establishing a system of governance principles and specific measures tailored to the Italian context, aimed at mitigating the risks and harnessing the opportunities associated with artificial intelligence.

56 Several European countries have adopted legislative proposals aimed at regulating specific aspects of AI. For instance, in September 2023 France has presented a "proposition de loi visant à encadrer l'intelligence artificielle par le droit d'auteur" (law proposal No. 1630/2023).

57 This is the case of drones, as clearly shown in Bertolini, A. (2018). Artificial Intelligence and civil law; liability rules for drones. Policy Department for Citizens' Rights and Constitutional Affairs. Brussel, European Parliament. and even more recently in Hartmann, J., A. Masutti, A. Bertolini, S. Truxal and B. I. Scott, Eds. (2024). Civil Regulation of Autonomous Unmanned Aircraft Systems in Europe. Cheltenham, Glos, UK - Northampton, Massachussets, USA, Edward Elgar. *passim*.

58 Please allow reference to Bertolini, A. and M. Riccaboni (2020). "Grounding the case for a European approach to the regulation of automated driving: the technology-selection effect of liability rules." European Journal of Law and Economics: 243-285.-285 and Evas, T. and A. Heflich (2021). Artificial intelligence in road transport – Cost of non-Europe report. Brussels, European Parliament.

1.3.3. The efficiency of the legal system

If we acknowledge that the mere absence of dedicated norms is not *per se* sufficient to argue the need of a normative intervention (see §2.3), the analysis needs then become functional, and possibly rooted —for the case here considered of civil liability rules—in considerations of efficiency[59].

Said otherwise, it is not true that any regulation is better than no regulation. Indeed, if the proposed norms do not clearly improve over the existing legal framework, their adoption should be discouraged. All legal systems, including the European one, have witnessed the adoption of bodies of norms that ultimately fell short of their original intentions, and that is a very relevant policy risk that needs to be radically avoided, as much as possible, in particular when it comes to innovation.

By way of example, we can take the case of the PLD. Although it is easy to understand the purpose of this text by reading the preamble, we could seriously doubt that it actually achieved a higher degree of approximation of laws between MS[60], given the obvious differences in its application (see Chapter 2). Even more so, we could doubt that it ensured a higher level of protection facilitating the recovery of damages for victims by adopting a strict liability rule[61]. In fact, not only is the liability rule not truly strict, but Member States continue to apply national rules that are stricter and easier to prove responsibility whenever possible (such is the case with Italy and art. 2050 of the Italian Civil Code, see §4.2).

In the case of the PLD, however, the limited efficiency of the European directive suggested the need for reform (see §§2.3 and 2.4), leading to the adoption of its revised version (PLDr), whose efficiency and capacity to meet both ends and expectations will have to be considered (see §2.5) and reassessed over time.

However, the necessary criticism to the PLD could not support a claim whereby its introduction in 1985 caused an increase in fragmentation between MS's legislation, or in uncertainty and *ex ante* foreseeability of outcomes. In fact, while one could argue that national implementations and judicial applications display a broad spectrum of alternative approaches, those differences are not today greater than those that could be observed in the absence of such a piece of legislation, when only MS's rules on contract and tort law applied. At the same time, even if claimants and courts often resort to other norms to obtain compensation, it may not be argued that the mere existence of the PLD diminishes legal certainty.

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59 The reference is to the concept of second-order efficiency, that is, efficiency understood not as an end in itself but as a measure of the suitability of the rule to achieve the intended result. For a more thorough examination of this issue, please refer to Mercuro, N. and S. G. Medema (2006). Economics and the Law. Princenton and Oxford, Princenton University Press., 48.

60 In this sense the recitals of the PLD: "Whereas approximation of the laws of the Member States concerning the liability of the producer for damage caused by the defectiveness of his products is necessary because the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property". On the point, see also §2.3.

61 Recitals of the PLD on the point: "Whereas liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production".

Put another way, one could argue that the framework emerging from the PLD is less than optimal and in need of improvement, but not that it is harmful and therefore altogether undesirable. A relevant consideration leading to this conclusion is that the legal regime resulting from the PLD represents, for all effects and matters, a special liability regime, parallel to and clearly distinct from the general (fault-based) liability regimes of the MS, with a clear scope of application - namely, damage caused by movable property sold on the market for profit.

In other cases, nonetheless, if the scope of application of a legal norm were uncertain or somewhat ambiguous, due to lack of clarity in definitions that determine the regulated matter, or if it overlapped with other pre-existing norms without clearly governing that potential conflict, it would most likely be altogether undesirable.

Finally, the risk of fragmentation is of paramount importance, especially when it comes to European legislation. This risk is twofold. On the one hand, the lack of normative intervention at European level certainly opens up a relevant risk of national initiatives taking place in the meantime, as already explained (see §3.3), leading to both normative and market fragmentation, which is particularly detrimental to emerging technologies and to European industrial competitiveness in this strategic field[62]. Such a consideration certainly impacts an efficiency analysis and leads to appreciating the so-called cost of non-Europe[63]. On the other hand, when adopting new liability rules, the possible interference with other liability rules - both European and national - should be clearly assessed, since if it could be argued that the proposed solution increases uncertainty and fragmentation, this would be sufficient to reconsider or reject it altogether. In the latter case, specific liability rules, well defined in their scope and not interfering with the general liability rules within the legal system of the MS, pose a much lower risk of increasing uncertainty and fragmentation.

1.4. What is the purpose of regulating civil liability for AI?

The obvious implication of the above analysis is that the rationale for regulating civil liability for damages arising from the use of AI and other advanced technologies is to optimize the existing legal framework.

It is not true that the existence of applicable norms, especially at MS level, suffices in excluding the need for regulation, especially because different approaches at national level could create path dependencies impossible to overcome at a later date, fragmenting the European market for AI-based products and services (see §3.3. and 3.4).

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62 Please allow reference to Bertolini, A. and E. Palmerini (2014). Regulating Robotics: a Challenge for Europe. Workshop on Upcoming Issues of EU Law. Policy Department C: Citizens' Rights and Constitutional Affairs. Bruxelles, European Parliament: 167-202. 167 ff.; Bertolini, A. (2020). Artificial Intelligence and Civil Liability. Bruxelles, European Parliament - Committee on Legal Affairs: 1-132. 11-14 ff.; Bertolini, A. and M. Riccaboni (2020). "Grounding the case for a European approach to the regulation of automated driving: the technology-selection effect of liability rules." European Journal of Law and Economics: 243-285.

63 See Evas, T. and A. Heflich (2021). Artificial intelligence in road transport – Cost of non-Europe report. Brussels, European Parliament. 1 ff.

At the same time, however, not any regulation is better than no regulation. Fragmentation and divergent outcomes at MS level are also the consequence of rules with a very broad and under-defined scope of application, highly dependent on MS's legal systems—for instance needing to enact a complex and articulated directive—, and which to some extent interfere with general concepts deeply rooted in each MS's legal tradition, and that have already proven to be hard to harmonize. Paramount examples in such a perspective, in the field of tort law, are the concepts of causation and fault, with respect to which the most sophisticated comparative law efforts carried out over the years have not yet successfully achieved the degree of uniformity that would allow to define a true European private law system. Well-defined, special liability rules certainly represent a preferable solution.

If fragmentation and ex ante uncertainty represent the negatives any European regulatory effort should avoid, several relevant positive criteria may be identified that ought to orient a legislative intervention.

While it is disputable that liability rules ensure a clear, measurable and relevant deterrence effect[64] (see §2.3), it is certain that they are essential to ensure victim compensation. Well-conceived liability rules should prioritize this profile, pursuing a solution that improves the position of the victim seeking to recover the damages suffered.

This objective has further implications. A clear liability rule that minimizes uncertainty, ensuring compensation, substantially diminishes and potentially eliminates litigation and other administrative costs. This proves beneficial in a multi-fold perspective. First, it increases users' confidence leading to early adoption of the technology, and the subsequent growth of the industry that develops said products and services[65]. Second, it simplifies the calculation and insurability of the liability risks for those that are called in to compensate, favouring the very internalization of such costs[66]. Third, it transforms *ex post* uncertainty into an *ex ante* calculable expenditure, that may then be factored into the cost-function of the firm offering that very product or service[67], and subsequently transferred—

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64 The so-called deterrence effect is the possibility for a liability rule to induce the agent to adopt a desired standard of conduct beforehand, in order to avoid being later held liable as a consequence of their misconduct, for a brief explanation see Posner, R. A. (2007). Economic Analysis of Law, Wolters Kluwer Law & Business. and Polinsky, M. A. and S. Shavell (2007). Handbook of Law and Economics, North-Holland..

65 Same opinion is expressed by European Commission (2018). 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. Artificial Intelligence for Europe. COM(2018) 237 final. Brussels, European Commission. p. 16; European Commission (2018). Commission Staff Working Document. Liability for emerging digital technologies. Accompanying the document 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 Artificial intelligence for Europe. SWD(2018) 137 final. Brussels, European Commission. p. 2; European Commission (2020). Report from the Commission to the European Parliament, the Council and the European economic and social Committee on the safety and liability implications or Artificial Intelligence, the internet of Things and robotics, COM/2020/64 final, European Commission. p.13; European Law Institute (2022). Response of the European Law Institute. European Commission's Public Consultation on Civil Liability Adapting Liability Rules to the Digital Age and Artificial Intelligence., ELI.9.

66 Cfr. European Commission (2020). Report from the Commission to the European Parliament, the Council and the European economic and social Committee on the safety and liability implications or Artificial Intelligence, the internet of Things and robotics, COM/2020/64 final, European Commission.13.

67 Cfr. Ibid. p. 13; European Commission (2021). Inception Impact Assessment. Adapting liability rules to the digital age and circular economy. Ref. Ares(2021)4266516. Brussel, European Commission.3.

through price mechanisms—to those that use and benefit from it. All these aspects will be specifically analysed and tackled, starting with the opinions rendered by experts on the matter (see §2.2.2), as well as through a law and economic analysis of the existing regulatory framework (see §2.3), and will guide the assessment of the AILD proposal (see Chapter 3). This will then guide the formulation of a proposal on an ideal liability framework (see Chapter 4) and the consideration of all policy options available (see Chapter 5).

1.5. The risk of overregulation and the cost of non-Europe

The considerations above, however, already allow to correctly frame the issue of overregulation as a potential concern for technological development, and the proliferation of a European industry in this strategic domain.

Indeed, regulation may hamper innovation, in particular when it creates uncertainty and fragmentation across MS. Since liability rules directly impact how technologies are designed, what characteristics they possess and what services may be offered through them, uniformity across European MS is of paramount importance. This entails both the existence of uniform rules, avoiding national initiatives that create path dependencies in the absence of a European intervention, but also conceiving rules whose application is clear, simple and as likely as possible to lead to comparable—if not identical—outcomes across MS.

Both the absence of European regulation—the so-called cost on non-Europe—and the adoption of a non-desirable regulatory framework pose, thence, a threat of overregulation, deterring innovation. Indeed, many national regulatory frameworks and divergency in application represent a form of over-regulation, leading to the creation of a complex and multifaceted series of legal solutions that will be later harder, if not impossible, to harmonize. Similarly, inadequate liability rules will represent a form of over-regulation, even if adopted at European level.

Finally, if we looked at the great reversal in the European regulatory approach in the field of AI, which begun in 2021 (see §1.2), it is highly disputable that the introduction of dedicated liability rules ought to be pointed at as a source of relevant concern for corporations, both comparatively and overall.

More specifically, the original approach focused on the elaboration of dedicated liability rules, and the adoption of a set of broad-soft law non-mandatory principles, elaborated by the HLEG, maintained by the European Commission (see §§1.2.2, 1.2.3, 1.2.4, 1.2.5) until the presentation of the AIA certainly represented a more minimalist option[68]. The ALTAI principles, that were never systematically applied beyond an initial exploratory phase, were replaced by a stringent and binding regulation—the AI Act—

[68] See Draghi, M. (2024). The future of European competitiviness. 30 where he criticizes the excessive amount of regulations in EU as an obstacle for SMEs: "The net effect of this burden of regulation is that only larger companies—which are often non-EU based—have the financial capacity and incentive to bear the costs of complying. Young innovative tech companies may choose not to operate in the EU at all".

compliance with which is calculated to cost companies an average initial cost of 400.000 euros, and between 20.000 and 100.000 euros in yearly fees[69].

In particular, compliance with liability rules cannot, by definition, increase costs. Indeed, one party may only respond for the damages it causes, and those depend on the safety and adequacy of the products sold, and of services rendered. An ideal liability rule is that which ensures internalization of damages caused, and, to the contrary, minimization of the subsequent administrative costs (including that of litigation). The only way a set of liability rules—or the absence thereof—may reduce costs for corporations is if they were so inefficient as to prevent damages internalization, discouraging access to justice and litigation by the victims.

Instead, an adequate regulatory framework, reflecting the characteristics described, preventing fragmentation between MS, would minimize administrative costs, favour their management through insurance mechanisms, and favour technological uptake by users (see Chapter 4).

The commendable concern for over-regulation and over-deterrence is therefore much more dependent on the specific characteristics of the regulatory framework conceived, which is what ought to be discussed in the following chapters.

[69] The implementation of this regulation poses a significant challenge for businesses, which are now required to comply with a stringent regulatory framework that governs the entire lifecycle of AI systems—from design to market placement and usage. At the European level, Intellera Consulting (2022). The AI Act: help or hindrance for SMEs? An analysis of the cost of compliance with the AI Act for SMEs: 1-36., estimates that compliance with the AIA will cost approximately €300,000, equivalent to 1.3% of the turnover of a small or SME. Similarly, the Center for Data Innovation (2021). How Much Will the Artificial Intelligence Act Cost Europe?: 1-16., estimates that the total cost for European businesses will exceed €10 billion by 2025—amounting to around €31 billion over the next five years—with SMEs facing a minimum cost of €400,000.

2. IS THE CURRENT REGULATORY FRAMEWORK SUFFICIENT?

KEY FINDINGS

1. Broad Consensus on the Inadequacy of the original PLD.

Both expert opinions and EU institutional reports converge in judging the 1985 Product Liability Directive (PLD) as inadequate for addressing risks associated with advanced technologies like AI systems. Central concerns include the limitations of the development risk defense, the narrow notion of "defect," and the difficulty in proving a causal nexus between defect and damage.

2. Need for dedicated rules beyond the PLD.

Experts and EU policy documents support the creation of a separate liability framework specifically tailored to advanced technologies. There is shared recognition that the original PLD was not designed to address evolving challenges like opacity, autonomy, and complexity in AI systems.

3. Divergence in Institutional follow-up.

Despite consensus among experts and initial Commission positions in favor of dual reforms (PLD and AI-specific legislation), only the PLD was eventually revised. This contradicts earlier policy trajectories and overlooks persisting gaps identified across multiple reports.

4. Original PLD offered inconsistent rationales.

The 1985 PLD attempted to balance ex ante deterrence (via design incentives) and ex post victim compensation through a semi-objective liability rule. However, it ultimately failed on both fronts: it reintroduced fault via the development risk defense and left victims inadequately protected due to evidentiary burdens and restricted damage recovery.

5. Product liability rules lack deterrent effect.

Empirical studies show no clear link between product liability rules and increased safety investments. Reputational harm, not liability, proved more effective in prompting manufacturers to invest in safety, together with *ex ante* product safety legislation.

6. PLD failed to ensure victim compensation.

Few legal cases were brought under the PLD framework, and even fewer were resolved using it. Courts and victims preferred general tort law or contractual remedies. Barriers include high litigation costs, evidentiary difficulties, and limited recoverable damages—especially in relation to complex, high-value technologies.

7. Advanced technologies exacerbate PLD failures.

AI's opacity and complexity aggravate the PLD's shortcomings. Establishing causation or identifying a defect becomes even more difficult when decisions result from human-machine collaboration. Furthermore, the PLD's exclusion of compensation for damage to the defective product itself (e.g., an autonomous car) significantly discourages litigation.

7. The Revised PLD (PLDr) Maintains Critical Weaknesses

While the PLDr expands the notion of "product" to include software and AI, and introduces evidentiary presumptions, it retains the core conceptual structure—including the "lack of safety" standard as a defining criterion for defectiveness, and the risk defense. Consequently, foundational issues remain unresolved.

9. New Procedural Rules Increase Legal Complexity.

The reformed PLD includes disclosure requirements and presumptions to ease the plaintiff's burden of proof. However, vague language (e.g., "excessive difficulty," "technical complexity") and the wide discretion granted to judges in the assessment risk inconsistent application, potentially turning product liability into de facto absolute liability without clear legislative intent.

10. Risk of market fragmentation remains high.

The PLDr fails to deliver the unified legal certainty it aims for. Without a dedicated AI-specific liability regime, courts in different Member States may interpret and apply PLDr provisions divergently, leading to regulatory fragmentation, undermining legal harmonization, and weakening consumer protection across the EU.

2.1. Introduction

Having established the reasons that originally led European institutions to consider regulating advanced technologies beginning with civil liability rules, as well as the theoretical concerns that a normative intervention in this domain ought to consider (Chapter 1), it is necessary to analyze the insights and assessments rendered over the years by numerous experts and consultants, upon request of the very same institutions (see §2.2.2). The issues those opinions, reports, and studies cover are diverse, but may be summarized into two main topics: (i) the adequacy of the current legal framework in accommodating advanced technologies, with a specific focus on the original formulation of the PLD, and (ii) the need for dedicated rules, and, eventually, the characteristics said rules ought to abide by.

The following paragraph will thence consider all the relevant studies, reports, expert opinions, rendered upon request of the European Parliament and Commission, respectively—some of which were briefly recalled in the first chapter for the purpose of highlighting the main policy steps that paced the debate—, and compare them one to the other, also through a table, intended to serve as a visual summary. The main purpose of this analysis is to highlight some clear convergences—namely an overall inadequacy of the PLD as originally formulated—and the need for a dedicated liability regime, grounded on strict liability rules. This outcome is coherently reflected in the policy debates and initiatives maintained by European institutions, up until the formulation of the AILD proposal, that already represents a clear departure from those considerations and conclusions.

The analysis will then proceed to consider the regulatory failures of the original formulation of the PLD, primarily in light of functional—law and economics based—considerations, addressing both deterrence—and therefore the ability of the PLD to encourage the production of safe products—and compensation—intended as the ability to ensure that victims obtain restoration for the damages they suffer—(see §2.3.4). Such failures, as well as the concerns specific to advanced technologies (also discussed under §1.3.5), represent the criteria that ought to have guided the reform of the overall European regulatory framework for civil liability and AI. Originally, this was intended to comprise two distinct acts, namely the reform of the PLD and another legislative text, specific to AI. The latter was first represented by the RLAI (see Chapter 1, lett.f above), then superseded by the AILD, now likely to be withdrawn.

However, the original plan of two normative interventions was dismissed, and only the PLD was reformed. Therefore, before moving on to consider the merits and limitations of the AILD (see Chapter 3), it is necessary to determine whether the reform of the PLD is sufficient in tackling all identified problems (see §§2.3 and 2.4), or whether some concerns appear not to be addressed or fully solved by the reformed directive (see §2.4.3).

The analysis will allow us to conclude that relevant aspects that deserve attention and possibly regulation are clearly left untouched by the PLDr (see §5), rejecting the often convergent findings of experts whose opinions have been gathered over the years (see §2.3). This, in turn, will also - but not exclusively - open up the possibility of regulatory fragmentation and divergent outcomes at Member

State level, which is one of the outcomes that the overall European regulatory effort in this area was designed to avoid from the outset[70].

2.2. A step back: what concerns ought a dedicated civil liability framework tackle?

In this section we will compare the expert opinions rendered over the years, in the form of official reports and studies adopted at the request of European institutions. This part of the analysis will not, instead, account for the numerous relevant contributions to the debate, presented in the form of scientific publications, primarily books, and journal articles. Indeed, while the latter do play an essential role in shaping the theoretical debate, and are, for this very reason, widely cited across the entire document, the purpose of this section is to highlight convergences and divergences in the analysis of those very experts EU institutions identified and appointed.

Such conclusions will then also be contrasted with the official statements adopted by European institutions in the form of reports, staff working documents and communications, in light of, or even independently from, the opinion of the experts they appointed.

The purpose is twofold. On the one hand, it will allow us to determine if a consensus was reached by experts as well as with EU institutions about the essential aspects of the analysis, better discussed below. On the other hand, it will allow us to determine whether the regulatory framework that emerged until today, at the end of this very complex and rich policy debate, primarily represented by the reform of the Product Liability Directive (PLDr) (see §1.2.8) is coherent with those findings, and sufficient to tackle the concerns identified in the already existing and applicable rules (see Chapter 2).

Considering the relevant amount of material, to keep the analysis sufficiently concise, two identical tables are presented, one specifically focusing on the expert opinions rendered (Table 2), and one on the policy statements (Table 3).

[70] On the point, see European Commission (2018). 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. Artificial Intelligence for Europe. COM(2018) 237 final. Brussels, European Commission., 17, where it is stated that: "[…] Sharing best practices, identifying synergies and aligning action where relevant will maximise the impact of investments in AI and help the EU as a whole to compete globally. Cooperating on interoperability and data sets and working together on legal solutions will prevent a fragmentation of the single market and therefore fuel the emergence of AI startups. […] The Commission will facilitate this dialogue and aim to agree a coordinated plan on AI with Member States by the end of the year" as well as the AIA which at recital 3 affirms that: "Certain Member States have already explored the adoption of national rules to ensure that AI is trustworthy and safe and is developed and used in accordance with fundamental rights obligations. Diverging national rules may lead to the fragmentation of the internal market and may decrease legal certainty for operators that develop, import or use AI systems. A consistent and high level of protection throughout the Union should therefore be ensured in order to achieve trustworthy AI, while divergences hampering the free circulation, innovation, deployment and the uptake of AI systems and related products and services within the internal market should be prevented by laying down uniform obligations for operators and guaranteeing the uniform protection of overriding reasons of public interest and of rights of persons throughout the internal market on the basis of Article 114 of the Treaty on the Functioning of the European Union (TFEU)".

Overall, the analysis will focus on two lines of inquiry, namely (i) whether the European regulatory framework applicable to AI is fit for purpose, and (ii) whether there is a need for reform and how said reform should be conceived, abiding which principles and displaying what characteristics.

To investigate the first line of inquiry, reference is made to the original version of the PLD that represented, until now, the main body of EU law addressing civil liability, theoretically applicable to AI[71] and other advanced technologies. Indeed, the issue was raised by the European Commission itself, ultimately commissioning three reports (Columns 1, 2 and 3 in Table 2 below). In such a perspective, the first line in the tables (Line A) summarizes an overall judgment rendered on the adequacy of the original formulation of the PLD as a tool to govern technological innovation and damages arising from its use, while the second line (Line B) attempts to isolate the primary reasons for concern, on the grounds of a more technical analysis. Those include the so-called development risk defence (art. 7, let. (e) PLD)[72], the notion of defect (art. 6 PLD)[73], and the issue with demonstrating the existence of a causal nexus between the defect and the damage (art. 4 PLD)[74].

In order to explore the second line of inquiry, a number of general aspects are highlighted in the opinions submitted, namely the need for reform at the European level itself (line C) and a focus on the essential purposes and rationales it should pursue (line D). The latter include the purpose of avoiding fragmentation due to alternative regulatory approaches and solutions developed at MS level, the need to ensure compensation for victims and to facilitate their position in such a perspective, as well as the need to promote innovation.

More specific ideas on the design of this alternative civil liability framework are set out in the following lines, including the need for a separate liability regime, distinct from the PLD (line E), the discussion of whether it should be a single regime, common to all AIS (line F), or instead a distinction based on risk levels (line G) - similar to the AI Act - and whether it should be strict - not fault-based - liability (line H). Finally, procedural aspects are considered (Line I) about the need to ensure access to evidence—through disclosure obligations (see §2.4.2)—and presumptions—specifically about elements such as fault (defect in the PLD) or the causal nexus.

2.2.1. Is the European regulatory framework—rooted in the PLD—fit for purpose?

The evidence presented in Table 2 underscores the depth and consistency of expert critique regarding the original Product Liability Directive's capacity to address advanced technologies. Five of the six reports surveyed—the Expert Group on Product Liability Formation (2019), the Expert Group on New

[71] Despite the uncertainty, now addressed with the PLDr, of whether software was to be included within the notion of product, put forth by art. 2 PLD, on this matter see §§2.3.2 and 2.3.3 below.

[72] That excludes the liability of the manufacturer, despite the product being defective and having caused harm, if the claim may be supported that no technical and scientific knowledge available allowed to identify the defect at the moment were the product was distributed onto the market, see §2.3.1 below.

[73] Intended as the lack of safety one is entitled to expect, see §2.3.3 below.

[74] Indeed, pursuant to art. 4PLD, the claimant needs to demonstrate the defect, the damage and the causal nexus between them, not the fault of the manufacturer, to obtain compensation, see §2.3.4 below.

Technologies Formation (2019), EPRS (2020), Bertolini (2020), and Hacker (2024)—categorically reject the PLD's adequacy, with only the 2018 Ernst & Young evaluation dissenting from this consensus.

Experts identify three interlocking structural defects that render the Directive ineffectual when applied to AI and similar systems. First, the development-risk defence under art. 7(e) PLD, which excuses manufacturers whenever a defect could not have been detected "given the state of scientific and technical knowledge," which provides a relevant limitation to the liability, and almost transforms its supposedly strict nature (see §§2.3.1 and 2.4.1).

Second, the Directive's narrow conceptualisation of "defect" as merely a "lack of safety" fails to capture performance deficits characteristic of AI systems—such as misdiagnoses by medical software—that may not be framed as safety hazards (see §2.3.2).

Third, the burden-of-proof regime in art. 4, requiring claimants to trace harm through opaque decision-trees, is practically untenable in "black-box" environments and when collaboration between humans and machines increases in the completion of a task (see §2.3.1). Experts thus converge on the view that mere procedural adjustments cannot rectify deficiencies that lie at the doctrinal heart of the PLD's liability regime.

By contrast, Table 3 reveals a markedly more restrained institutional posture. While the 2017 European Parliament Resolution on Civil Law Rules on Robotics and the 2020 Report on Safety and Liability Implications for AI, IoT, and Robotics acknowledge certain limitations of the PLD, notably its development-risk defence and defect definition, two of the six policy statements—the 2018 Staff Working Document on Liability for Emerging Digital Technologies and the 2018 EC Evaluation of the PLD—assert that the Directive remains broadly adequate.

Furthermore, whereas experts insisted unambiguously that the Directive's foundational liabilities needed substantive overhaul, institutions couch their critiques in terms of "further study," "guidance," or "targeted procedural remedies," reflecting a preference for preserving the harmonising architecture that the PLD has historically provided.

This divergence seemed more apparent than real, especially considering the proposals advanced first by the European Parliament (RLAI) and then by the Commission, the latter of which with the joint proposal of the PLDr and AILD, clearly demonstrating the intention to pursue a more comprehensive reform and devise a European-led framework.

2.2.2. Is there a need for reform and how should it be conceived?

The second line of inquiry elicits broad agreement on the need for change as well as on the essential elements of that change. Table 2 demonstrates that five of the six expert reports expressly call for a Europe-wide, stand-alone liability regime for advanced technologies, grounded in strict (no-fault) liability, with measures to ease claimants' evidentiary burdens (e.g., mandatory disclosure and rebuttable presumptions). Experts emphasise three reform objectives: preventing Member State divergence, ensuring effective victim compensation, and sustaining innovation through predictable risk-pricing.

On the design front, most experts favour either a strict-liability rule mirroring at least a risk-tiered approach akin to the AI Act's classification mechanism, so that liability exposure corresponds to technological criticality. Procedural aspects, despite considered, do not represent the focus of the solutions proposed, since emphasis is primarily placed on conceiving a strict liability rule, accompanied by provisions of joint and several liability, to minimize the risk for the victim not to achieve compensation.

European institutions, while endorsing the principle of reform in four out of six statements, advance a more cautious vision. Table 3 records that although four policy documents acknowledge the necessity of new, AI-specific liability rules, only three endorse risk-based differentiation over a single standard, and just half explicitly support strict liability.

Moreover, while institutions agree on procedural enhancements—disclosure obligations and limited presumptions—these are positioned as incremental judicial tools ("guidance for national courts," "targeted evidentiary rules") rather than as foundational pillars of a new regime.

In sum, experts press for a transformative liability regime whereas European institutions favour calibrated, procedural reforms embedded within the existing harmonisation framework.

The resulting policy dynamic suggests that while the call for reform is now undisputed, the pace and depth of change will hinge on reconciling experts' demand for clarity and victims' protection with institutions' imperative to preserve legal certainty and promote innovation. Even the latter, however, is best served through clear liability rules that minimize the need for litigation.

Table 2: Experts' opinions and reports

			1	2	3	4	5	6
			Ernst&Young Evaluation, 2018[75]	Expert Group Product Liability Formation 2019[76]	Expert Group New Technologies Formation, 2019[77]	EPRS, 2020[78]	Bertolini, 2020[79]	Hacker, 2024[80]
A	Ineffectiveness of PLD[81] in addressing advanced technologies		No	Yes	Yes	Yes	Yes	Yes
B	Main reasons for	Development Risk Defence	Yes	Yes	Yes	Yes	Yes	Yes
		Notion of Defect	Yes	Yes	Yes	Yes	Yes	Yes

[75] Ernst&Young, Technopolis and VVA (2018). Evaluation of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products. Brussels, European Commission.

[76] Expert Group on Liability and New Technologies – Product Liability Formation (2019). Minutes. Meeting of the Expert Group on "Liability and New Technologies – Product Liability Formation". Brussels, European Commission.

[77] Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission.

[78] Evas, T. (2020). Civil Liability Regime for Artificial Intelligence. Brussel, European Union.

[79] Bertolini, A. (2020). Artificial Intelligence and Civil Liability. Bruxelles, European Parliament - Committee on Legal Affairs: 1-132..

[80] Hacker, P. (2024). Proposal for a directive on adapting non-contractual civil liability rules to artificial intelligence: Complementary impact assessment, European Parliament.

[81] As it is clear from the acronym used, reference is made to the original formulation of the PLD from 1985, not its recent revision.

	concern in the PLD	Causal nexus	Yes	Yes	Yes	Yes	Yes	Yes
C	Need for Reform		No	Yes	Yes	Yes	Yes	Yes
D	Objectives of reform	Avoid Fragmentation at MS level	Not covered	Not covered	Yes	Yes	Yes	Yes
		Ensure victim compensation	Not covered	Not covered	Yes	Yes	Yes	Yes
		Favour innovation	Not covered	Not covered	Yes	Yes	Yes	Yes
E	Need for a dedicated liability rule for advanced technologies, different from the PLD		Not covered	Not covered	Yes	Yes	Yes	Yes
F	Need for a single rule of responsibility (for all technologies and/or risk levels)[82]		Not covered	Not covered	No	No	No	No
G	If not, should rules be differentiated pursuant to risk levels[83]		Not covered	Not covered	Yes	Yes	Yes, not only based on risk	Yes

[82] This line aims at pointing out whether the expert(s) believe(s) that a horizontal approach to regulating civil liability for damages arising from the use of advanced technologies is desirable, therefore adopting a one-solution-fits-all approach.

[83] This line aims at specifying the rationale for distinguishing between different.

H	Need for a strict liability rule, distinct from the PLD		Not covered	Not covered	Yes	Yes	Yes	Yes
I	Need for procedural rules	Rules on disclosure/disclosure obligations	Not covered	Yes	Not covered	Yes	Not covered	Yes
		Presumptions (e.g.: fault/defectiveness/causal nexus)	Not covered	Yes	Yes	Yes	Not covered	Yes

Table 3: Statements by EU Institutions

		1	2	3	4	5	6
		EP, Resolution on Civil Law Rules on Robotics[84]	EC, Staff Working Document. Liability for emerging digital technologies[85]	EC, SWD Evaluation of Council Directive 85/374/EEC[86]	EC, Report on the safety and liability implications for Artificial Intelligence[87]	EP, Resolution on a Civil Liability Regime for Artificial Intelligence[88]	EC, Inception Impact Assessment[89]
A	Ineffectiveness of PLD[90] in addressing advanced technologies	Yes	No	No	Yes	Yes	Yes

84 European Parliament (2017). European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics. 2015/2103(INL), European Parliament.

85 European Commission (2018). Commission Staff Working Document. Liability for emerging digital technologies. Accompanying the document 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 Artificial intelligence for Europe. SWD(2018) 137 final. Brussels, European Commission.

86 European Commission (2018). Commission Staff Working Document. Evaluation of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. SWD(2018) 157 final. Brussels, European Commission.

87 European Commission (2020). Report from the Commission to the European Parliament, the Council and the European economic and social Committee on the safety and liability implications or Artificial Intelligence, the internet of Things and robotics, COM/2020/64 final, European Commission.

88 European Parliament (2020). Civil liability regime for artificial intelligence. European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL)). Brussels, European Parliament.

89 European Commission (2021). Inception Impact Assessment. Adapting liability rules to the digital age and circular economy. Ref. Ares(2021)4266516. Brussel, European Commission.

90 As it is clear from the acronym used, reference is made to the original formulation of the PLD from 1985, not its recent revision.

B	Main reasons for concern in the PLD	Development Risk Defence	Yes	Yes	Yes	Yes	Not covered	Not covered
		Notion of Defect	Yes	Yes	Yes	Yes	Yes	Yes
		Causal nexus	Yes	Yes	Yes	Yes	Yes	Yes
C	Need for Reform		Yes	Not covered	No	Yes	Yes	Yes
D	Objectives of reform	Avoid Fragmentation at MS level	Yes	Not covered	Not covered	Yes	Yes	Yes
		Ensure victim compensation	Yes	Not covered	Not covered	Yes	Yes	Yes
		Favour innovation	Yes	Not covered	Not covered	Yes	Yes	Yes
E	Need for a dedicated liability rule for advanced technologies, different from the PLD		Yes	Not covered	Not covered	Yes	Yes	Yes
F	Need for a single rule of responsibility (for all technologies and/or risk levels)		Not covered	Not covered	Not covered	No	No	No

G	If not, should rules be differentiated pursuant to risk levels		Not covered	Not covered	Not covered	Yes, risk-based	Yes, risk-based	Yes, risk-based
H	Need for a strict liability rule, distinct from the PLD		Not covered	Not covered	Not covered	Yes	Yes	Yes
I	Need for procedural rules	Rules on disclosure/disclosure obligations	Not covered	Not covered	Not covered	Not covered	Not covered	Yes
		Presumptions (e.g.: fault/defectiveness/ causal nexus)	Not covered	Not covered	Not covered	Yes	Yes	Yes

2.3. An assessment of the Product Liability Directive, and its failure(s)

Considering how the PLD represented, until its recent reform (PLDr), the main body of European regulation theoretically applicable to advanced technological products[91]—despite no case having been so far litigated in this domain[92]—it is important to conduct a synthetic, yet more in depth analysis of that piece of legislation, to point out its theoretical and practical limitations, considering it overall and, specifically, in relation to the peculiarities displayed by AIS.

The purposes of the PLD—as clearly stated also in the directive itself—were threefold: (i) remedy the profound fragmentation of the solutions adopted in this domain by individual MS[93]; (ii) induce manufacturers to invest in safe products' design[94]; (iii) ease victims in obtaining compensation. As per the latter the directive clearly states that:

> "[…] liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production"[95]

The purpose of the legislator was, therefore, that of conceiving a uniform liability rule, applicable across all MS, holding manufacturers' liable, irrespective of their fault, for all damages arising from the use of

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91 Despite the uncertainty about the possibility to include software in the definition of product laid down by art. 2 PLD, on which see Machnikowski, P. (2016). European product liability: an analysis of the state of the art in the era of new technologies, Intersentia. 205-236; Alheit, K. (2001). "The applicability of the EU Product Liability Directive to software." Comparative and International Law Journal of Southern Africa XXXIV: 188-209. ff.; Allee, J. S., T. V. H. Mayer and R. W. Patryk (2017). Product Liability. New York, Law Journal Press. 284, all AIS may be deemed things, artifacts and products of human intellect, please allow reference to Bertolini, A. (2013). "Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules." Law Innovation and Technology 5(2): 214–247. ff.

92 This clearly emerges also from the assessment conducted by Ernst&Young, Technopolis and VVA (2018). Evaluation of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products. Brussels, European Commission., 21-23.

93 The PLD states "Whereas approximation of the laws of the Member States concerning the liability of the producer for damage caused by the defectiveness of his products is necessary because the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property", Council, E. (1985). Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, in O.J.L. 210, 7.8.1985: 29–33.

This aspect is of lesser importance with respect to the subject matter of this study and, therefore, we limit ourselves here to a few preliminary considerations. Instead, reference is made to the more relevant literature for more in-depth analysis. It only seems appropriate to point out that the practical application of the PLD has clearly demonstrated that it has not achieved the expected results. On the one hand, in fact, by virtue of art. 13 PLD according to which «The liability of the producer arising from this Directive may not, in relation to the injured person, be limited or excluded by a provision limiting his liability or exempting him from liability» very different national legislations have survived; on the other hand, the national courts have adopted different solutions contributing to create an uncertain framework regarding the application of the discipline. On this point, see Borghetti, J.-S. (2016). Product Liability in France. European Product Liability. An Analysis of the State of the Art in the Era of New Technologies. P. Machnikowski. Cambridge, Intersentia: 205-236.; Koziol, H., M. D. Green, M. Lunney, K. Oliphant and Y. Lixin, Eds. (2017). Product Liability. Fundamental Questions in a Comparative Perspective. Berlin, De Gruyter.

94 This may be derived from the very definition of defect, pursuant to art. 6 PLD, see §2.3.2 below, as well as the recital whereby «[…] to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect […]», Council, E. (1985). Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, in O.J.L. 210, 7.8.1985: 29–33.

95 Ibid., 29.

their products, so long as the latter could be deemed defective. Indeed, that is the rule that appeared to emerge from the joint reading of articles 1 and 4 PLD[96].

2.3.1. A brief theoretical introduction: the standard of liability

A closer reading however challenges that conclusion, since the so-called development risk defence (art. 7, let. (e) PLD)[97] allows the manufacturer to escape liability despite the product being defective and despite there being a causal nexus between the defect and the damage, so long as it may be argued that with existing technological and scientific knowledge it was impossible to identify the defect at the moment the product was distributed onto the market.

The rationale of the provision is clearly that of balancing the interest of the manufacturer and that of the victim, limiting the liability of the former in all those cases where nothing could be done to prevent harm. However, this rationale contrasts with the idea that the liability of manufacturers should not depend on their fault. Indeed, the producer cannot be blamed for failing to achieve a better and safer design, but a strict liability rule is designed precisely to overcome the need to prove that a better behaviour or standard could have been maintained.

So conceived, the defence reintroduces an element of fault into the liability equation designed by the PLD, despite a reversed burden of proof. Indeed, the claimant needs not demonstrate the defendant's fault—like, instead, it is the case in all torts of negligence—in order to obtain compensation; yet the latter may escape liability by proving that nothing more of what he did could have been demanded at the time when he acted, selling the product on the market. For this very reason the liability rule defined by the PLD was deemed semi-objective and based on a rebuttable presumption of the manufacturer's fault[98].

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[96] Thus art. 1 PLD for which «The producer shall be liable for damage caused by a defect in his product» and art. 4 PLD "The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage".

[97] Whereby "the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered".

[98] This is still regarded as objective by Ponzanelli, G. (1989). "Art. 1 Responsabilità del produttore." Le nuove leggi civili commentate: 508., il quale, tuttavia, più recentemente lo ha qualificato come fattispecie di responsabilità presunta Ponzanelli, G. (1994). "Dal biscotto alla «mountain bike»: la responsabilità da prodotto difettoso in Italia." Foro Italiano(I): 252.; Castronovo, C. (2006). La nuova responsabilità civile. Milano, Giuffrè.; Franzoni, M. (2010). L'illecito. Trattato della responsabilità civile. M. Franzoni. Milano, Giuffrè. I., 651-652.

It is deemed as semi-objective Bigliazzi Geri, L., U. Breccia, F. D. Busnelli and U. Natoli (2001). Diritto civile 3 Obbligazioni e contratti. Torino, Utet., 870-871; Cabella-Pisu, L. (2008). "Ombre e luci nella responsabilità del produttore." Contratto e impresa., 631-632; Stella, G. (2017). "Causa ignota del danno derivante dall'uso del prodotto e responsabilità del produttore per prodotto difettoso." Responsabilità civile e previdenza 5: 1444.ff.

In the same perspective Cass., sentenza n. 13458 del 2013, in «Il Foro italiano», I, 2013, c. 2118; compliant Cass., sentenza n. 12665 del 2013; Cass., sentenza n. 13225 del 2015; Cass., sentenza n. 15851 del 2015; Cass., sentenza n. 22887 del 2015; Cass., sentenza n. 3258 del 2016; Cass., sentenza n. 11317 del 2022, in Danno e Responsabilità, 2023, pp. 363 ff; The study of economic analysis of law corroborates this perspective. For an overview see Schäfer, H.-B. and F. Müller-Langer (2009). Strict liability versus negligence. Tort Law and Economics. M. Faure. Cheltenham, UK - Northampton, MA, USA, Edward Elgar: 109-133.

The rationale is clear. The European legislator wanted to strike a balance between the position of the two parties and felt that holding the producers liable beyond the limits posed by scientific and technological knowledge to be unjust. However, if the manufacturer may not be blamed, much less so the victim who suffered harm as a result of the defective product. Moreover, the latter did not benefit from the development and distribution of the product, unlike the former, which may have anticipated the need to compensate for damages by insuring itself and passing on the cost of insurance to buyers through price mechanisms. In other words, leaving the victims to bear the costs is not a politically desirable outcome either, and manufacturers are in the best position to manage the costs of liability anyway - even if they could not be blamed due to the inherent limitations of the technical and scientific knowledge available at the time.

In fact, this is the aspect in which a clash of the essential rationales of the Directive can be observed. Economic theory demonstrates that the best rule to ensure *ex ante* deterrence—or compliance with a desired standard or conduct—is a fault-based one[99]; when *ex post* compensation of the victim is the primary objective, instead, a truly strict liability rule is certainly preferable. Considering that the PLD pursues both ends—inducing the production of safe products and ensuring victim compensation—it is impossible to choose a liability rule that is truly satisfactory for both, at the same time.

In such a perspective, it is particularly worthwhile deepening the understanding of the concept of defect on theoretical grounds (see §2.4.1), before moving on to consider the effectiveness and efficiency of product liability rules in general in ensuring high standards of safe design (see §2.5).

2.3.2. Continued: The notion of defect

Art. 6 PLD defines defect as the lack of safety that can be legitimately expected of a product, taking into account the (i) presentation of the product; (ii) the use that can reasonably be expected of goods of the same kind; (iii) the time at which the product was put into circulation.

Thus, a product is not defective in the sense of the PLD because it does not meet a certain standard, but only because it lacks safety. A computer that does not turn on and function will be deemed defective for the purposes of the consumer sales' directive[100], and may trigger a contractual warranty, forcing the reseller to repair or replace the item, or reimburse the consumer (art. 13 SGD). However, if it does not turn on at all and function it may not materially cause harm[101], and thence, it may not be defective for the purposes of the PLD.

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[99] See, for instance, Posner, R. (2007). Economic analysis of law. New York, Aspen. 787; Schäfer, H.-B. and F. Müller-Langer (2009). Strict liability versus negligence. Tort Law and Economics. M. Faure. Cheltenham, UK - Northampton, MA, USA, Edward Elgar: 109-133. If there is no direct correlation between the effor made to avoid damage and the duty to compensate, incentives to be prudent or invest in safety are weaker. This is the reason why fault-based rules are better to achieve *ex ante* deterrence, compared to strict liability ones, see also § 2.3.3.

[100] European Parliament and Council (2019). 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, OJ L 136, 22/05/2019. 28-50 (so called SGD).

[101] Here we are assuming that nothing happens to the defective product, which cannot function as a computer normally would. Of course, if it also caught fire and thence caused an accident, it could be deemed defective for the purposes of

Moreover, the more complex the product, and the more distinct and broader the uses it may be put at, the harder it is to determine *ex ante* what a "reasonable standard of safety" ought to be[102]. This is particularly relevant a problem for AIS.

2.3.3. Pursuing ex ante deterrence: the importance of reputation (not liability rules)

Considering the rationale of the PLD of ensuring *ex ante* adequate investments in safety, and how that may lead to choosing a non-strict standard of liability (see §4.3.3), it is useful to consider the overall effectiveness and efficiency of such kind of rules in ensuring safe products.

To do so, we may resort to both theoretical and empirical research in the field of law and economics that clearly pointed out how product liability rules do not produce any measurable and observable impact in terms of *ex ante* safety investments, especially when compared to reputational mechanisms, which instead prove to be both effective and efficient[103].

Indeed, while the effect of liability rules depends on slow and costly judicial procedures—namely, litigation—with uncertain—and often unforeseeable—outcomes, the impact of a negative event—displaying the defectiveness of a product—is immediate, measurable, and often serious, only requiring relevant information to become public. Suffice it to mention, as an example, the case of the American Boeing 737 MAX, involved in two fatal accidents very close in time one to the other, that were traced back to a design defect in the flight control system[104] . Once the news spread, the market reaction was immediate, producing a 10% loss in value of Boeing's stock price[105], as well as further negative financial consequences that lasted for some time[106]. The need to correct the error prompted immediate action on the part of the manufacturer, and the mere spread of the news produced a much more relevant blow. From an ex ante perspective, this certainly induces a rational actor - such as a corporation - to adhere to the highest available safety standards, regardless of any fear of subsequent liability-based litigation.

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the PLD, as well, yet on entirely different grounds and not due to the mere circumstance it did not turn on and function as a computer normally would.

[102] Debates periodically occur about what ought to be deemed a normal and foreseeable use. At times the line is blurred with so-called foreseeable misuses. Such would most likely be the case of a chair, whose primary use is that of sitting onto it, yet it is commonly used also for standing onto it to reach for high objects and plains. The option to expressly include foreseeable misuses in the definition of the standard of safety one is entitled to expect was considered and then dismissed in the final formulation of the PLDr.

[103] See Polinsky, M. A. and S. Shavell (2009-2010). "The uneasy case for product liability." Harvard Law Review 123: 1437-1492.

[104] Please refer to https://www.faa.gov/newsroom/updates-boeing-737-9-max-aircraft. See also Cavaliere, A. (2004). "Product Liability in the European Union: Compensation and Deterrence Issues." European Journal of Law and Economics 18(3): 299-318.

[105] Cfr. Boeing stock is tanking because its new 737 plane suffered another deadly crash, available at https://www.barrons.com/articles/boeing-stock-ethiopian-airlines-crash-737-max-8-51552310854.

[106] It could be objected that this mechanism depends on the dissemination and availability of information to the public, unlike the legal standard, which, on the other hand, can operate independently of such considerations. For a detailed discussion, please allow reference to Bertolini, A. (2024). Intelligenza Artificiale e responsabilità civile. Problema, sistema, funzioni. Bologna, Il Mulino., 180-190.

This intuition is then clearly confirmed by the findings of an empirical study conducted in the field of the American civil aviation. Indeed, before 1992 the number of product liability cases litigated in that domain was so relevant as to challenge the very survival of the corresponding American industry, manufacturing non-commercial planes. As a result of lobbying, an exemption from the application of all product liability rules was introduced, shielding manufacturers from legal claims[107]. However, 20 years after the introduction of such an exemption, the number of accidents involving civil aviation planes was unaltered[108]. Afterall, the exemption did not induce manufacturers to lower their productions standards, certainly due to the need to preserve the high quality of their products, as well as their safety, and ultimately their reputation and market value. At the same time, strict up-front product safety regulations ensured that all aircraft produced met high standards of safety and reliability[109].

This empirical analysis then confirms the idea that strict liability does not produce any evident deterrence effect, in the form of a measurable reduction in the risk of damage[110], let alone that there is actually any correlation between the level of litigation and product safety (see also §2.3). The opposite is also true, in as much as to date there is not a single case where it may be demonstrated a positive correlation between strict liability rules and the reduction in the number of accidents.

To clarify the lack of correlation between ex ante safety investments and product liability rules, we may also consider Europe, in a comparative perspective with the United States. Indeed, the legal framework in place is largely comparable[111], yet litigation levels are extremely different, by entire orders of magnitude. In the US more than tens of thousands of cases per year[112] are litigated, while in Europe, considering 25 MS, between 2000 and 2016 only 798 cases were altogether brought before a judge[113].

Since claiming that European products are radically safer—by entire orders of magnitude—than American ones—in a globalized economy—seems quite implausible, those differences need to be justified otherwise, most likely through considerations of the incentives provided by the overall legal

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[107] This is the *General Aviation Revitalisation Act (GARA*) available at the following link: https://www.congress.gov/bill/103rd-congress/senate-bill/1458.

[108] See Helland, E. A. and A. Tabarrok (2012). "Product Liability and Moral Hazard: Evidence from General Aviation." The Journal of Law and Economics 55(3): 593-630.

[109] For a more detailed discussion, allow reference to Bertolini, A. (2024). Intelligenza Artificiale e responsabilità civile. Problema, sistema, funzioni. Bologna, Il Mulino., 180 ff.

[110] See also Priest, G. L. (1988). Products Liability Law and the Accident Rate. Liability: Perspectives and Policy. R. E. Litan and C. Winston. Washington, D.C., Brookings Institution. 184: 187-194.1; and Polinsky, M. A. and S. Shavell (2009-2010). "The uneasy case for product liability." Harvard Law Review 123: 1437-1492., *passim.*

[111] Product Liability in the US is regulated at State level, however, the Restatements provide a good synthesis of the standing point of case law and its doctrinal interpretation, and the *Restatement (Second) of Torts, Product Liability* § 402° (1965), Section 402A is very much the provision that inspired the PLD. On the influence of the American model on the European model see Owen, D. G. (2008). Products Liability Law. St. Paul (MN), Thompson West. 52 ff.

[112] Please refer to the data cited by Polinsky, M. A. and S. Shavell (2009-2010). "The uneasy case for product liability." Harvard Law Review 123: 1437-1492.

[113] Cf. Ernst&Young, Technopolis and VVA (2018). Evaluation of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products. Brussels, European Commission., 20.

system, in particular in terms of level of damages awarded, and procedural rules, including the propensity to resort to *quota litis agreement* and *class actions*[114]. Indeed, product liability litigation is complex and expensive (see §2.3) requiring to demonstrate defectiveness and a causal nexus between that and the damage suffered, often requiring expert opinions and articulate evaluations. This is best balanced out when ultra-compensatory damages are awarded[115], and when class actions—bringing together multiple injured parties, and thence sharing on litigation costs—are commonplace.

One could object that the desirable litigation levels are not the American ones, and since those create undesirable imbalances in market mechanisms. While that could also be true, the purpose of the analysis here conducted is to show that there is no correlation between product safety on the one hand, and litigation—thence product liability rules—on the other hand, because other factors play more relevant a role. Litigation is primarily dependent on other elements that provide incentives to sue or not to sue, such as the economic relevance of the interest at stake, especially compared to the chances of success and cost of trial (see also §2.3.6).

However, considering the lack of a clear deterrence effect of product liability rules, as well as the possibility to tackle such a concern much more effectively through product safety legislation[116], it seems preferable to give primacy to the rationale of ensuring victim compensation, focusing on the ex post efficiency of those very rules.

2.3.4. Ensuring victim compensation: the failure of the PLD

In order to judge the effectiveness of the 1985 PLD in achieving its intended outcome of ensuring victims' compensation (see §2.3.4)—beyond the criticism brought to the formulation of a liability rule that is not truly "without fault", in contrast to the intention declared by the European legislator—attention may be drawn to the findings of a study, requested by the Commission in 2018[117].

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[114] In the US, class actions are primarily regulated by Rule 23 of the Federal Rule of Civil Procedure available at the following link: https://www.uscourts.gov/forms-rules/current-rules-practice-procedure/federal-rules-civil-procedure. On this point, see also Cotterrell, R. (2001). "Is there a logic of Legal Transplants?" Adapting legal cultures 71: 82. ff.

[115] For an overview of "excessive" damages and, in particular, punitive damages in Italy see Ponzanelli, G. (2024). Danni punitivi. Enciclopedia del diritto, I Tematici. Milano, Giuffrè. VII Responsabilità civile.; De Menech, C. (2019). Le prestazioni pecuniarie sanzionatorie: studio per una teoria dei "danni punitivi". Padova, CEDAM.; Cicero, C. (2018). Danni punitivi. Digesto delle discipline privatistiche: 100 ss.; Gallo, P. (1996). Pene private e responsabilità civile. Milano, Giuffrè.. For pivotal steps of jurisdictional evolution please refer to Cass. Civ., 19 January 2007, n. 1183 in *Resp. civ. e prev*., 2008, 1, 188 ff commented by G. Miotto, *La funzione del risarcimento dei danni non patrimoniali nel sistema della responsabilità civile*; Cass. Civ., 8 February 2012, n. 1781 in *Danno resp*., 2012, 609 ff commented by G. Ponzanelli, *La Cassazione bloccata dalla paura di un risarcimento non riparatorio*; Cass., sez. un.,15 July 2017, n. 16601 in *Banca borsa*, 2017, 46 ff commented by F. Benatti, *Benvenuti danni punitivi ...o forse no*!.

For comparative profiles refer to Benatti, F. (2024). Danni punitivi (profili di diritto comparato). Enciclopedia del diritto, I Tematici. Milano, Giuffrè. VII Responsabilità civile..

[116] This body of legislation is based on the so-called *New Approach* as set out in (1985). Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards OJ C 136, 4.6.1985. C. o. Europe: p. 1–9., under which European directives and regulations lay down essential safety requirements that must be met in order to distribute a product on the single market.

[117] Ernst&Young, Technopolis and VVA (2018). Evaluation of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products. Brussels, European Commission.

The latter shows, on the one hand, a very low total number of cases brought to court, in 25 MS, over a period spanning from 2001 to 2016[118]. On the other hand, it underlines the limited practical application of the PLD in solving such cases. Indeed, in 20% of judgments on accidents involving a defective product[119], the solution was reached by resorting to either general disciplines such as contract or tort law, or special liability rules[120], thence preventing that harmonization the PLD was pursuing (see §2.5). More importantly, that data demonstrates that the original intention of increasing users' protection by devising a dedicated liability rule—"[…] without fault [because it] is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production[…]"– was not achieved, since more general principles and norms are often preferred by courts and claimants seeking the compensation for their losses. Indeed, this is due on the one hand to the victim's low probability of success—not exceeding 60% of total cases[121] when the 1985 PLD is applied— mainly because of the difficulty in demonstrating the defect and the causal link and, on the other hand, to the limits to compensable damages put forth by artt. 8, 9 and 16 PLD.

While art. 9 sets a 500-euro threshold, excluding the possibility of claiming damages for a lower amount, art. 8 prevents compensation of damages suffered to the defective product itself. Such a limitation is rooted in the distinction between the PLD—compensating damages due to products that lack the safety one is entitled to expect—and the consumer sales directive—compensating damages for a product that lacks conformity, intended as the ability to function as it should, delivering its utility and performance –. Most certainly it reduces the incentive to sue[122], and creates specific problems for advanced technologies (see §3.5), in particular if product liability is intended to become the main body of regulation addressing damages arising from the use of AIS (see §4 and 5)

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118 Ibid., 19-20, table 4. According to the latter only 798 cases were brought to the courts. The consistency of the number can be more appreciated in a comparative fashion. It is noteworthy that the Italian Court of Cassation, serving as the court of last resort, issues approximately 30,000 judgments on an annual basis. This suggests that the number of cases involving defective products is minimal, particularly when the three levels of judgment are taken into account.

119 Ibid., 21.

120 A case in point is represented by the German law on medicines, Gesetz über den Verkehr mit Arzneimitteln (Arzneimittelgesetz – AMG). Indeed, the PLD saved such norms, expressly stating "Whereas under the legal systems of the Member States an injured party may have a claim for damages based on grounds of contractual liability or on grounds of non-contractual liability other than that provided for in this Directive ; in so far as these provisions also serve to attain the objective of effective protection of consumers, they should remain unaffected by this Directive ; whereas, in so far as effective protection of consumers in the sector of pharmaceutical products is already also attained in a Member State under a special liability system, claims based on this system should similarly remain possible", Council, E. (1985). Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, in O.J.L. 210, 7.8.1985: 29–33.

121 Ernst&Young, Technopolis and VVA (2018). Evaluation of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products. Brussels, European Commission., 23.

122 According to Cass. civ., 11 October 2016, no. 20370 the destruction of a camper van set on fire would not be considered compensable if the defective item was the vehicle itself, as only the destruction of the goods contained therein (certainly of lesser value) could be compensated. Indeed, the judge refused to award compensation for the damages suffered to the caravan itself, since that was the defective good that caught fire, and only considered the possibility to award damages for the lost items contained within it. It is however clear that the claimant was interested in recovering damages for the lost vehicle (costing over 70.000 euros) and not for the burned clothes stored inside of it.

2.3.5. The peculiarities of advanced technologies, and their interference with the PLD

In this perspective, it is then important to emphasize some aspects and characteristic peculiar to advanced technologies, which risk exacerbating the failures already identified.

A common element to all AIS is the intrinsic complexity that often leads to the opacity[123] of the system, whereby it is not always possible to determine all the intermediate steps that led a given AI system to formulate a conclusion or generate an output from a given input or information provided to it. That is, the operation of the system is almost never transparent.

Complexity and opacity make it even more difficult and costly for the plaintiff to demonstrate the defect as well as the existence of a precise causal nexus between the defect and damage[124]. This

[123] Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission., 32-33 recognised

"Digitalisation brings fundamental changes to our environments, some of which have an impact on liability law. This affects, in particular, the (a) complexity, (b) opacity [...]" "(a) Complexity: Modern-day hardware can be a composite of multiple parts whose interaction requires a high degree of technical sophistication. Combining it with an increasing percentage of digital components, including AI, makes such technology even more complex and shifts it far away from the archetypes of potentially harmful sources on which the existing rules of liability are based. Where, for example, an AV interacts with other AVs, a connected road infrastructure and various cloud services, it may be increasingly difficult to find out where a problem has its source and what ultimately caused an accident. The plurality of actors in digital ecosystems makes it increasingly difficult to find out who might be liable for the damage caused. Another dimension of this complexity is the internal complexity of the algorithms involved. (b) Opacity: The more complex emerging digital technologies become, the less those taking advantage of their functions or being exposed to them can comprehend the processes that may have caused harm to themselves or to others. Algorithms often no longer come as more or less easily readable code, but as a black-box that has evolved through self-learning and which we may be able to test as to its effects, but not so much to understand. It is therefore becoming increasingly difficult for victims to identify such technologies as even a possible source of harm, let alone why they have caused it. Once a victim has successfully claimed damages from a tortfeasor, the tortfeasor may face similar difficulties at the redress level".

[124] In a strict liability system, the injured party is not required to prove fault or negligence on the part of the producer. Instead, they must demonstrate that the product was defective, that damage occurred, and that there is a causal link between the two. This framework is intended to reduce the burden on the claimant by shifting the focus away from the producer's conduct. However, in the context of complex AI systems, establishing the existence of a defect and the causal relationship to the damage can become particularly difficult. When the system behaves opaquely—without transparent reasoning or traceable decision paths—it may be nearly impossible for a claimant to demonstrate where the system deviated from expected behavior. This issue is exacerbated in scenarios involving shared human-machine interaction, such as semi-autonomous driving, where the line between user error and machine malfunction is blurred. Even if strict liability does not require a showing of fault, proving that a specific defect in the AI caused the harm may demand access to system logs, algorithmic structures, or training data that the claimant typically cannot obtain. By contrast, fault-based liability systems, such as general tort law regimes, require the injured party to establish that the defendant breached a duty of care—effectively, that they were at fault—and that this fault caused the damage. In the case of emerging technologies, particularly AI and robotic systems, the opacity of the system's functioning and the layered responsibility between developers, operators, and users make it significantly harder to identify and prove such fault. For instance, in a partially automated vehicle scenario, the plaintiff would need to demonstrate not just that harm occurred but that the producer or user failed to take reasonable care in the design, use, or supervision of the autonomous function. This might involve extensive technical evidence, including expert testimony, to reconstruct how and why the AI acted in a certain way and whether a different outcome was reasonably foreseeable and preventable. An illustrative example is offered by Koopman, P. and M. Wagner (2017). "Autonomous Vehicle Safety: An Interdisciplinary Challenge." IEEE Intelligence Transportation Systems Magazine 9(1): 90-96. who examined the safety implications of autonomous vehicles. Their research highlighted that investigations involving AI systems typically require ten to fifteen times more data and effort than traditional accident investigations. They emphasized that access to this data is often controlled by the manufacturer or service provider,

becomes ever more complex and relevant if we consider the progressive overlapping of product liability with other sources of liability. This, in fact, is the consequence of the increasing collaboration between humans and machines in completing tasks that previously were entirely led by humans.

Driving represents a perfect case in point. Traditional vehicles are entirely controlled by a human task and liability rules traditionally point at the driver himself, and/or at the owner, to ensure the compensation of the victim. With increasing—yet not full—automation, the driving task is shared by the human and the machine, whose autonomous driving function may or may not be activated. As a result, an accident could be due to (i) a human error—when in control of the driving function, or when failing to supervise the system and intervene[125], or when erroneously deciding to turn on or off the autonomous function, given the current conditions of weather and traffic—, (ii) a failure of the system—when the autonomous function is activated—, (iii) a failure in the connection of the vehicle to other vehicles and/or the infrastructure. Such a complex human-machine collaboration causes the overlap of distinct liability rules, pointing at towards the (a) driver, (b) owner, (c) producer, (d) connection and infrastructure provider. Disentangling such a complex liability scenario requires potentially very costly litigation and may lead to a situation of profound causal uncertainty[126].

Moreover, in the case of AIS the defective product itself would most frequently represent the highest value at stake. Indeed, in the autonomous vehicle example, the car would be the defective product and most likely the most relevant asset damaged by the accident. Yet the PLD does not allow the recovery of such damages. If a car crashed against a guard rail as a consequence of the malfunctioning of its autonomous driving function, the owner would not be allowed to claim damages to the vehicle and, therefore, would not sue the manufacturer, despite its clear responsibility.

2.3.6. The change in role of the PLD due to increasing automation in AIS, and the need for reform

In such cases, product liability, originally conceived as a residual type of liability[127] with rare and well-defined cases of application (the occasional defect in a mass-produced good), is called upon to play a

leading to an evidentiary asymmetry that poses serious obstacles to plaintiffs in fault-based liability cases. While this asymmetry also exists under strict liability, the burden is somewhat reduced by the absence of the need to prove negligence or misconduct.

125 *Straßenverkehrsgesetz*, The Law of June 11, 2017 (Federal Law Gazette. I pg. 1607 BGBl. I pg. 160), amending The Road Traffic Act, as announced on 5 March 2003 (Federal Law Gazette. 1 pg. 310, 919) https://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl216s1306.pdf#__bgbl__%2F%2F*%5B%40att_r_id%3D%27bgbl216s1306.pdf%27%5D__1516706616435, last accessed June 2025. German law on autonomous driving requires the human driver to supervise the system to be ready to intervene and resume control if needed. This is extremely complex a task for the human user, since humans tend to distract themselves even when driving, and much more so if they have relinquished control to the vehicle itself, for a more detailed discussion please allow reference to Bertolini, A. and M. Riccaboni (2020). "Grounding the case for a European approach to the regulation of automated driving: the technology-selection effect of liability rules." European Journal of Law and Economics: 243-285., 31.

126 For a detailed discussion, please allow reference to ibid., 30.

127 European Commission (2022). Commission Staff Working Document Impact Assessment Report Accompanying the document Proposal for a Directive of the European Parliament and of the Council on liability for defective products,

much more relevant and frequent role, precisely because of the increase in automation and human-machine collaboration.

The associated litigation costs, which have already led to the fact that the PLD is rarely applied by the courts, would in most cases be unjustified on a day-to-day basis, and the difficulty of proving the defect and the causal link would probably be disproportionate to the economic interests at stake (e.g. the amount of damages to be awarded in a normal car accident). As a result, litigation would likely be directed towards the weaker defendant in a lawsuit, rather than the one who is responsible and/or best positioned to internalize and successfully manage the costs.

Unless a specific strict liability regime is designed to deal with cases of damage arising from the use of AIS (see §4.3), if the PLD were the only piece of European legislation in place to provide redress for damage arising from increasing automation, some of its most important limitations would have to be overcome. These include the problems and costs of proving the defect and the existence of a causal link; the need to overcome the overlap of different liability regimes—as described above—in order to avoid problems of causal uncertainty; the need to ensure the possibility of recovering damages suffered by the defective product itself. Many of these concerns have not been effectively addressed by the recently adopted reform, as will be shown and discussed in the following section (see §2.4.3).

2.4. Is the reform of the PLD sufficient to govern AIS?

The recent approval of the reformed PLD[128] marks a significant change in the European regulatory framework for advanced technologies, even more so after the possible withdrawal of the proposal for an AILD. Indeed, that represented a radical departure from the perspective maintained by the European Commission since 2018 (see §1.2), whereby the liability framework was conceived as based on two pillars, the revision of the PLD and a dedicated set of liability rules for advanced technologies.

The change has very relevant implications for EU law, as well as for its role compared to that of MS's legal systems, allowing for greater uncertainty and likely market fragmentation (see Chapter 5).

At the same time, it has a direct impact on the assessment of the PLDr itself and its overall adequacy. In fact, while the prospects for certain solutions that maintained the original structure of the Directive unchanged (see §4.1) could be positive overall, as long as their role remained identical and mainly residual, the same is no longer true when these norms have to play a central role in ensuring redress for users of increasingly autonomous devices, such as AIS.

An overview of the reformed directive needs therefore to consider the specific solutions enacted in both perspectives, as a mere adaptation of the pre-existing legal framework, and as the guiding European framework in the field of AI. A brief account of the main points of reform needs to take place

SWD(2022) 316 final. Brusseles., 9, stated "the PLD, which is the EU's harmonised no-fault liability regime, exists in parallel to Member States' fault based liability regimes"

[128] Union, E. P. a. t. C. o. t. E. (2024). Directive (EU) 2024/2853 of European Parliament and the Council of the European Union of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC. Brussel.

(see §§4.1 and 4.2) before broader—both technical (see §4.2) and policy-related (see Chapter 5)—considerations may be drawn.

2.4.1. The notion of product, defect, and the—unaltered—liability rule

A pivotal component of the reform pertains to the expansion of the concept of "product" as delineated in art. 4(1) of the PLDr. This concept now encompasses «all movables, even if integrated into, or interconnected with, another movable or immovable; it includes electricity, digital manufacturing files, raw materials and software»[129]. The explicit reference to software undoubtedly encompasses artificial intelligence and numerous other applications, including, most likely, blockchain. This wording is inspired by a technologically neutral approach[130], aimed at ensuring the text is future proof, therefore ready to accommodate possible emerging technologies.

The notion of "defect", defined as «the lack of safety that can reasonably be expected» (art. 7 PLDr)[131], is left substantially unaltered in its importance as a condition to obtain compensation (see §§2.3.2 and 2.3.3). However, the terms relevant for its assessment were changed to include, next to the foreseeable use (art. 7(2) let (b) PLDr), both the effect on the product of any ability to continue to learn or acquire new features after it is placed on the market or put into service (let (c)), and its ability to interact with and be influenced by other systems, including connected systems, to be used together with the product, including by means of inter-connection (let (d)). Furthermore, any recall of the product by

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[129] Ibid.

[130] For technologically neutral approach is intended the will to uniformly apply the law across various technologies, preventing favoritism or discrimination. However, technology neutrality is a complex and often vague concept that has been used differently across diverse contexts. The concept of neutrality has been subject to markedly divergent interpretations. For instance, Maxwell, W. J. and M. Bourreau (2015). "Technology neutrality in Internet, telecoms and data protection regulation." Computer and Telecommunications Law Review(1).identify three distinct conceptions of neutrality: as a mechanism to structure markets, as a constraint to mitigate harmful externalities, and as a criterion to delineate the scope of regulation. In contrast, Hildebrandt, M. and L. Tielemans (2013). "Data Protection by Design and Technology Neutral Law." Computer Law & Security Review 29.contend that technologically specific legislation may effectively employ neutrality instruments to advance its core objective—the safeguarding of fundamental legal principles.

Anyway, relating to PLD, European Union stated on its neutral approach several times. See European Commission (2018). Commission Staff Working Document. Evaluation of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. SWD(2018) 157 final. Brussels, European Commission., p. 67; European Commission (2018). Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Application of the Council Directive on the approximation of the laws, regulations, and administrative provisions of the Member States concerning liability for defective products (85/374/EEC). Brussels, European Commission., 7 and 10.

For a more detailed discussion of technology neutrality and its implications in a regulatory perspective, please allow reference to Bertolini, A., F. Fedorczyk, M. M. Mollicone and G. Migliora (forthcoming, 2025). "The Brussels Sphinx's Riddle. What is a high-risk AI System?" Working Paper., 10 ff.

[131] The provision in question explicitly refers to the complex body of product safety regulations, which establish the characteristics that any product must meet in order to be certified and marketed. In conjunction with art. 10(2) let(b) of the PLD, which establishes the burden of proof, it can be concluded that noncompliance with the established requirements results in the product being classified as defective. However, in the event that noncompliance with safety regulations results in an intrinsic defect in the product, the aforementioned statement becomes null and void. For further elucidation on this matter, refer to the scholarly article by Wagner, G. (2024). "Next Generation EU Product Liability–For Digital and Other Products." Journal of European Tort Law 15(2): 172-224.

competent authorities (such as notified bodies tasked with certifying products in a RAPID procedure)[132] must be considered. Overall, the enriched list of elements considered in order to assess the existence of a defect appears to be coherent with emerging technologies and the characteristics they display. The policy debate had for a moment considered the opportunity of extending relevance beyond the foreseeable use to the foreseeable misuse, yet that option was ultimately dismissed. However, the idea that defect is dependent on a lack of safety and not of performance is of paramount importance, and could represent a very relevant constraint, preventing the application of the PLDr to many incidents caused by increasingly autonomous AIS (see §2.3.5).

The extant defenses for manufacturers have also been corroborated, incorporating development risk (art. 11 let (e) PLDr) and compliance with legal requirements (let (d)). Of particular interest is the introduction of a defence for suppliers who have followed the main manufacturer's design (let (f)) and for those who have modified the product, provided they can demonstrate that the defect does not depend on the altered part (let (g)). It is important to note that the presence of the defect does not need to be verified at the time the product is placed on the market. Rather, it should be verified at a subsequent stage, when the manufacturer no longer exercises sufficient control over the product and has suspended its updates[133].

Regarding potentially liable parties, the directive significantly broadens the scope to include not only the manufacturer, but also the importer, the authorised representative, the supplier, and the operator of the platform through which the product is sold (art. 8 PLDr). However, the burden of proving the existence of a defect, damage and causation remains with the injured party (Art. 10(1) PLDr), except in cases where codified presumptions apply (see §2.4.2.).

As was the case in the previous version of the directive, and as has been retained in the reformed proposal, a key aspect is the exclusion of compensation for damage to the defective item itself or to the defective component integrated into the complex product (art. 6(b) PLDr).

It is evident that all the fundamental theoretical issues—from the not entirely objective nature of liability to the possible defenses and limitations of compensable damage—remain essentially unchanged. In this sense, the solution adopted is consistent with the approach repeatedly taken by the Commission, according to which the current rules have so far proved to be essentially adequate and effective[134].

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[132] RAPID procedures (*Rapid Alert Procedure for Involuntary Withdrawal*) are mechanisms provided by the European Union to ensure timely and effective action in the event of the withdrawal of products from the market that may pose risks to the health and safety of consumers. These procedures constitute a critical component of the European product safety system, primarily governed by European Parliament and of the Council (2023). Regulation (EU) 2023/988 on general product safety, amending Regulation (EU) No 1025/2012 and Directive (EU) 2020/1828, and repealing Directive 2001/95/EC and Directive 87/357/EEC, OJ L 135, 23.5.2023: 1–51. Additionally, the RAPEX system (*Rapid Alert System for dangerous non-food products*) plays a pivotal role in ensuring product safety and can be accessed via the following link: https://ec.europa.eu/safety-gate/#/screen/home.

[133] For a more thorough examination of this topic, please refer to Wagner, G. (2024). "Next Generation EU Product Liability–For Digital and Other Products." Journal of European Tort Law 15(2): 172-224.

[134] The European Commission has stated that the existing product liability rules have proven to be essentially adequate and effective. For instance, it was recognised in Commission, E. (2018). Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Application of the Council Directive on the approximation of the laws, regulations, and administrative provisions to the Member States concerning liability for

Conversely, the critical issues encountered in practice, some of which are also recognised by the EU legislator itself, are addressed exclusively through procedural and evidentiary measures.

To this end, a provision on access to evidence (art. 9 PLDr) and a rule on presumptions regarding defects and causal link (art. 10 PLDr) are provided for.

2.4.2. Rules on disclosure and presumptions

Art. 9 PLDr introduces a mechanism of disclosure of evidence, according to which the injured party may ask the court to order the producer to disclose the information necessary to prove the defect and the causal link. Access is granted upon a showing of a *fumus boni iuris* - i.e., the apparent validity of the claim - and the court is tasked with balancing the interest in information with the protection of any trade secrets or confidential data.

While the underlying intention of this provision is praiseworthy, its practical implementation appears to be challenging. Firstly, satisfying the requirement for *fumus* can be formidable a task, assuming that one has access to the relevant information and is able to comprehend it.

Secondly, the judicial assessment of the necessity and proportionality of the information requested is complex and may expose the trial to delays as well as intentional dilatory tactics on the side of the defendant. Indeed, among other concerns, the producer may adopt a strategy of "information overflow"[135], delivering such an amount of information that hinders the ability of the victim to identify the salient elements supporting the claim, therefore increasing litigation costs associated with the processing and understanding of such information.

In such cases, the disclosure rule risks becoming an additional complicating factor rather than a genuine instrument of justice. The chosen solution to the lengthy, costly and burdensome litigation typical of product liability cases would, in fact, exacerbate the existing problems (see §3.4).

Furthermore, art. 10 PLDr codifies certain judicial presumptions that, over the years, have sought to lighten the burden of proof on the injured party. The provision, which is divided into five paragraphs, initially establishes the general rule that the injured party bears the burden of proving the defect in the product, the damage suffered, and the causal link between the two (paragraph 1).

The ensuing paragraphs introduce presumptions regarding the defect (paragraph 2) and the causal link (paragraph 3), respectively. Paragraph 4 establishes additional presumptions concerning these elements in cases characterized by "particular technical complexity". The language employed in this

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defective products, COM(2018) 246 final. where it was concluded that: "the Product Liability Directive continues to be an adequate tool." However, it also acknowledged that the Directive is not perfect and that given the ubiquity of digital products and services now available to consumers or forming part of the supply chain, "its effectiveness is hampered by concepts, such as 'product', 'producer', 'defect' or 'damage', that could be more effective in practice."

[135] Ben-Shahar, O. and C. E. Schneider (2014). More Than You Wanted to Know. The Failure of Mandated Disclosure, Princeton University Press. The Author emphasizes the common misperception that an increase in information leads to improved decision-making. This is due to the fact that the processing of such information incurs a substantial and occasionally prohibitive cost, which the agent is not willing to assume. In this regard, see also the studies by Kahneman, D. (2012). Thinking, Fast and Slow. London, Penguin Books., *passim* on the distinction between slow and fast reasoning and how, naturally, the latter is preferred in a variety of contexts.

paragraph is susceptible to interpretation ambiguity and may result in inconsistent application by courts of first instance. Paragraph 5 ultimately elucidates that these presumptions are *iuris tantum,* thereby acknowledging the manufacturer's prerogative to overcome it.

Focusing on paragraph 2, it introduces three presumptions relating to defects: (a) failure to disclose; (b) failure to comply with safety requirements; (c) obvious malfunction of the product under normal conditions of use. The first one sanctions disobedience to the judge's order to disclose. The second one recalls products certification regulation whose violation hinders lawful marketing of the product on one hand, and establishes a presumption *iuris tantum* of defectiveness on the other hand. Their relevance is most likely going to be more theoretical than practical[136].

The third provision, instead, represents an attempt at codifying the solutions adopted by a quite fragmented case law, whereby often, over the years, European courts resorted to *res ipsa loquitur*[137]—namely an inversion of the burden of proof, considering the unproven elements to be self-evident, and thence established—to ease the position of the claimant. This is especially beneficial in situations where the aggrieved party is unable to identify the precise nature of the defect but can demonstrate a malfunction to such an extent that defectiveness is presumed, in the absence of other plausible

[136] It is unlikely that a defendant will refuse to obey the Court's order, as well as it is very unlikely that someone selling a product on the European market will fail to comply with safety requirements, since certification is an essential part of the design process and engineers typically abide by all existing and relevant standards to have guidance on how the system ought to function.

[137] The phrase, frequently employed in the context of medical liability, particularly within Anglo-Saxon legal traditions, is defined as "circumstantial evidence that establishes a presumption of negligence", as articulated in Italian Cass. civ., sez. III, judgment no. 4852 of 1999; Italian Cass. civ., sez. III, judgment no. 11488 of 2004. According to Martorano, F. (1966). "Sulla responsabilità del fabbricante per la messa in commercio di prodotti dannosi (a proposito di una sentenza della Cassazione)." Il Foro Italiano 89(1): 13-32. "the formula indicates an inductive evidentiary procedure of the *circumstantial evidence* type, which is characterized by its reliance on the occurrence of a harmful event that falls outside the normal risks inherent in the performance of a certain activity (in this case, the use of a certain type of product)".

With regard to the matter of liability for defective products, "proof of the defect is considered to have been established when there is specific evidence that the events occurred as claimed by the injured party, even if proof of the defect has not actually been established but can only be presumed", see Fusaro, A. (2017). "Responsabilità del produttore: la difficile prova del difetto." La Nuova Giurisprudenza Civile Commentata(6): 896-906. For further elucidation on this point, an examination of Reimann, M. (2003). "Liability for Defective Products at the Beginning of the Twenty-First Century: Emergence of a Worldwide Standard?" The American Journal of Comparative Law 51(4): 751-838., is recommended.

This reduction in the evidentiary burden can be traced back to an interpretation of *Restatement Third* in the United States that appears to absolve the plaintiff of the responsibility to demonstrate the existence of a defect when the product in question manifests a deleterious effect during its intended utilization.

While the *Escola v. Coca-Cola case* was emblematic in the United States, one of the first cases in Europe was the *Riboux v. S.A. Schweppes Belgium case*, which involved the explosion of a glass bottle of a beverage taken from a shelf. The Court of Justice of the European Union has also repeatedly employed the aforementioned formula when adjudicating the burden of proof in matters of product liability. In essence, the injured party was granted the opportunity to substantiate the existence of a defect through a series of uncomplicated tests, thereby aligning with a pro-consumer interpretation of the proof of defect. This approach enables the presumption of a defect's presence in the absence of alternative causative factors (EUCJ, March 5, 2015, joined cases, *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt*, C-503/13 and EUCJ, March 5, 2015, *Boston Scientific Medizintechnik GmbH v Betriebskrankenkasse RWE, C-504/13*, in *Danno e resp*., 2016, 5 ff., with a note by A. Bittetto.; in *Resp. civ. e prev*., 2015, 751, with a note by F. Nobile De Santis.

For a more detailed discussion of these issues concerning new technologies, please refer to Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission., 50.

explanations. While it is certain that the rationale for such a solution is the intention to favour the claimant, it is as certain that its application will be extremely fragmented, since it allows for maximum discretion on the side of the single court adjudicating the case.

Conversely, paragraph 3 presupposes a causal relationship, predicated on the assumption that the observed damage is indicative of the defect in question. The provision is based on the principle of *id quod plerumque accidit*[138] and again incorporates into law solutions elaborated by courts over the year, in many Member States. In other words, in the absence of conclusive evidence, causation is presumed by arguing that even in the present case, what typically happens must have happened. With such a legal fictio, courts can reverse the burden of proof in cases they deem extremely burdensome for the party. As in the previous case, however, the discretionary power of the courts is greatly expanded in the absence of any real normative criteria to guide such decisions. As a consequence, discrepancies in the application of these very principles will inevitably be observed, leading to market fragmentation.

Finally, paragraph 4, allows for the presumption of the defect, the causal link or both, whenever claimants face «excessive difficulties, in particular due to technical or scientific complexity [...]», so long as (i) they previously resorted to the provision of art. 9 PLDr—demanding disclosure of information by the producer—and (ii) it is "more likely than not" that either the defect, the causal nexus or both are, indeed, present.

The provision is highly problematic, largely underdefined and allowing for excessive discretionary power for courts to assess all those elements, in a way that could profoundly alter the overall liability rule. Indeed, if interpreted in a very relaxed way, courts could find producers responsible when only the damage was actually fully demonstrated by the claimant, and both the defect and causal nexus were presupposed. The opposite is also true, and very conservative courts, on the base of identical facts could find in the opposite way, leading to great *ex ante* uncertainty, to the detriment of all parties involved. Indeed, on the one hand, it will be very difficult for claimants to decide whether to take the risk of such complex and costly litigation on the grounds of the applicable provisions and the information they possess. On the other hand, corporations will find it hard to trace a clear line of their exposure in terms of liability and subsequently insure themselves.

The critical elements of such an evaluation, entirely left to the single judges called in to adjudicate the case, are at least three, all extremely vague in isolation and even more so, if jointly read and considered. What exactly amounts to "excessive difficulties" is not stated, nor "technical and scientific complexity" is defined and criteria to assess it are offered. Finally, what satisfies the "likelihood" put forth by paragraph 4, let. (b) is also entirely left with the single judge to decide.

[138] Rizzo, N. (2022). La causalità civile. Torino, Giappichelli.. In civil liability, the principle of *"id quod plerumque accidit"* denotes a factual presumption rooted in ordinary experience, used by courts to infer causal relationships based on what typically occurs under analogous conditions. As Nicola Rizzo notes (see p. 66), this principle serves both a pragmatic evidentiary function and a normative shortcut in complex causal scenarios, allowing judges to fill gaps in direct proof. However, its use demands caution: without empirical support or doctrinal discipline, it risks injecting arbitrariness into causal attribution and disrupting the equilibrium of burdens in adjudication.

As per the latter, it shall be noted that, already today, the evidentiary requirement about the defect or causal nexus does not amount to absolute certainty. Instead, it is often based on the criterion of "more likely than not" or on forms of scientific regularity, thereby allowing the court wide discretion. However, the new rule risks further shifting the balance, giving the injured party an advantage in court which, in the most extreme cases, could result in almost strict liability for the manufacturer, based solely on proof of damage during the use of a technologically complex product.

Indeed, in some instances, the overall effect of those provisions will be that of transforming product liability into an absolute liability rule[139], more stringent than a mere strict liability rule, with no possibility for defendants to free themselves from responsibility. At the same time, while such a solution could be a reasonable alternative in a risk management perspective, it is no longer so when such a decision is not openly and clearly made by the legislator but left to the unnecessary uncertainty arising from vague language in the regulation and excessive discretionary powers left with courts.

Indeed, the main benefit of absolute liability rules is that of ensuring maximum ex ante foreseeability of the outcome (the responsible party knows she will always have to pay) and subsequently allow for easier management of said costs through insurance and price mechanisms (eventually transferring the cost entirely on those that use the product or service, see Chapter 5). However, vague language and regulatory uncertainty offsets all such benefits, and in this case most likely will cause divergent applications of the identical norms, and consequently market fragmentation.

Ultimately, the complex and costly assessments required, will increase litigation costs, as well as courts' administrative costs, and overall these provisions may exacerbate the very inefficiencies they seek to rectify.

2.4.3. The new PLD under scrutiny: the unsolved issues

The 1985 Directive on product liability serves as a paradigmatic example of a failed *legal transplant*[140]. The reasons for its failure are twofold. Firstly, there is the difference in litigation culture between Europe and the United States. Secondly, there is a lack of uniformity in the procedural systems of European MS. Nevertheless, the failure of the transplant cannot be regarded as entirely negative: the absence of the elevated levels of litigation and compensation typically associated with product liability

[139] An absolute liability rule is one for which no defences of any kind are allowed, eventually not even an act of God, and certainly not compliance with standards or requirements. It is considered a more extreme variation of a strict liability rule. For this reason, some scholars argue it is more of warranty than a true liability rule, Castronovo, C. (2006). La nuova responsabilità civile. Milano, Giuffrè. 195; see also Wigmore, J. H. (1894). "Responsibility for Tortious Acts: Its History." Harvard Law Review(7): 315, 383, 441.; Winfield, P. H. (1926). "The Myth of Absolute Liability." L.Q.R.(42): 37.; Rogers, H., P. H. Winfield and J. A. Jolowicz (2002). "on Tort." 63, 36.; Coleman, J. L. (2002). Markets, Morals, and the Law. Oxford, Oxford University Press.; McBride, N. and R. Bagshaw (2018). Tort Law. Harlow, Pearson.

[140] The necessary reference is Watson, A. (1974). Legal Transplants: An Approach to Comparative Law, University Press of Virginia., pp. 21 ff.; Ewald, W. (1995). "Comparative jurisprudence (II): the logic of legal transplants." The American Journal of Comparative Law 43(4): 489-510.; Legrand, P. (1997). "The impossibility of 'legal transplants'." Maastricht journal of European and comparative law 4(2): 111-124., pp. 111 ff.; Berkowitz Daniel, K. Pistor and J.-F. Richard (2003). "The Transplant Effect." The American Journal of Comparative Law 51(1): 163-203.

disputes in the US is not inherently detrimental. That model is not optimal, as evidenced by the necessity for corrective measures such as the GARA.

Nevertheless, the European approach is also unsuccessful. The directive saw limited application, primarily due the costs of litigation, ultimately failing to protect the interests of victims, who often resorted to other pieces of legislation to seek redress. This, in turn, resulted in fragmented application across MS, thereby hindering the development of consistent and predictable case law.

Said otherwise, while extremely high levels of product liability litigation—such as the tens of thousands of cases in the US—are detrimental for the industry and the economy, very low levels of litigation demonstrate the difficulty in applying those very norms and principles in the interest of the claimants, in particular when redress is pursued applying other remedies in their place.

In this particular context, the reformed text, whilst found upon a broad consensus regarding the issues to be addressed, appears to be somewhat inconsistent. The reformed text merely consolidates the fragmented case law—and mostly its procedural escamotages— as opposed to effecting a comprehensive structural overhaul[141]. Despite the broadening of the definition of the product - a sign of the pervasive regulatory policy based on a principle of technological neutrality - and the circle of liable parties, significant defences remain available to the producer, such as the development risk defence, and the defect is still defined in terms of lack of safety, not inadequate performance.

A piece of software used for diagnostic purposes, who does not detect a lesion in the patient, does not lack safety but may display an insufficient performance. While courts could force the interpretation of the concept of defect as defined by art. 7, to encompass lack of performance, that outcome is again left to a discretionary and to some extent questionable interpretation of single courts.

Moreover, the circumstance that damage to the defective product itself still cannot be compensated, radically reduces the chances that claimants will deem such complex system preferable to alternative rules, and it is therefore doubtful that the revised directive will yield superior results in terms of frequency of application, compared to its original formulation.

All that criticism, would have more limited a bearing if the role of the PLDr in the European regulatory framework was unaltered, as a liability rule that is intended to be applied on rare occasions, to force the internalization of clear, and economically relevant, harmful consequences that arise from mass-produced goods. Ideally, class actions ought to have a prominent role in the application of these provisions, causing litigation costs to become proportionate to the claim and the effort required by the trial justified. Indeed, when the reform of the directive was initiated, this was the intention of European policymakers, who were not focusing on those norms as the primary solution to the problem of increasing automation due to AI and advanced technologies.

Instead, those elements that appear already inadequate if we consider the limited scope of the directive, as just described, become paradigmatically more serious and a matter of relevant concern if we intend the application of the PLDr to become frequent, if not ubiquitous, whenever a task is

[141] An alternative viewpoint is that of Wagner, G. (2024). "Next Generation EU Product Liability–For Digital and Other Products." Journal of European Tort Law 15(2): 172-224. who talks about "complete overhaul".

automated through AI. In other words, the PLDr was not intended to be the primary source of legal protection for users of AIS, but in the absence of specific European rules, it could be invoked to serve as such. The alternative is for Member States to develop solutions at national level, leading to fragmentation and greater ex ante uncertainty.

2.5. What problems are left unsolved and why the sole revision of the PLD is insufficient

The comparative analysis of experts' opinions on the one hand, and of policy statements by European institutions on the other hand, shows great convergence on the need to conceive a dedicated liability rule for advanced technologies (see §3.4.10).

The main reason for such a need is dictated by the technological complexity of AIS that could discourage claimants from seeking redress from those that design or are in control of the technology, and economically benefit from their distribution or from the offering of services based on those applications. Both from a—purely—economic as well as from a social justice perspective it would, instead, be beneficial to induce those very subjects to internalize—and manage—the costs associated with the sale and distribution of AIS based products and services.

Further, it shall be noted that this does not *per se* entail that all costs associated with the development and diffusion of technology ought to be borne by the parties that are held *prima facie* liable. Rights to sue in recourse along the value chain, as well as price mechanisms (see Chapter 4) can allow for the distribution of costs to all those that participate in creating the product or offering the service, and use them and benefit from them.

For this very reason, and to pursue this end, the main focus of a dedicated liability system should be that of achieving maximum *ex ante* certainty about (i) who is liable and (ii) when, (iii) minimizing the need for and the complexity of litigation, and of (iv) associated administrative costs, leading to (v) insurability and the possibility of managing those costs and risks efficiently. The overall purpose should therefore be that of favouring the compensation of the victim, since the deterrence effect of liability rules is hardly observable and secondary with respect to that what is achieved through product safety legislation, and market mechanisms such as reputation (see §2.3.3).

In such a perspective, strict liability rules are preferable, and the consensus by experts on this point is absolute (see §2.2.2).

Given the overall framework described, the PLD and its revision are insufficient solutions. Firstly, the liability rule that characterized the PLD as well as the recently approved PLDr is not truly strict, both due to the existence of defences and of the need to demonstrate defectiveness. The latter, in particular, is an elastic concept that compares the level of safety achieved with a "reasonable standard" which is not narrowly defined, but varies according to context. This kind of evaluation is not so different from

the assessment of negligence[142], and therefore a fault-based rule[143]. Indeed, in such cases we compare the specific behaviour of the agent to the ideal behaviour a model agent ought to have maintained in the given circumstances. It is therefore convincing the conclusion reached by many academics as well as by some European courts that the PLD and its revision display a mere reversal of the burden of proof with respect to negligence, but still described a fault-based standard of liability (see §§2.3 and 2.4).

Procedural norms on disclosure obligations and presumptions (see §2.4.2) represent the most relevant innovation of the PLDr, transposing into law the fragmented solutions European courts elaborated to remedy the clear shortcoming of the PLD in allowing victims to recover damages. However, these solutions are inadequate in that they only crystallized what judges were already doing in most cases, particularly in terms of presumption, with the unsatisfactory results that led to the identification of the need for reform (see §3.4).

In any case, these norms will ensure a similar - but not identical - result to a truly strict liability rule only in limited cases and as a result of complex and costly litigation, the outcome of which is highly uncertain, given the discretionary powers of the judge in applying Art. 10 PLDr (see § 4.2). If the litigation costs associated with the PLD were perceived to be too high, discouraging claimants from using it to seek redress (see §3.4), the reformed text certainly will not reduce them. Indeed, even the provision of Art. 9PLDr on discovery obligations requires dedicated litigation to secure access to information that is then necessary to support a claim at trial. In other words, if all experts as well as the European institutions agreed on the need to reduce the costs associated with access to justice and product liability litigation, the reformed text seems to have missed such a clearly defined objective.

Moreover, the notion of defect, defined as the lack of safety one is entitled to expect, cannot accommodate lack of performance. Failing to identify a lesion in a radiologic image cannot be framed as a lack of safety, eventually is should be questioned if the performance of the system is adequate, to same extent in the same way as you would question the performance of the practitioner assessing that very image. Instead, if the MRI machine used to capture the image, generated an anomalous magnetic field, or short-circuited causing damages to the patient, that would fall into the scope of application of the PLD and its revised version.

Finally, the PLDr extends its scope to software and thence AI. However, in many instances, AIS will be used to conceive and deliver services. The latter fall outside the scope of the PLDr. Yet it is disputable

[142] See for instance the description of the judgment of negligence exemplified by Padovani, T. (2002). Diritto Penale. Milano, Giuffrè., 193 ff. First, one should determine whether the given knowledge is possessed by even a single person on the entire planet. Second, one should determine whether this specific knowledge could be required of the specific agent. If science has not yet discovered the causes of a given disease, then a judgment of fault stops at the first stage. Instead, if that information is already available, the judge should assess whether the specific practitioner can be required to possess that knowledge. The conclusion could differ according to the specific characteristics of the agent, whether she is a specialist in this field or not.

[143] In this sense Cass., sentenza n. 13458 del 2013, in «Il Foro italiano», I, 2013, c. 2118; conformi Cass., sentenza n. 12665 del 2013; Cass., sentenza n. 13225 del 2015; Cass., sentenza n. 15851 del 2015; Cass., sentenza n. 22887 del 2015; Cass., sentenza n. 3258 del 2016; Cass., sentenza n. 11317 del 2022, in Danno e Responsabilità, 2023, pp. 363 ss. The study of the economic analysis of law agrees with this and this is exemplified by Schäfer, H.-B. and F. Müller-Langer (2009). Strict liability versus negligence. Tort Law and Economics. M. Faure. Cheltenham, UK - Northampton, MA, USA, Edward Elgar: 109-133., 31-32.

that less protection is needed by those that are offered an AI-based service. It is true that other legal frameworks will apply (in particular contract law in many instances), and that the injured party could still sue the producer of the AIS used to offer the service, yet none of this solutions achieves the desired level of simplification and cost reductions that had been identified as necessary in this domain.
The points raised represent a limited concern for the PLDr if that is intended as a liability rule that closes an otherwise complex regulatory framework for civil liability, primarily determined at MS level, through numerous national liability rules.

However, the policy statements rendered over the years (see Chapters 1 and 2) demonstrated the intention to have Europe play a leading role, to prevent fragmentation, and the adoption of diversified solutions at MS level, to ensure high levels of protection of users, leading to trust and technological uptake. If that were still the intention of the European legislator, the PLDr is clearly not fit for that purpose, and the adoption of a dedicated liability rule is still of primary importance.

3. THE PROPOSAL FOR AN AI LIABILITY DIRECTIVE: A CRITICAL ASSESSMENT

KEY FINDINGS

1. Departing from Expert Recommendations and Previous Legislative Approaches

The AILD marked a sharp departure from both the European Parliament's 2020 RLAI and the expert opinions previously endorsed by the Commission itself. While earlier proposals advocated for strict liability regimes tailored to high-risk AI applications, the AILD adopted a procedural and fault-based approach, thereby diverging from the Commission's earlier recognition of the inadequacy of national fault-based rules in addressing the specificities of AI-related harms.

2. An Ostensibly Minimal yet Substantively Invasive Instrument

Although formally limited to procedural norms, the AILD introduced notions of fault (objective) and causation that are difficult to coordinate with the heterogeneous legal traditions and fault-based rules of the Member States (MS), especially since the proposed directive does not define an autonomous liability rule.

3. Unclear and Potentially Overbroad Scope of Application

The scope of the AILD—nominally restricted to non-contractual, fault-based claims involving AI systems—is underdefined. In particular, the inclusion of both high-risk and non-high-risk AI systems, without clear delineation mechanisms or ex ante classification, risks uncontrolled regulatory expansion and legal uncertainty. This is further exacerbated by the ambiguity surrounding the high-risk qualification under Article 6 AIA, which courts may interpret divergently in the absence of definitive certification mechanisms.

4. Complex, Costly, and Inefficient Procedural Mechanisms

Articles 3 and 4 AILD introduce burdensome procedures, including disclosure duties contingent upon prior failed attempts at evidence collection and complex thresholds for triggering rebuttable presumptions. These mechanisms do not offer a significant reduction in the evidentiary burden for claimants and may instead increase litigation costs, particularly due to risks of opportunistic behaviours and information overload by defendants.

5. Ineffectiveness in Achieving Legal Certainty and Victim Compensation

The procedurally complex mechanisms conceived yields minimal practical benefits to claimants who obtain only a rebuttable presumptions. This undermines the AILD's declared aim of reducing litigation complexity and enhancing victim protection and may induce plaintiffs to disregard such norms and apply alternative – possibly strict – liability frameworks that exist at MS level, leading to fragmentation.

6. High Dependence on Judicial Interpretation and Resulting Fragmentation

The AILD defers critical assessments to judicial discretion, including what constitutes sufficient evidence (*fumus boni iuris*), the level of causal proof required, and the interpretation of technical norms from the AIA. This places disproportionate responsibility on courts, risks inconsistent applications across jurisdictions, and ultimately invites the very fragmentation the directive sought to preclude.

7. Risk of Triggering Over-Regulation through National Divergence

In the absence of a functional and widely applicable EU-level framework, MS are likely to fill the regulatory void through divergent national initiatives. This outcome would paradoxically fulfil the very risk of over-regulation—via regulatory fragmentation—that the Commission purported to avoid.

8. Disproportionate Regulatory Effort Relative to Policy Gains

The AILD entails a high political and technical cost for what amounts to a modest and uncertain gain in ensuring victim protection. In light of these shortcomings, the creation of a special strict liability regime, limited in scope and clearly distinct from product liability norms, would have represented a more coherent and less disruptive approach—better aligned with expert recommendations and previous institutional declarations.

3.1. Introduction

According to the original design of the European Commission the issue of civil liability arising from the use of advanced technology was supposed to be tackled with a two-pronged approach[144], the adoption of a revised version of the PLD and a Directive on adapting non-contractual civil liability rules to artificial intelligence (AILD)[145].

This articulate proposal, subsequent to that of the AIA, overcame the one formulated by the European Parliament, namely the 2020 proposal for a Regulation on Liability for the Operation of Artificial Intelligence Systems (RLAI). This latter text respected very much the recommendations of the experts appointed both by the Commission[146] and the Parliament[147] to address the matter, and proposed the strict liability of the operator, defined as "both the frontend and the backend operator as long as the latter's liability is not already covered by Directive 85/374/EEC" (art. 3), device or process driven by that AI-system, for all high-risk applications[148] (see §4.2.3).

To the contrary, the AILD adopted a radically new perspective, departing from the advice and opinions rendered, presenting a novel solution and approach compared to those the Commission had appeared to be expressly evaluating over the years, in all its statements. So conceived, the AILD represented already *per se* an innovation and the departure from a series of policies already under scrutiny.

Yet, its recent likelihood to be withdrawn represents a further change in the regulatory approach maintained by the Commission, completing the reversal (see §1.2) initiated with the proposal for an AIA, whose implications were, in part, already discussed (see §1.2.7), and need to be deepened. Indeed, the decision did not come with an alternative proposal to replace the AILD, nor with analytical considerations of the reasons that led to such a decision, beyond broad statements of caution, the need to avoid over-regulation, and the difficulty in finding a political compromise among MS.

It was already clarified, however, how over-regulation can be the consequence of both the adoption of new pieces of legislation as well as of the lack thereof (see §1.5), especially when that leads to the proliferation of national norms, that fragment the legal framework businesses will have to comply with.

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144 European Commission (2022). Proposal for a directive of the European Parliament and the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive) COM(2022) 496 final. Brussels. stressed out the fact that: "[…] this proposal [for a AILD] contributes to the enforcement of the requirements for high-risk AI systems imposed by the AI Act, because the failure to comply with those requirements constitutes an important element triggering the alleviations of the burden of proof. […] The Commission takes a holistic approach in its AI policy to liability by proposing adaptations to the producer's liability for defective products under the Product Liability Directive as well as the targeted harmonisation under this proposal. These two policy initiatives are closely linked and form a package, as claims falling within their scope deal with different types of liability. The Product Liability Directive covers producer's no-fault liability for defective products, leading to compensation for certain types of damages, mainly suffered by individuals".

145 Ibid.

146 Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission.

147 Bertolini, A. (2020). Artificial Intelligence and Civil Liability. Bruxelles, European Parliament - Committee on Legal Affairs: 1-132. See also the library information briefing issued by EPRS Evas, T. (2020). Civil Liability Regime for Artificial Intelligence. Brussel, European Union.

148 Considering how the proposal preceded the AIA by a few months, the definition of high-risk did not coincide with the one formulated by art. 6 AIA, which is also quite problematic.

Indeed, over-regulation is a serious concern that needs to be attentively assessed at European level, and such concerns are commendable. Yet it is hard to consider—efficient—liability rules as a source of compliance costs for companies, considering how they only operate ex post, when harm that should anyway be avoided. Moreover, the absence of European norms will lead to the proliferation of different regimes at MS level (see Chapter 1). Over-regulation is much more of a risk when *ex ante* compliance, such as that demanded by the AIA is considered (see §1.2.7).

Finally, difficulties in finding a political agreement at MS level over the text may, instead, depend on the merits of the proposal, on the technical choices it entails, such as its scope of application (see 3.4.2), the regulatory approach (entirely relying on procedural norms) (see §3.4.3), and possible interferences with national liability frameworks in a largely unforeseeable fashion (see §3.4.5).

To conclude, only efficient civil liability rules—ensuring ex ante certainty, minimizing litigation and its costs, easing damage recovery by the victims, allowing for efficient risk and cost management, also trough insurance and price mechanisms—prevent over-regulation and benefit both users and developers of technology.

In such a perspective, having already shown that the PLDr does not take into account all the problems and regulatory needs that have been identified (see Chapter 2, §§ 4 and 5), a detailed analysis is required to determine whether the proposal for an AILD (i) was an adequate response to such needs or, instead, (ii) the concerns raised that led to its possible withdrawal were justified.

First, the intention of the Commission when presenting the AILD needs to be investigated (see §3.2.1), by referring to its own statements and to the commentaries that accompanied the proposal. Second, the proposal will be presented and analysed (see §3.3), focusing on disclosure obligations (see §3.3.1) as well as presumptions (see §§3.2-3.4) to point out the concerns and reasons for uncertainty with respect to the possible outcome of the application of those provisions. Third, an articulate assessment of the proposal (see §3.4) will address both technical profiles (see §§3.4.1-3.4.6) as well as their policy implications (see §§3.4.7-3.4.10).

3.2. The proposal for an AI Liability Directive in the intention of the European Commission: complementarity and independence from the PLDr

The directive was conceived as an autonomous text, parallel and distinct from the PLDr, thence complementary and mutually independent, providing for procedural norms, intended to integrate MS's fault-based liability rules, in all cases where AIS are involved. Indeed, in the very wording of the European Commission it may be read:

> "These two policy initiatives are closely linked and form a package, as claims falling within their scope deal with different types of liability. The Product Liability Directive covers producer's no-fault liability for defective products, leading to compensation for certain types of damages, mainly suffered by individuals. This proposal covers national liability claims mainly based on the fault of any person with a view of compensating any type of damage and any type of victim. They complement one another to form an overall effective civil liability system. Together these

> rules will promote trust in AI (and other digital technologies) by ensuring that victims are effectively compensated if damage occurs despite the preventive requirements of the AI Act and other safety rules"[149].

To further clarify the relationship between these two bodies of norms, further statements were issued, such as:

> "[...] the proposed revision of the Product Liability Directive aims to modernize the current regime [...] and would apply to claims brought by individuals against the producer for damage caused by defective products. The new AI liability directive, on the other hand, proposes a targeted reform of national fault-based liability regimes and would apply to claims, brought by any natural or legal person against any person, for fault in influencing the AI system that has caused the damage"[150].

Several considerations may be drawn.

Firstly, it is undoubted that, at least pursuant to the original scheme maintained by the Commission up until 2022, past the presentation of the AIA, and also considering the proposal to reform the PLD—and thence the peculiar legal solutions it enacted—the legal framework was deemed incomplete, absent specific dedicated norms on civil liability for AI.

Secondly, a clear distinction between the cases that ought to be governed by the two pieces of proposed legislation was made that, despite being possibly simplistic, captured the limitations intrinsic to the PLDr, despite it encompassing software, thence AI. Indeed, the clear separation seems more theoretical than real, for MS's liability rules—fault based and strict—have always been applied, next to or in place of the 1985 directive on product liability, to ensure victims' compensation, so long as national norms offered easier and more efficient protection to the claimant[151] (for a more detailed discussion, see Chapter 2).

At the same time, it has already been discussed (see §2.3.6) how the increasing human-machine collaboration in performing tasks is blurring the clear line of distinction that used to characterize product liability from all other areas. With automation, responsibility is being shifted back to the entity that designed the machine, much more frequently than in the past when tasks were left entirely to a human agent. At the same time, the non-residual role of the human agent leads to the application of

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[149] See European European Commission (2022). Proposal for a directive of the European Parliament and the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive) COM(2022) 496 final. Brussels., 3.

[150] See T. Madiega, *Artificial intelligence liability directive*, Strasbourg, European Parliamentary Research Service, 2023, 5.

[151] See the data collected by Ernst&Young, Technopolis and VVA (2018). Evaluation of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products. Brussels, European Commission., 117. The data demonstrates that in 20% of cases where the PLD was theoretically applicable national contract and tort law rules were preferred, see § 2.3.4. See also Wagner, G. (2022). "Liability Rules for the Digital Age. Aiming for the Brussels Effect." Journal of European Tort Law 13(3): 191., who affirms that the Proposal on AI Liability has practical significance "only in those areas which the (reformed) Product Liability Directive cannot reach. [...] This raises the question as to the precise range of the interests that remain outside the scope of protection of a reformed Product Liability Directive. The answer is clear: liability under national tort law is broader than product liability in three areas, namely damage to property, infringements of personality rights, and pure financial loss".

different liability rules, which overlap with the framework emerging from the PLD (now PLDr) and raise the very problems of causal underdetermination and liability apportionment that increase ex ante uncertainty and litigation costs[152].

3.2.1. Continued: the Commission's awareness of the limitations to fault-based rules

Third, the choice of a set of procedural norms intended to apply in combination with countless fault-based rules existing at national level, in each MS, whenever an AIS is involved, is indeed peculiar, and appears to contrast with relevant statements issued by the Commission itself over time, such as:

> "Current national liability rules, in particular based on fault, are not suited to handling liability claims for damage caused by AI-enabled products and services. [...] The specific characteristics of AI, including complexity, autonomy and opacity (the so-called "black box" effect), may make it difficult or prohibitively expensive for victims to identify the liable person and prove the requirements for a successful liability claim. In particular, when claiming compensation, victims could incur very high up-front costs and face significantly longer legal proceedings, compared to cases not involving AI. Victims may therefore be deterred from claiming compensation altogether"[153].

Indeed, the Commission not only questioned the adequacy of protection offered by national negligence-based rules, but also stressed the risk of fragmentation such an option leads to, whenever relevant space for interpretation and divergent application is left with single judges:

> "If a victim brings a claim, national courts, faced with the specific characteristics of AI, may adapt the way in which they apply existing rules on an ad hoc basis to come to a just result for the victim. This will cause legal uncertainty. Businesses will have difficulties to predict how the existing liability rules will be applied, and thus to assess and insure their liability exposure. The effect will be magnified for businesses trading across borders, as the uncertainty will cover different jurisdictions. It will particularly affect small and medium-sized enterprises (SMEs), which cannot rely on in-house legal expertise or capital reserves"[154].

More specifically, however, the AILD advances a solution that requires the application of MS's individual fault-based rules, in conjunction to the procedural provisions put forth by directive. The interference such rules could create when being applied together one with the other is very hard to anticipate and govern. Indeed, the AILD requires both concepts of fault and causal nexus to be applied that may conflict with those defined by national liability rules. Those elements of a tort of negligence are, in fact,

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[152] See Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission.; Commission, E. (2022). Commission Staff Working Document. AI Subsidiarity Grid Accompanying the document Proposal for a Directive of the European Parliament and of the Council on adapting non contractual civil liability rules to artificial intelligence (AI Liability Directive) {COM(2022) 496 final} - {SEC(2022) 344 final} - {SWD(2022) 319 final} - {SWD(2022) 320 final}.; Bertolini, A. (2020). Artificial Intelligence and Civil Liability. Bruxelles, European Parliament - Committee on Legal Affairs: 1-132.

[153] European Commission (2022). Proposal for a directive of the European Parliament and the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive) COM(2022) 496 final. Brussels., 1.

[154] Ibid., 2.

often characterized in profoundly different ways in different European legal traditions (see §2.4). However, if, to date, all attempts to standardize general European private law have failed despite very rich and profound comparative law studies'[155], a directive composed essentially by two prescriptive rules will not be able to produce that general harmonization between different legal systems in an indistinct—and ex ante indistinguishable—multiplicity of liability cases. Not even the obvious Germanic roots of the proposals under comment, will be able to allow this partial graft to produce a fruit of uniformity of protection (see §3.4.1).

3.3. A brief overview of the liability rules according to AILD

The AILD has a horizontal nature—rooted in the principle of technological neutrality (see Chapter 3)—and yet replicates a similar distinction to that of the AIA, providing for two distinct regimes for high-risk AIS (h-AIS) and non-high-risk AIS, residually identified. While the focus is clearly on the former, some rules (art. 4, (1)(4) and (5)) apply also to the latter.

Both the prescriptive rules (art. 3 and 4 AILD) have a procedural nature that is very similar to that of the PLDr, artt. 9 and 10 (see §2.3), introducing disclosure obligations (see §3.3.1) and presumptions (see §3.3.2) respectively.

3.3.1. Disclosure obligations

In the case of h-AIS, art. 3 AILD provides for the possibility for the court to order the provider or deployer to disclose information necessary for the plaintiffs to demonstrate the constitutive elements of their claim.

The discipline mirrors the one provided for by art. 9 PLDr and departs from it only on two aspects. The first relates to the procedure itself. The order of disclosure may be issued by the court only where the plaintiff has "previously made every proportionate effort to obtain such evidence by the defendant" (paragraph 2) and he was refused the information. Similarly to art. 9 PLDr, the plaintiff will then have to prove *fumus boni iuris* (paragraph 1, last sentence), and the court will have to balance the opposing interests of the parties by identifying appropriate measures to protect the defendant's intellectual property and trade secrets whose disclosure it may require (paragraph 4). The second relates to the consequence of the breach of the duty to disclose. In this case the rebuttable presumption (paragraph 5) will arise against the defendant, however, only with respect to the "duty of care [...] that the evidence

[155] Beginning with European Group on Tort Law (2005). Principles of European Tort Law. Text and Commentary. Wien-New York, Springer., *passim*, to PECL O. Lando, H.G. Beale and C.E.C. Law, *Principles of European Contract Law: Parts I and II*, Dordrecht, Springer Netherlands, 2000, *passim*, to the optional instrument resulting from the *Draft Common Frame of Reference*, C. von Bar and E. Clive, *Principles, Definitions and Model Rules of European Private Law: Draft Common Frame of Reference (DCFR). Full edition*, München, Sellier, 2009, *passim*, with respect to which the best European literature has spoken, without, however, arriving at a concrete harmonization result. For discussion of possible reasons for such a failure in perspective, see Micklitz, H.-W. (2016). Failures or Ideological Preconceptions? Thoughts on Two Grand Projects: The European Constitution and the European Civil Code. The Many Constitutions of Europe, Routledge: 109-140.; allow me to refer to Bertolini, A. (2023). European Commercial Contract Law. Bruxelles, European Parliament - Committee on Legal Affairs: 1-103.

requested was intended to prove for the purposes of the relevant claim for damages", while it is not possible to presume the existence of other constitutive elements of the claim, such as causation.

With regard to this provision, all the criticisms already made of Art. 9 PLDr can be repeated (see §2.4.3). In particular, the complexity and cost of such a procedure should be emphasized, aggravated by the need to prove that measures have been taken to obtain information out of court, directly from the defendant. This also increases the risk of strategic obstructionism by the defendant, increasing the time and cost of the entire litigation, most likely for an already weaker party. In other words, the provision conflicts with the need for certainty and speed of judgments and the reduction of costs, which are at the basis of the need to regulate this area (see §1.4, and §§2.3 and 2.4).

Moreover, the circumstance that failure to comply with the judge's order to disclose produces a mere rebuttable presumption, limited to the element of fault, seems arbitrary and unjustified, considering how it can be equally if not more problematic for the injured party to prove causation.

3.3.2. The presumption with respect to causation

The latter, however, may benefit from a rebuttable presumption laid down by art. 4 AILD, for the cases in which the supplier or deployer, acted in the course of their professional activities (paragraph 6)[156], even when the AIS is not high risk.

The presumption operates whenever three conditions are met, namely: (art. 4(1)(a) AILD) the injured party demonstrates—or this has been presumed, in accordance with art. 3 AILD—that the defendant violated a duty of care, laid down either by European or MS's law, that is designed to prevent the type of damage that occurred, and (art. 4(1)(b) AILD) it is reasonably probable that the fault influenced the result of the AIS, and (art. 4(1)(c) AILD) the output—or failure to produce an output—of the AIS caused the damage.

Indeed, while the link between the defendant's conduct and the output of the system may be presumed, the same cannot be said for the link between the output and the damage, which must be proven as a condition for the application of the presumption just described.

On closer inspection, however, the existence of a clear causal nexus between the operation of the machine and the occurrence of the damage may not be evident. That primarily depends on the recalled human-machine cooperation in the completion of tasks, that gives rise to causal uncertainty.

Finally, the presumption will always apply to h-AIS unless the defendant proves that the plaintiff has sufficient evidence and expertise to prove the existence of the causal link (paragraph 4). Instead, for all other claims, the ability to rely on the presumption depends on the discretionary assessment of the court, which must determine that it would otherwise be unduly difficult for the plaintiff to prove the constituent elements of the claim (paragraph 5).

[156] If the supplier and deployer had made personal use of the system-they could suffer the application of the presumption only to the extent that they "materially interfered with the operating conditions of the IA system or if the defendant was required and able to determine the operating conditions of the IA system and failed to do so," see art. 4(6).

3.3.3. Continued: provisions applicable only to h-AIS

As far as h-AIS are concerned, the fault of the defendant may only be established through the complex, and convoluted provisions contained in paragraphs 2 and 3 of art. 4 AILD respectively, distinguishing between providers and distributors on the one hand, and deployers on the other hand.

With regard to providers[157]—subject to the discipline of Sections 2 and 3 of Chapter III of the AIA—or distributors[158]—subject to the obligations set forth in art. 24(1) and (3) AIA—fault can be proven only by demonstrating the violation of any of the obligations stated in art. 4(2) let (a)-(e) AILD.

Those include having developed an AI system by (a) making use of data sets-for training, validation and testing that do not meet the quality requirements (provided for in art. 10(2) (4) AIA), or (b) violating transparency requirements (as set forth in art. 13 AIA) or, again, (c) not allowing effective human surveillance (as set forth in art. 14 AIA) and (d) not achieving adequate levels of accuracy, robustness, and cybersecurity (artt. 15 and 16 (a) AIA). Fault is then demonstrated where (e) steps were not taken in a timely manner to bring the system back into compliance with the requirements laid down in Chapter III Section 2 AIA, or to withdraw or recall it, as appropriate.

To assess such violations one must, then, consider the so-called risk management system, the actions taken with it and the results achieved. Now, the risk management system is understood as a "as a continuous iterative process planned and run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic review and updating" (art. 9(2) AIA). Thus, the European legislator designs a continuous obligation, consisting of a plurality of performances, interconnected with one another, and intended to be repeated cyclically throughout the life and supply of the system. The overall rationale—despite a wording that leaves broad margins of discretion and subsequent uncertainty—is that of mitigating or eliminating " through the development or design of the high-risk AI system " (art. 9(3) AIA), i.e., to manage "the relevant residual risks associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged to be acceptable" (art. 9(5) AIA), requiring, to this end, that systems be tested (art. 9(6) AIA).

It is, then, through this procedure that the risks and corresponding obligations with which the provider is required to comply will be determined; the violation of those duties will then ground the fault of the defendant for the purposes of art. 4 AILD.

By contrast, the deployer's fault (art. 4(3) AILD) will be measured alternatively with respect to (a) failure to comply with obligations to take the necessary technical and organisational measures to ensure use

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[157] Pursuant to art. 3 (3) of the European Parliament and of the Council (2024). 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) (Text with EEA relevance), OJ L, 2024/1689, 12.7.2024. Brusselles, Official Journal of the European Union. a provider is "means a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge".

[158] Pursuant to art. 3(3) ibid. a distributor means a natural or legal person in the supply chain, other than the provider or the importer, that makes an AI system available on the Union market.

of the system in accordance with instructions (art. 26(1) AIA), or (b) for providing input data that is not relevant and sufficiently representative, with respect to the purposes of the system (art. 26(4) AIA) or, again, (c) for failing to monitor the operation of the system, possibly suspending it when appropriate (art. 26(5) AIA).

3.3.4. Continued: a critical assessment

The outlined framework raises concerns of particular theoretical and systematic relevance, with respect to the concept and role of fault, and its—logical and legal—connection with the causal nexus, with a very relevant practical bearing as well as policy implications.

On the one hand, the purpose of the AILD is to ensure minimum harmonisation[159], integrating the numerous fault-based liability rules existing at MS level through some procedural norms, whenever AIS are concerned. On the other hand, however, it reverses the traditional relationship between the objective and subjective elements of fault liability, in a way that presupposes a specific notion of fault, that is not typical of all MS's legal systems.

Indeed, traditional tort law theory describes fault as a two-tiered subjective judgment where (i) you need to establish if a given knowledge existed and was possessed even just by one single human being, and/or a standard of conduct could have been maintained that could have prevented the harm suffered by the victim, and (ii) determine whether that specific knowledge or conduct may have been demanded of the specific agent in the given circumstances, everything considered[160].

Preliminary to such a judgment, is the need to establish that the given outcome is the consequence of the very conduct. Said otherwise, before discussing the agent's fault you need to establish the existence of a causal nexus between the damage suffered and the conduct considered.

Instead, the European Commission elaborated an extremely complex solution (see §§3.2 and 3.3), where the notion of fault is defined in an objective fashion (the violation of a rule of conduct that is not necessarily the reason why harm occurred), inverting the relationship between that component and the

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[159] Pursuant to recital 14 of the European Commission (2022). Proposal for a directive of the European Parliament and the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive) COM(2022) 496 final. Brussels., 17, the Directive "should follow a minimum harmonisation approach". See also Madiega, T. (2023). Artificial intelligence liability directive. Brussels, European Parliament: 1-12.

[160] The concept of "guilt" in tort law serves as a pivotal element in assessing civil liability. It denotes not merely the occurrence of damage, but the normative evaluation of the conduct that caused it. As Padovani, T. (2015). Diritto penale. Parte generale. Milan, Giuffrè., 92, explains: "civil fault does not necessarily coincide with criminal fault, although it derives historically from it: it is rather configured as a judgment of blame regarding conduct that caused an unjust harm". His account emphasizes that the function of fault in civil liability is compensatory rather than punitive, distinguishing it from the criminal law context. In a similar vein, Galgano, F. (1993). Le obbligazioni in generale. Trattato di diritto civile e commerciale. A. Cicu and F. Messineo. Milan, Giuffrè.188 states that: "civil fault is a legal construct aimed at balancing freedom of action and the protection of others' legal spheres". More recently, Trimarchi, M. (2001). Rischio e responsabilità oggettiva. Milan, Giuffrè., 110, has argued for an increasingly objective understanding of fault, noting that "the judgment of blame in civil liability tends more and more to disregard the psychological element of the injurer, and instead focuses on the breach of conduct rules evaluated ex ante". Anglo-American legal theory also reflects this evolution. For instance, Honoré, T. (1999). Responsibility and Fault. Oxford, Oxford: Hart Publishing. 14, stresses that: "responsibility in tort is primarily about the breach of a duty that society recognizes as owed to others, regardless of moral fault".

objective element of the causal nexus; moreover, the latter is also artificially split in two. Indeed, the existence of a causal link between the operation of the machine and damage, must still be proven by the plaintiff.

Probably the division of the ascertainment of the causal nexus in two phases, besides being artificial and problematic from a theoretical point of view, is rooted in a—simplistic and incorrect—understanding, whereby it is easier to observe how the functioning or failure of the system produced the damage than determine what, in fact, led the system to function that way.

Indeed, it has already been pointed out several times that the interaction between humans and machines in the completion of tasks in which the former maintains autonomous operating spaces produces an overlapping of responsibility rules (see Chapter 2). It is precisely these scenarios, which will increase in number and relevance with automation, that make the factual and material assessment of accident dynamics increasingly complex. In other words, it is not always easy to disentangle the interplay between human behavior and machine operation in the causation of a given injury.

To better understand such concepts, we may refer to two examples:

> Example 1
> A vehicle with increasing automation, with a human driver who can decide whether and when to activate the autonomous driving function, goes off the road in a turn, hitting a parked vehicle. What reason caused the vehicle to steer off road is not immediately or simply determinable.

The accident could be due to a malfunction of a component of the vehicle or the steering system, for which the manufacturer could be held responsible, regardless of whether he manufactured all of these parts himself or merely assembled them into his final product (both pursuant to the PLD and PLDr).

However, the accident could also have been caused by human behavior, either because the driver was driving after disabling the autonomous system, or because the driver failed to maintain control of the system as required by German law[161]. The driver could be deemed liable also for failing to pay attention to the warning signals of the vehicle that demanded the resuming of manual driving, in case road or weather conditions were less than optimal. The driver could be considered a deployer for the purposes and effects of the AIA, and subsequently of the AILD.

All of these considerations, although also relevant to the assessment of the agent's fault, are still relevant to the assessment of the causal link. Only once it is established that the vehicle veered off the road because the autonomous driving function was disabled, after the car had unsuccessfully signaled to the driver to regain control, can it be discussed whether it was actually possible for the human to intervene in time to avoid the collision.

Now, it may be questioned whether, in order to apply the presumption, the injured party may argue that there is a clear link between the operation of the vehicle and the damage (within the meaning of

[161] See § 1b *Straßenverkehrsgesetz* (German Road Traffic Act) as last amended by art. 1 of the Act of July 12, 2021 (Federal Gazette I, 3108) and available at: https://www.gesetze-im-internet.de/stvg/index.html (last accessed June 30, 2025).

Section 4(1)(c) AILD). The positive or negative answer depends on the interpretation of two elements, the notion of AIS and the understanding of the causal nexus respectively.

If the AIS is the car in and by itself considered, there is no doubt the collision occurred because the former was proceeding on the road and, for some reason, bumped into the parked vehicle. Yet, that vehicle is a complex system with an AI component, which causes the entire vehicle to be deemed an AIS for the purposes of all European norms (both the AIA and the AILD). Nevertheless, part of its operation is left entirely to human control, and part involves the cooperation of both. In other words, the driving function is to some extent shared between man and machine.

A first formal solution, which would consider the entire vehicle an AIS, regardless of any further assessment of the driver's conduct, would allow the presumption to operate. However, a second solution, which would analyse the entire etiological development, would require to assess the concrete role the human played in causing the accident, before any consideration of fault. If we abide by this latter interpretation, the requirement laid down by art. 4(1)(c) could only be met by demonstrating the whole causal nexus, not just a portion of it, artificially isolated. A first formal solution, which would consider the entire vehicle as an AIS, regardless of any further assessment of the driver's behavior, would allow the presumption to work. However, a second solution, which would analyse the entire etiological evolution, would require an assessment of the concrete role played by the human being in causing the accident before any consideration of fault. If we follow this latter interpretation, the requirement of art. 4(1)(c) could only be satisfied by proving the entire causal link, and not just a part of it artificially isolated.

In fact, it would be necessary to establish that the vehicle left the road for a reason that may be traced back to the functioning of the driving system and not to human behavior. It is precisely this material assessment, however, that, in the words of the European Commission itself, may prove excessively burdensome for the victim.

The example appears, in perspective, almost trivial. If only it entailed the collision between two vehicles the complexity of the dynamics would radically increase, and so the uncertainty about the dynamics.

It is also clear how, of the two possible interpretations offered, only the first one really benefits the injured party. Yet, such a solution would imply such a degree of simplification in establishing the liability of the provider or deployer that it would closely resemble a strict liability rule, establishing liability for all accidents occurring during the use of the technology, not properly because of it.

Moreover, even the notion of fault embedded in the AILD seems peculiar, intended in objective terms—the violation of a rule of conduct—that is typical of some legal orderings, not all[162]. How easily that would

[162] For an overview on German concept of fault as norms of conduct violation see Wagner G. (2020). § 1 Prod- HaftG para 26; § 823 para 28 ff. Münchener Kommentar zum BGB (hereafter MünchKomm).; Markesinis BS., Bell J. and Janssen A. (2019). Markesinis's German Law of Torts Case 53.; Jansen N. (2010). Developing Legal Doctrine: Fault in the German Law of Delict. The Development and Making of Legal Doctrine, Comparative Studies in the Development of the Law of Torts in Europe. Jansen N. 6: 96 ff.; Deutsch E. (1995). Fahrlässigkeit und erforderliche Sorgfalt.. For a French point of view see Dugué M. (2019). The Definition of Civil Fault. French Civil Liability in Comparative Perspective. B. J. and W. S. 79.

coordinate with the numerous liability rules in individual MS is by no means easy to anticipate and, certainly, will lead to very different results.

> Example 2
>
> Consider the case of physicians who, in their private practice, use AIS for diagnostic purposes. Clearly, they would integrate the role of the deployer if not that of the provider, depending on whether, for example, they merely adopt a standardized system, or commission one with peculiar characteristics, to carry out their own activity.

Firstly, it is not clear how the AILD could be coordinated with the liability of medical practitioners, typically framed as a tort that requires the exact assessment of the conduct of the agent, based on the two-prong subjective evaluation described above. If the use of the AIS justified the application of the rules just commented upon, the judgment would, instead, be reduced to whether they followed the instructions on the use of the system, as provided for deployers by art. 4, paragraph 3 AILD. Since such a conclusion seems implausible, and the source of a multitude of unjustified disparities—not least those with respect to the professionals who do not use an AIS— a distinction should then be made between cases in which harm is the consequence of the mere operation of the machine and those in which, on the other hand, human conduct is relevant. However, the difficulty of making such a clear separation has already been shown and entails a very complex disentangling of an articulate and hard to observe causal relationship.

Ultimately, either the AILD would be most frequently disapplied, arguing that damage is never a consequence of the functioning of the machine (as instead required by art. 4, paragraph 1, letter (c) AILD) or, to the contrary, with an outcome that is hardly agreeable on both a theoretical and policy perspective, apply it always, flattening the liability of the practitioner onto that of the deployer, radically transforming its nature. This ambiguity of potential outcomes will increase *ex ante* uncertainty and fragmentation.

After all, considering the pervasiveness of technology and the ever-increasing number of areas in which it will be employed, these kinds of considerations-about the complexity of coordination between these provisions and those with which they will have to be integrated-are bound to increase.

3.4. The AILD as a solution to the issue of civil liability and AI: a critical assessment

To summarize the assessment of the proposal for an AILD, several points may be raised, that are both of technical and political relevance.

Indeed, we need to acknowledge that the Commission had a two-pronged proposal, consisting of the PLDr and the AILD respectively, to address the issue of civil liability and advanced technologies. In fact, irrespective of the very broad formulation of the notion of product—characterizing the PLD as a horizontal, technology-neutral piece of legislation—the application of those norms appears too costly and too complex for daily use, and has been residual, until today. By presenting the AILD together with the PLDr the Commission demonstrated that it was aware of the insufficiency of the latter in tackling

the issue of civil liability arising from the use of AIS through rules merely holding the manufacturer responsible.

In such an overall perspective, the AILD represented an attempt to minimize the effects of European intervention, compared to what had been advanced by experts over the years (see §2.3), as well as proposed by the European Parliament with the RLAI, and frequently stated by the Commission itself (see Chapter 2). A closer look will, instead, question the truth of such an idea.

3.4.1. A technical perspective: the unintended interferences with MS's general principles of tort law

However, irrespective of all other considerations, the Commission's declared intentions of providing—with the AILD—for a minimal normative intervention that "[…] can fit without friction in existing civil liability systems […]"[163] is plainly implausible.

It is true that articles 3 and 4 AILD provide for mere procedural rules, however, those rules recall a specific notions of fault—intended in an objective fashion, as the violation of a rule of conduct (*Verkehrspflicht*)—that is not common to all MS's legal systems and, within the same legal system, does not apply to all fault-based liability rules. A case in point is offered by example n. 2, whereby the application of the presumption would require applying the objective variation of fault, and medical malpractice, instead, requires a subjective assessment of the reprehensibility of the behaviour of the practitioner.

Similarly, the way the causal nexus is framed—and its artificial splitting in two parts—is also not typical of MS's legal systems, certainly not all of them and does not truly simplify the task of the claimant (see below), as per the intentions of the European legislator.

We can therefore not agree with the statement issued by the commission to accompany the proposal, whereby the text

> "[…] does not touch the definition of fundamental concepts such as "fault" or "damage," [given how] the meaning of these concepts varies considerably in the member states. Thus, beyond the presumptions it establishes, this Directive does not affect Union or national rules determining […] how fault is defined"[164].

This very aspect represents one of the most problematic profiles in a policy perspective, potentially increasing conflict that prevents the reaching of political agreement on the proposal (see Chapter 3).

3.4.2. Continued: complex application, limited efficiency

If the purpose is to provide an easy to apply solution, minimally invasive for MS's legal frameworks, the AILD is not an ideal proposal. On the one hand, the provision on disclosure obligations (art. 3 AILD, see §3.3.1) describes a sufficiently complex and costly procedure that will only be applied in a limited set

[163] European Commission (2022). Proposal for a directive of the European Parliament and the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive) COM(2022) 496 final. Brussels., 11.

[164] Ibid.

of cases, as discussed above. Litigation costs are increased by such norms, that open to the possibility of defendants' strategic behaviour—such as information overflow—merely allowing for access to evidence (or a rebuttable presumption of fault, when the obligation is violated). Afterall, such a measure may be useful only in high-stake litigation, absent more favourable and alternative liability rules that claimants will, most likely, prefer.

On the other hand, presumptions still require the party to prove a breach of one of the enumerated rules of conduct, but even more so, to prove at least part of the causal nexus. We have clarified that the bifurcation of the causal nexus is artificial and that in most cases it will still be necessary to assess the entire causal chain of events, actions and omissions leading to the incident (see §3.4). Once all these requirements are successfully met, the result is the operation of a mere rebuttable presumption. The benefit to be gained is thus limited and uncertain in its outcome (see also §4.3), while the costs to be incurred are both relevant and certain. It is therefore very likely that claimants will apply other, more favorable rules applicable at the MS level.

3.4.3. Continued: Limited cases of concrete application

Moreover, a closer scrutiny demonstrates that, despite the relevant ambiguity about the real scope of application of the proposed directive (see §4.2), the cases where it might find concrete application are indeed limited.

Based on the examples discussed above (see §3.4), a broader analytical framework emerges that reveals the practical limitations of the AILD's approach when applied to concrete cases involving AIS. Three distinct scenarios can theoretically be identified:

- Scenario 1: The defendant violates a duty of care that is not AI-specific (e.g.: general traffic rules or professional standards) while using an AI system.
- Scenario 2: While using an AI system, the defendant violates AI-specific obligations as defined by the AIA or related legislation.
- Scenario 3: While using an AI system, the defendant does not violate any AI-specific rules, but damage occurs due to the conduct of other parties or external factors.

According to the AILD's scope of application, since an AI system is involved in all three scenarios, the directive would theoretically apply. However, in practice, the directive's application is far from assured.

- In Scenario 1, the injured party would be unable to satisfy the prerequisite under art. 4(1)(a) of the AILD, since fault is defined as the violation of an AI-specific rule of conduct. Since the defendant breached general duties of care, the claimant cannot access the procedural advantages of the directive and must rely entirely on national tort law.
- In Scenario 2, the injured party can demonstrate fault in the form of a breach of an AI-specific obligation and potentially satisfy the other conditions laid down by art. 4(1). This would allow them to benefit from the presumption.

- In Scenario 3, despite AI involvement, the injured party cannot establish fault under the AILD since no AI-specific duty was violated, having no access to the procedural advantages of the directive.

Thus, when faced with a concrete case, the primary challenge for the claimant is to determine whether damage resulted from the functioning of the AI system or from other causes. This entails solving the most complex part of the case, namely the disentangling of a potentially complex and obscure causal nexus. Any effort to discuss fault beforehand would result potentially unproductive.

In example 1 above, before attempting to prove the violation on part of the driver of AI-specific deployment obligations, the injured party should first establish whether the accident resulted from the operation of the AIS or purely from human conduct. This preliminary assessment of causation - precisely what the Directive sought to facilitate through presumptions - thus becomes a prerequisite for access to those very remedies. This creates a circular problem that undermines the purpose of the Directive.

3.4.4. Continued: the multiplicity of alternative interpretation and the role of courts

Both norms—art. 3 and 4 AILD—leave broad room for interpretation to courts. Considering the breadth and diversity of AIS and their possible applications[165] this could be seen as an optimal choice, allowing for the flexibility of the overall legal system, respectful of MS's national liability rules.

Yet, this is not the case. On the one hand, these norms inevitably lead to profound interferences with substantive law on very delicate profiles, such as causation and fault (see §4.1). On the other hand, they are so vaguely formulated that they do not benefit the judge, who is called upon to apply them without any meaningful guidance and with the sometimes impossible task of reconciling these concepts with national ones, in the application of rules that already have their own interpretation and corresponding case law.

At the same time, to defer to the individual interpreter the clarification of such complex boundaries and concepts, that a decade-long policy debate failed to transpose into a precise, well-defined and timely solution, is tantamount to renouncing regulating this domain entirely.

The result can only be fragmentation and a-systematicity of solutions processed (see §3.4.8).

3.4.5. Continued: the underdefined and excessively broad scope of application

The exact scope of application of the AILD is underdefined. The pervasiveness of AIS and their progressive diffusion in most domains will cause a regulatory expansion of those norms that is hard to anticipate. Indeed, pursuant to art. 1, paragraph 2 "[t]his Directive applies to non-contractual fault-based civil law claims for damages [...]".

Above all, such an approach seems excessive. Given the very broad spectrum of applications that can be ascribed to the concept of AI and the extreme diversity that characterizes them, a more analytical

[165] This is actually a reason of concern and criticism towards a purely horizontal approach to regulation. On this please allow reference to Bertolini, A. (2022). "Artificial Intelligence does not exist! Defying the technology-neutrality narrative in the regulation of civil liability for advanced technologies." Europa e diritto privato(2): 369. ff.

method would be preferable, both with respect to kinds of applications (see also §4.6), and to the liability rules it could apply to.

Moreover, given how complex coordination between European and MS's law in fields such as fault-based liability rules, deeply rooted in the respective legal traditions, a more minimalist approach in such a perspective would have been wiser in a policy perspective too (see Chapter 4).

3.4.6. Continued: the problem with definitions

The AILD relies on the distinction between h-AIS and non-h-AIS that may be derived from the application of art. 6 AIA. A detailed assessment of art. 6 AIA falls beyond the purposes of this very study and yet it is most certainly one of the most complex norms to interpret and apply within the AIA[166]. However, two aspects would need to be clarified.

Firstly, art. 6(4) AIA allows for manufacturers to draft declarations whereby they support the conclusion that their otherwise h-AIS should not be classified as such, for the purposes of the application of the AIA as well as other pieces of legislation, including the AILD. Yet, there is no official procedure that allows a final conclusion to be reached, whereby the competent national authority accepts or rejects such documented claim. Similarly, the very classification of a given system as h-AIS is dependent upon a number of complex factors to be balanced (art. 6, (1) and (2) AIA), as well as exceptions (art. 6, (3) AIA), and the result is not so tightly necessitated. Uncertainty may very well persist. Absent a clear moment where the conclusion about a given AIS being high risk or not is clearly reached, and possibly certified by competent authorities, it may be possible that single courts conclude a given AIS is high-risk for the purposes of applying the—specific provisions that are only applicable to h-AIS within the—AILD. Different courts could reach different conclusions, leading to inconsistent application and regulatory uncertainty for manufacturers.

Secondly, the provisions applicable to non-h-AIS leave even more room for interpretation to national courts and are, most likely, radically superfluous, especially considering the breadth of the notion of AI embedded in the AIA. Indeed, most of the applications captured will be completely unproblematic, not requiring any intervention. It would therefore be advisable to avoid such unnecessary complexity and limit the scope of application of the AILD to h-AIS only.

3.4.7. Some policy implications: inefficiency, lack of adequate protection and risk of disapplication

The technical analysis conducted so far has direct policy implications, some of which were already anticipated in the previous sections. However, some specific concerns emerge that deserve to be directly addressed, also in light of the conclusions reached in the previous chapters (see §1.4 and §2.5).

[166] Please allow reference to Bertolini, A., F. Fedorczyk, M. M. Mollicone and G. Migliora (2025). Defining High-Risk AI Systems Understanding the Complexity of the AIA Definitions. European Robotics Forum 2025. Cham, Springer.and for a more in-depth discussion Bertolini, A., F. Fedorczyk, M. M. Mollicone and G. Migliora (forthcoming, 2025). "The Brussels Sphinx's Riddle. What is a high-risk AI System?" Working Paper.

The primary concern with respect to the AILD seems to be that of overall inefficiency. In particular, a limited procedural benefit (a rebuttable presumption) is achieved through complex assessments (see §3.4) that do not substantially reduce the effort required by the claimant (see §3.4.7), and that is only possible in a limited number of cases (see §3.4).

Similar considerations may be drawn with respect to the advantages ensured by possible disclosure obligations (see §3.4.10).

Absent more efficient protection of the claimant's interests, it is reasonable to expect seldom application of the AILD, and the elaboration of alternative solutions at MS level, most likely rooted in substantive—not procedural—law. The same already occurred with the PLD (see §2.4.3) for the same reasons of a limited benefit compared to the complexity and cost of litigation.

3.4.8. Continued: uncertainty and (the risk of) fragmentation

At the same time, the wide scope for interpretation given to the courts by the AILD will inevitably lead to *ex ante* uncertainty of outcomes, discouraging litigation to recover damages and preventing efficient internalization of costs by business parties.

In particular, the very definition of h-AIS may cause uncertainty about the exactly applicable liability regime to each single system (see §3.4.5). As per disclosure obligations, instead, both the exact definition of *fumus*—thence the amount of evidence one needs to reach to trigger the duty to disclose—as well as the need to balance opposing interest of the parties, leave relevant discretionary power to judges (see §3.1). This also applies to the conditions for the application of the presumption, in particular with regard to the part of the causal link that must be proven anyway (see §3.4). The first hypothesis considered, is one where the liability of the defendant is transformed in a very strict liability rule, almost amounting to a vicarious liability. The second hypothesis corresponds, instead, to a solution that would render the presumption almost useless, having the party already demonstrated the most complicated aspect of causation (see §3.4).

As a consequence, fragmentation will result from divergent decisions that will be difficult to harmonize, as well as from the tendency to resort to national solutions that appear to be more efficient (see §4.7) in protecting the interests of claimants.

Overall, this risks triggers that very form of over-regulation that European policymakers aim to avoid, that is the consequence of both the adoption of inefficient rules and of the proliferation of divergent national regimes, multiplying the rules firms will have to abide by (see §1.5).

3.4.9. Continued: a politically-complex task of—unnecessary—harmonization of tort law

One of the issues raised by the European Commission when considering withdrawing the proposal was that of the difficulty in achieving a political agreement among MS[167].

A peculiar aspect that might justify such concern is that the AILD, while pursuing a minimally invasive intervention, would most likely cause a strong interference with MS legal systems in the area of fault-

[167] See §1.2, lett. i.

based liability rules (see §§3.4 and 4.1). In order to achieve a very limited result in terms of protection of AIS users, it forces complex interpretations of the concepts of fault and causal link, which are not so homogeneously defined and applied in national legal systems. The harmonization of general tort—and contract—law rules among MS has always proven most complex, technically and politically speaking[168], and many attempts have failed, even with respect to disciplines that had a rather limited scope of application, such as the proposal for a Common European sales law[169].

In a policy perspective, the effort the AILD requires seems disproportionate compared to the benefit it could bring to claimants; in particular, the fact that it extends horizontally to all MS's fault-based liability regimes seems unjustified.

3.4.10. The need for a special, strict liability rule

Consistently with the findings of the experts, whose opinions were delivered over the years (see Chapter 2), as well as with the concerns here discussed, the solution of conceiving a special liability rule, with a very well-defined scope of application, parallel to and distinct from that of the producer, seems more limited and less problematic an option.

Moreover, still in accordance with the opinions rendered, and the previous statements of European policymakers[170], it should be structured in terms of strict liability, to ensure victim compensation, cost minimization and management, as well as homogeneous application across MS.

In the end, the AILD did not respond to the recommendations made by experts over the years, nor to the concerns expressed by the European Parliament and the Commission.

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168 Please allow reference to Bertolini, A. (2023). European Commercial Contract Law. Bruxelles, European Parliament - Committee on Legal Affairs: 1-103.

169 Commission, E. (2011). Proposal for a Regulation of the European Parliament and of the Council on a Common European Sales Law, COM (2011) 635 final.. For some criticism in academic circles on the introduction of a 'twenty-ninth regime' of sale of goods, see Micklitz, H.-W. and N. Reich (2012). The Commission Proposal for a 'Regulation on a Common European Sales Law (CESL)' – Too Broad or Not Broad Enough? EUI Working Paper LAW 2012/04 ERPL-03. Florence, European University Institute Florence: 1-87.; Zimmermann, R. (2012). "Diritto privato europeo: 'Smarrimenti, disordini'." Contratto e impresa/Europa 17(1): 7-36.; Ajani, G. Ibid."Un diritto comune europeo della vendita? Nuove complessità." 71-85.

170 See European Commission (2020). Report from the Commission to the European Parliament, the Council and the European economic and social Committee on the safety and liability implications or Artificial Intelligence, the internet of Things and robotics, COM/2020/64 final, European Commission.; European Parliament (2020). Civil liability regime for artificial intelligence. European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL)). Brussels, European Parliament.; European Commission (2021). Inception Impact Assessment. Adapting liability rules to the digital age and circular economy. Ref. Ares(2021)4266516. Brussel, European Commission.

4. CONCEIVING AN IDEAL REGULATORY FRAMEWORK FOR CIVIL LIABILITY AND AI

KEY FINDINGS

1. Threefold Regulatory Purpose

An optimal liability regime for advanced technologies must pursue three mutually reinforcing objectives: (i) substantive harmonisation to prevent regulatory fragmentation within the internal market; (ii) effective victim compensation through simplified liability mechanisms; and (iii) regulatory clarity ensuring ex ante predictability for economic operators. These aims collectively justify EU-level legislative intervention only insofar as they enhance coherence without introducing additional complexity.

2. Limitations of Existing Proposals (PLDr and AILD)

Neither the revised Product Liability Directive (PLDr) nor the AI Liability Directive (AILD) adequately address the distinctive risks posed by AI. Their formal adherence to technological neutrality and procedural generality fails to reduce litigation costs or adapt to domain-specific liability challenges. This lead to a *de facto* underutilisation of the PLDr and a misalignment between the AILD and national fault-based systems.

3. Ambiguity and Inefficiency of Technological Neutrality

The notion of technological neutrality is conceptually unstable and practically inadequate for AI regulation. It obscures the heterogeneity of AI systems—ranging from LLMs to autonomous vehicles—and fails to accommodate their divergent risk profiles, thereby either over-regulating low-risk systems or under-regulating high-risk ones.

4. Superiority of a Class-of-Application Approach

A granular regulatory strategy, based on the classification of AIS by domain of use and technical characteristics, offers superior legal clarity and incentive alignment. It ensures regulatory proportionality, avoids overreach, and accommodates sector-specific policy rationales. Over time, this model permits the reabsorption of AI regulation into broader sectoral frameworks, as with traffic, medical, or financial regulation.

5. Conditional Adoption of the High-Risk AIS Criterion

The risk-tiered model introduced by the AI Act, particularly the definition of high-risk AI systems (h-AIS), may serve as a pragmatic criterion to delineate the scope of liability rules. However, this requires the development of a certification mechanism to ensure ex ante clarity and avoid divergent judicial determinations. Moreover, the creation of residual categories of non-high-risk AIS must be avoided to preserve legal certainty and avoid disproportionate expansion of ill-defined liability regimes.

6. Merits of Strict Liability and the Operator Model

A strict liability rule targeting the operator of an AIS—understood as the party in control of its functioning and deriving benefit from its use—emerges as the most coherent and effective approach. This model bypasses the limitations of defect-based liability and internalises risk through clearly assigned obligations. The European Parliament's 2020 RLAI proposal illustrates the feasibility and advantages of this model.

7. Critique of Joint and Several Liability under Causal Uncertainty

The simultaneous designation of multiple "operators" leads to normative confusion and fails to resolve causal uncertainty, particularly in complex human-machine interactions. Unlike alternative causation scenarios, pure causal uncertainty—prevalent in AI-related incidents—cannot be addressed through joint and several liability. A one-stop-shop approach identifying a single liable party is therefore preferable.

8. A One-Stop-Shop Model Anchored in Risk Management

The most effective liability model would designate a sole defendant based on the principle of risk management. The liable party—be it a provider or deployer under the AI Act—would be best placed to prevent harm and manage its costs. This approach would significantly reduce litigation, enhance foreseeability, and facilitate insurance coverage and cost distribution across the user base. Holding both the provider and the deployer liable pursuant to a strict liability would prove coherent with the overall regulatory framework (AIA), and would not cause causal uncertainty because it would always be possible to determine which one of the two is liable for the specific operation.

7. Exclusion of Liability Defences and Alignment with a Compensatory Rationale

The exclusion of liability defences, except for force majeure, supports the compensatory rationale of strict liability. Attempts to balance deterrence and compensation through layered defences increase complexity and undermine legal certainty. The framework may, however, allow limited defences where the victim's grossly negligent conduct is the exclusive cause of harm.

8. Risk Redistribution and Efficiency Gains

A robust right to recourse for the liable party—against upstream actors in the value chain—ensures equitable cost-sharing and encourages the internalisation of risk. Combined with market-based insurance mechanisms and economies of scale, this structure promotes efficient risk management while reducing systemic litigation costs. Moreover, comprehensive damages should be compensable, including those suffered by the AIS itself, to ensure the attractiveness of the dedicated regime over fragmented alternative remedies

4.1. Introduction

The analysis carried out showed that both experts (see (see §2.3.3) and European institutions (see §1.2) consider it necessary to design a European legal framework for civil liability arising from the use of advanced technologies.

While general tort law principles permit courts to address novel harms, this reliance on domestic judicial discretion is likely to produce three structural shortcomings.

First, the proliferation of divergent national rules and case-law interpretations generates a fragmented liability landscape that corrodes the unity of the internal market. Second, the burdens of proof and procedural complexity inherent in conventional tort litigation impede swift victim redress and inflate the costs of dispute resolution. Third, the lack of clear, uniform liability criteria renders risk assessment opaque for businesses, undermining their ability to forecast potential obligations and to allocate insurance or capital accordingly.

Against this backdrop, the three interrelated purposes are identified that any optimal civil-liability regulation for emergent technologies must serve.

In a strategic regulatory perspective, the prevention of fragmentation at the national level through the adoption of a directly applicable, Union-wide instrument is of paramount importance. Such an instrument would pre-empt the emergence of disparate domestic statutes and judicial doctrines—whether in automated-driving regimes, sector-specific AI bills or other bespoke measure—that risk crystallising into barriers to cross-border deployment, also leading to over-regulation (see §1.5). By harmonising substantive—non merely procedural—tort rules, in a well-defined domain—of advanced technologies, or better a sub-domain within it—(see §2.3), a uniform European framework ensures that similar acts of technological operation yield comparable outcomes irrespective of the Member State in which harm occurs. This legal cohesion both sustains the free movement of goods and services and obviates costly forum shopping and regulatory arbitrage.

If a primary policy purpose were to be identified for such a framework, that would be ensuring effective victim compensation while reducing litigation and its associated—administrative—costs. In the context of advanced technologies, harm may be diffused, complex and costly to prove, especially in comparison to the euro amount of damages caused. Such kind of prejudices are those whereabout it is hardest to force internalization.

A regulatory regime that incorporates clear presumptions of causation or strict-liability rules for operators of high-risk systems will lower evidentiary hurdles and transform indeterminate legal exposure into quantifiable, insurable liabilities (see Chapter 4). By internalising risks and imposing predictable obligations on suppliers and deployers of technology, the system incentivises prompt compensation, discourages protracted disputes and conserves judicial resources. In turn, this streamlined approach enhances access to justice for injured parties and bolsters public confidence in technological innovations.

Finally, the combination of both rationales leads to the simplification of the regulatory framework, leading to foreseeability of outcomes for businesses. Regulatory clarity—achieved through narrowly

tailored, unambiguous provisions—reduces interpretative uncertainty and eliminates overlaps between different legal regimes and multiple tort law rules (see §2.5 and §3.4). When enterprises can anticipate their potential liability ex ante, they are better equipped to price products, to secure appropriate insurance cover and to integrate liability costs into commercial planning, eventually distributing it to the pool of users (see §1.3, and §1.4). This predictability fosters a stable environment for investment, mitigates risk-averse behaviour and supports the early adoption of beneficial technologies.

These three aims—harmonisation, compensation-efficiency and predictability—are mutually reinforcing and collectively define the parameters of any future Union-level intervention in tort law. Regulatory action is justified only to the extent that it demonstrably advances these ends without engendering additional complexity or undermining the very coherence it seeks to establish. Having enunciated these guiding purposes, the chapter will proceed to sketch the characteristics of an optimal liability system that aligns fully with the foundational objectives set forth (see §4.1).

4.2. A well-defined scope of application

In a policy perspective, the PLDr was not intended to be the sole regulatory intervention in the field of civil liability arising from the use of advanced technologies (see §3.2), and with its current structure, it will not be able to solve all the originally identified concerns associated with ensuring compensation for damages arising from AI (see §2.4). In particular, the notion of defect—intended as lack of safety, not performance—the limitations to recoverable damages—including the exclusion of those to the defective product itself—and the overall costs of litigation—not reduced by disclosure obligations and presumptions—will most likely widespread a diffused application of those norms, for smaller—in value—and more frequent claims, which will, instead increase in frequency with the diffusion of automation (see §2.5).

Similarly, the proposal for an AILD seems inadequate to tackle those concerns efficiently—in light of its merely procedural provisions—but also due to the complexity of combining those general principles—and the concepts of causation and fault they implied—with all—the numerous—MS's fault-based liability rules, so long as an AIS was involved (see §3.4.10).

Indeed, both the PLDr and the AILD maintain a horizontal approach to regulation—inspired by principles of technological neutrality[171]—attempting to conceive a single liability rule for all defective products in the first case and devising a single procedural remedy for all AIS (despite a differentiation in between high-risk and non-high-risk AIS) in the second case.

At the same time, however, liability rules self-select the cases they apply to, irrespective of the theoretical scope defined by policymakers. Indeed, if the incentives offered do not suffice (e.g.

[171] For a more in-depth examination of the principle of technological neutrality please refer to Bertolini, A., F. Fedorczyk, M. M. Mollicone and G. Migliora (forthcoming, 2025). "The Brussels Sphinx's Riddle. What is a high-risk AI System?" Working Paper., 10; Almada, M. (2024). Delegating the Law of Artificial Intelligence. A Procedural Account of Technology-Neutral Regulation, European University Institute., 73; Maxwell, W. J. and M. Bourreau (2015). "Technology neutrality in Internet, telecoms and data protection regulation." Computer and Telecommunications Law Review(1).; Hildebrandt, M. and L. Tielemans (2013). "Data Protection by Design and Technology Neutral Law." Computer Law & Security Review 29.; Greenberg, B. A. (2016). "Rethinking Technology Neutrality." Minnesota Law Review 100: 1495..

litigation costs are too high compared to the value of the claim) parties will either not sue, or will resort to other pieces of legislation, somewhat applicable, that ensure a different balance of incentives. This is exactly what was observed with PLD-based litigation (see §2.3.4), where strong clustering was observed in only a few domains[172]—despite the absolute breadth of the notion of "product" according to art. 2 PLD—and where, in many instances, other norms—in tort and contract law— have been preferred by plaintiffs seeking compensation[173].

4.2.1. Selecting what AIS to regulate

At a closer look, technological neutrality is per se ambiguous[174] and does not necessarily ensure rules will be fit for technological evolution without adaptation. A case in point is offered by the PLD that, already in its original formulation, adopted a technology neutral stance, and yet required reform to adapt to emergent technologies (see §2.3.5). The same is true for fault-based rules that operate in each MS's legal system as a general rule of liability, applicable across domains. Those general norms—often referred to as general clauses of liability[175]—are often replaced in specific domains through the adoption of dedicated norms that provide a preferable incentive structure, given the specific interests at stake.

Indeed, liability rules determine the incentives each party involved will face to entertain a given activity or maintain a given conduct or pursue a specific enterprise. Legal systems shape those incentives very differently according to the domains considered. Civil liability rules applicable to medical malpractice

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[172] If you refer to Ernst&Young, Technopolis and VVA (2018). Evaluation of Council Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products. Brussels, European Commission. you can notice that most of the cases where litigation occurred were clustered in 4 domains.

[173] Ibid., xii, where it is said that: "Courts uphold most claims based on the Directive in favour of the injured person, and sometimes this happens on a different legal basis (such as tort law or contract law) even if the claimant invoked the Product Liability Directive."

[174] Indeed, the term may be used in different ways and to imply different concepts. For instance, technological neutrality can be interpreted as (i) a means to structure markets, (ii) a limit on harmful externalities, or (iii) a way to define the scope of regulation. Please allow reference to Bertolini, A., F. Fedorczyk, M. M. Mollicone and G. Migliora (forthcoming, 2025). "The Brussels Sphinx's Riddle. What is a high-risk AI System?" Working Paper., 10-11. It is also not true that all technologies should be treated the same, and, in such a perspective, not even the AIA is a technology neutral piece of legislation, in as much as it distinguishes according to levels of risk and prohibits certain practices (art. 5 AIA).

For some criticisms to a uniform and horizontal regulatory approach, please refer to Bertolini, A. (2020). Artificial Intelligence and Civil Liability. Bruxelles, European Parliament - Committee on Legal Affairs: 1-132.

[175] In a comparative perspective, for general clauses of non-contractual liability, see *Art. 2043 of the Italian Civil Code* ("Qualunque fatto doloso o colposo, che cagiona ad altri un danno ingiusto, obbliga colui che ha commesso il fatto a risarcire il danno"), which establishes a general principle of liability based on fault and unjust damage; *§ 823(1) of the German BGB* ("Wer vorsätzlich oder fahrlässig das Leben, den Körper, die Gesundheit, die Freiheit, das Eigentum oder ein sonstiges Recht eines anderen widerrechtlich verletzt, ist dem anderen zum Ersatz des daraus entstehenden Schadens verpflichtet"), which identifies specific protected interests and conditions for liability; art. *1382 of the Code Napoléon* (now *Article 1240 of the French Civil Code*), which states that "Tout fait quelconque de l'homme, qui cause à autrui un dommage, oblige celui par la faute duquel il est arrivé à le réparer". These general clauses have historically provided the foundational framework for extra-contractual liability, subject to refinement or replacement in sectors where more specific regulatory objectives require tailored rules of responsibility. For an in-depth analysis see Franzoni, M. (2020). Fatti illeciti. Artt. 2043-2059. Commentario al codice civile. V. S. G. B. F. Galgano. Bologna, Zanichelli: 1-968, Wagner, G. (2020). sub § 823. Münchener zum BGB. München, Beck: 1677.

do not correspond to those laid down for traffic accidents, or for intermediaries operating in financial markets because the incentives policy makers intend to provide differ substantially.

On the one hand, AI is pervasive and will be used in most domains. If identical rules for civil liability are adopted for all AI-based applications, this will have a very strong horizontal effect in fields that have been kept radically distinct until today, abiding by different rationales and influenced by at times opposed incentive structures. A horizontal approach will reduce the power of policymakers to shape incentives in different domains of human activity (see §2.3).

On the other hand, AI is used as such a broad and all-encompassing concept that treating all those applications uniformly is unjustified also in a purely technological perspective[176] . Neither autonomy, nor the ability to learn or modify itself over time are traits that are common to all AI-based applications, and the domains today encompassed by this notion are as diverse as to include large language models and industrial robotics alike. AI-based applications range between diagnostic tools, to high-frequency trading algorithms, to social and bio-inspired robotics, autonomous vehicles, and software agents. Any attempt to identify a common minimum denominator from a technical standpoint is doomed to fail[177].

Moreover, the dynamic nature of machine-learning processes renders any one-size-fits-all definition of "intelligence" inherently unstable. Techniques that once appeared novel inevitably become absorbed into standard software practice, thereby blurring the boundary between "AI" and "mere automation." To the extent that liability rules hinge on an amorphous conception of "artificial intelligence," they will either over-capture legacy systems whose functions no longer justify heightened scrutiny or under-capture emergent applications whose risks have not yet been fully appreciated. A technology-neutral approach thus risks perpetuating uncertainty for both developers and end-users.

Finally, the risk profiles associated with these diverse systems likewise diverge: an algorithmic decision-support tool in medical diagnostics implicates questions of clinical risk—and, for other purposes—informed consent, whereas an autonomous vehicle system raises issues public safety, on top of individual harm. At the same time, while from a technological standpoint some similarities could be drawn with other mobile robots—be it a household application[178], or an industrial cobot[179]— the

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[176] AI is a constellation of methodologies—from supervised and unsupervised machine learning models to reinforcement-learning agents and rule-based expert systems—whose modes of operation, data dependencies and autonomy levels vary fundamentally. AI is a moving target—see Bertolini, A. (2024). Intelligenza Artificiale e responsabilità civile. Problema, sistema, funzioni. Bologna, Il Mulino., 20 ff—and what is deemed to fall under this notion varies over time. Originally the term was conceived by Alan Turing but most likely its fortune, also in terms of the development the field witnessed over the years, is a consequence of the ambiguity of its very notion, see Agre, E. P. (1997). Toward a Critical Technical Practice: Lessons Learned in Trying to Reform AI. Social Science, Technical Systems, and Cooperative Work: Beyond the Great Divide. G. Bowker, L. Gasser, L. Star and B. Turner. Erlbaum, Psychology Press: 496. 131.

[177] Please allow reference to Bertolini, A. (2022). "Artificial Intelligence does not exist! Defying the technology-neutrality narrative in the regulation of civil liability for advanced technologies." Europa e diritto privato(2): 369.

[178] Such as a vacuum cleaner, which is an autonomous mobile devices equipped with sensors, actuators, and increasingly, artificial intelligence components. This robot represents a prominent case of service robotics deployed in domestic environments. See Ebers, M. (2019). "Regulating Domestic Robotics: Legal Challenges and the Role of Standards." Law, Innovation & Technology 11(2): 190-213.

[179] Industrial robots are defined under ISO 8373 as "automatically controlled, reprogrammable, multipurpose manipulators programmable in three or more axes". They are widely used in manufacturing, logistics, and assembly lines. The allocation

peculiarities of the environment where it is intended to be used also influence both the amount and kind of harm it may inflict.

A horizontal liability regime that treats these technologies interchangeably would risk both regulatory overreach—by imposing excessive constraints on low-risk applications—and harmful under-inclusiveness—by failing to address the unique dangers of high(er)-risk systems.
As per other aspects of the design of an ideal civil liability framework for advance technologies, broad agreement was reached by experts on this point as well[180].

4.2.2. Alternative criteria: regulating classes of applications

There are multiple alternative approaches to the regulation of civil liability for AI that may be considered, with higher or lower degree of granularity, and that—to some extent, at least—could be combined one with the other.

A first approach would be a bottom-up, class-of-application-by-class-of-application approach[181]. AIS could be classified according to both technical characteristics and domain of use, thence taking into account the specific risks they give rise to.

Regulation would then be conceived for such specific classes that demonstrate the need for a direct intervention, both to favour the diffusion of the technology[182], to limit the exposure of the professional user of the technology[183], to clarify how responsibility should be apportioned among a multiplicity of potentially liable parties[184], to prevent systemic risks that could lead to relevant public concerns[185].

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of responsibility becomes particularly challenging in collaborative robotics (cobots), where operator error, programming flaws, or sensor failure may contribute simultaneously to an accident. On the point, see Pagallo, U. (2013). Laws of Robots. New York, NY, Springer. 214-247.

180 See Expert Group on Liability and New Technologies – Product Liability Formation (2019). Minutes. Meeting of the Expert Group on "Liability and New Technologies – Product Liability Formation". Brussels, European Commission., 36 ff. Please also allow reference to Bertolini, A. (2020). Artificial Intelligence and Civil Liability. Bruxelles, European Parliament - Committee on Legal Affairs: 1-132. and Evas, T. (2020). Civil Liability Regime for Artificial Intelligence. Brussel, European Union.

181 Please allow reference to Bertolini, A. (2013). "Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules." Law, Innovation and Technology 5(2): 214 - 247.; Bertolini, A. (2020). Artificial Intelligence and Civil Liability. Bruxelles, European Parliament - Committee on Legal Affairs: 1-132.

182 An example could be that of prosthetic limbs and exoskeletons, used by people with disabilities for the purposes of improving their quality of life, as required by art. 4 (g) of the UN Convention on the Rights of People with disabilities, on this matter please allow reference to Bertolini, A. (2015). "Robotic prostheses as products enhancing the rights of people with disabilities. Reconsidering the structure of liability rules." International Review of Law, Computers & Technology 29(2-3): 116-136. and Bertolini, A. (2024). Intelligenza Artificiale e responsabilità civile. Problema, sistema, funzioni. Bologna, Il Mulino. 235-236, fn 60.

183 That could be the case of the medical practitioner, on which please allow reference to Wei, J., E. Verona, A. Bertolini and G. Mengaldo (forthcoming). "Explainability matters: The effect of liability rules on the healthcare sector." preprint arXiv:6585771.

184 This could be the case of traffic accident, on which please allow reference to Bertolini, A. and M. Riccaboni (2020). "Grounding the case for a European approach to the regulation of automated driving: the technology-selection effect of liability rules." European Journal of Law and Economics: 243-285.

185 Such as it could be in the cases of high-frequency trading. Cfr. Azzutti, A. (2022). "AI trading and the limits of EU law enforcement in deterring market manipulation." Computer Law & Security Review 45: 105690.

Such a more fragmented approach, stratifying over the years, and adopted through multiple normative acts, allows for greater precision in the analysis, as well as targeted solutions. By anchoring regulatory criteria to technical peculiarities and to social stakes, it allows to maximize legal clarity and to align liability incentives with the real-world operation of each system class. At the same time, it minimizes risks of both legal uncertainty and over-regulation, since definitions will be unambiguous and the scope of the legislation well-defined as a consequence thereof.

A class-of-application framework also accommodates the plurality of stakeholder interests that AI deployment engages. Developers require clear, predictable liability benchmarks in order to invest in research and to obtain insurance coverage. End-users and bystanders demand accessible mechanisms for redress when harms materialise. Public authorities must safeguard fundamental rights—such as privacy, equality and non-discrimination—without impeding legitimate innovation. By eschewing a horizontal, technology-neutral paradigm in favour of a nuanced regulatory schema, legislators can reconcile these competing objectives within each application domain.

The natural evolution of such an approach is that of regulating all human activities, as we did until today as a society, taking into account, alongside other relevant factors, the use of AIS and other advanced technologies. Put another way, the ubiquitous nature of AI will soon lead us to regulate the medical profession, capital markets, traffic on public roads, and all the other areas of human activity that we already regulate, taking into account the use of AI there and the specific risks it poses in each area. Instead of regulating AI, we will soon be back to regulating human activities in light of the use of advanced technologies[186].

The main downside of such a regulatory approach is that of the greater costs and time, potentially associated with the development of a multiplicity of normative acts. However, having a more specific object to regulate, discussions could be most on point and limited.

Often policymakers state that after more general and broader normative intervention, dedicated provisions and acts will follow[187]. While this is certainly possible, and maybe necessary in specific

[186] In a theoretical perspective this reasoning entails refusing so-called exceptionalism—Calo, R., A. M. Froomkin and I. Kerr (2016). Robot Law. Cheltenham (UK) - Northampton (MA, USA), Edward Elgar Publishing.—the law of the horse to embrace a legal-technical approach, whereby the existing legal tools need to be used to tackle the new challenges posed by advanced technologies. Techlaw or robolaw or AI-law is not a separate field of law, next to private, constitutional, criminal, international law (to name a few), and does not need to abide by its own peculiar principles. This does not entail reducing advanced technologies to "the horse"—Easterbrook, F. H. (1996). "Cyberspace and the Law of the Horse." University of Chicago Legal Forum(1).– for they pose challenges that may require to question the adequacy of existing legal categories and solutions alike—see also Castronovo, C. (2006). "Diritto privato generale e diritti secondi la ripresa di un tema." Europa e diritto privato(2): 397-423.—but certainly it rejects an approach rooted in pure exceptionalism, please allow reference to Bertolini, A. (2020). Artificial Intelligence and Civil Liability. Bruxelles, European Parliament - Committee on Legal Affairs: 1-132.. Similar considerations appear to be shared by Wagner, G. (2019). "Robot, Inc.: Personhood for Autonomous Systems?" Fordham Law Review 88: 591-612.

[187] See European Commission (2020). White Paper - On Artificial Intelligence - A European approach to excellence and trust. COM(2020) 65 final. Brussels, European Commission., 10; European Parliament (2020). Civil liability regime for artificial intelligence. European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL)). Brussels, European Parliament., 4 and 10; Commission, E. (2020). Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee. Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics.

domains, excessive stratification should be avoided, for they give rise to problems of coordination between legislative acts, especially when they are layered at MS and European level.

4.2.3. Continued: regulating high-risk AIS

An alternative approach, that may pursue a similar end, is that of focusing the regulation of civil liability for AI on h-AIS, especially excluding the regulation of residual categories.

Indeed, the AIA has certainly created a path-dependency in European technology law by embracing a distinction articulated pursuant to so-called risk levels. The choice could per se be criticized. In particular, it could be argued that the grouping of applications provided for by the AIA (especially art. 6 AIA) is not based on the real assessment of a measurable level of risk. The applications that are classified as high-risk are very different one from the other, and no criteria were laid down to calculate their respective impact on users (e.g. on fundamental rights)[188]. The classification is thus rooted in specific policy choices, that are certainly admissible on the part of the legislator, yet do not necessarily justify considering those application equally dangerous. While this is lesser of a concern when *ex ante* safety rules are considered—of the kind laid down by the AIA—[189] it may give rise to more problematic implications if applied to liability rules. Indeed, that could be the case if more stringent a regime of responsibility was established that only applies to a specific AIS and not to a similar one—in terms of characteristics and functionalities—[190], only because—at least temporarily[191]— the latter escapes art. 6 AIA.

However, reasons of harmonization and internal coherence of European law could encourage the adoption of the notion of h-AIS as a plausible criterion to clearly define the scope of a normative intervention in the field of civil liability. Towards this end two further considerations are necessary.

First, art. 6 AIA does not devise a procedure that allows to undoubtedly conclude that a given system is indeed high-risk or not. The qualification depends on a number of assessments that leave room for relevant uncertainty[192] and paragraph 4 allows the producer to differ and provide technical

COM(2020) 64 final. Brussels, European Commission., 11; European Commission (2022). Proposal for a directive of the European Parliament and the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive) COM(2022) 496 final. Brussels., 2.

188 For a detailed discussion please allow reference to Bertolini Andrea (forthcoming 2025). La definizione di sistemi di intelligenza artificiale. Il regolamento europeo sull'intelligenza artificiale: problemi e sistema. S. Orlando and G. Cerrina Feroni.

189 According to Bertolini, A., F. Fedorczyk, M. M. Mollicone and G. Migliora (forthcoming, 2025). "The Brussels Sphinx's Riddle. What is a high-risk AI System?" Working Paper., 3 ff, "Despite being a complex and highly extremely articulated discipline, the AIA can, with some approximation, be qualified as a new example of product safety legislation".

190 Two industrial robots used in a similar setting, both using AI for some obstacle avoidance solution, but only one of the two is necessarily subject to third party certification by a notified body (art. 6 (1)(b) AIA) and the latter, instead, may also choose to self-certify, complying with a harmonized European standard (hEN). For a discussion, please allow reference to ibid.

191 Art. 6, §7, AIA allows the European Commission to modify the list of h-AIS over time.

192 Especially in the assessment of the requisites of paragraph 1, let. (b) and in the concretization of the broad domains of applications recalled by paragraph 2, especially in light of the exceptions granted by paragraph 3, AIA. For a discussion please allow reference to Bertolini, A., F. Fedorczyk, M. M. Mollicone and G. Migliora (forthcoming, 2025). "The Brussels Sphinx's Riddle. What is a high-risk AI System?" Working Paper., 19 ff.

documentation to justify the refusal to qualify the AIS as high risk (see §3.3.3). It would therefore be advisable to conceive a clear mechanism that would assess and certify the correctness of the conclusion reached by the producer or provider of the AIS, and not leave it to the individual assessment of the judge called in to apply the correct liability regime. This would provide much needed legal certainty and foreseeability of outcomes.

Second, it is necessary to avoid creating residual categories of non-high-risk AIS for the purposes of applying a different liability regime, typically less stringent than the one conceived for h-AIS. Indeed, while the benefits in terms of enhanced protection of the victim are limited, the risks in terms of legal certainty are particularly relevant. This was the case in the RLAI and in the AILD alike. However, considering the extremely broad notion of AIS (as per art. 3 AIA) capable of encompassing all sorts of applications (e.g. including a smart toothbrush), any residual category will be too underdefined. On the one hand, it will be impossible to determine ex ante with absolute certainty—absent very precise and stringent criteria—what product would satisfy the requirement to fall into the category and different judges would diverge in their conclusions. On the other hand, the pervasive nature of AI would cause the residual liability regime to expand disproportionately, and eventually replace most tort rules, also at MS level[193].

4.3. A strict liability rule

The main purposes a dedicated set of liability ought to pursue are (i) the simplification of the liability framework, identifying a prima facie responsible party, thus avoiding uncertainty and high litigation costs, that impair access to justice by those who suffer harm[194]; (ii) ensuring mechanisms to sue in recourse all other parties alongside the value chain, who have most directly contributed to generating harm[195]; (iii) preventing the overlapping of different liability regimes, in order to avoid problems of causal uncertainty (see also §2.4 and §3.3.2)[196]; (iv) pursuing as much harmonisation as possible at the European level, to avoid market fragmentation[197].

The ideal approach to achieve such an outcome is through the adoption of a strict liability rule, as experts systematically agreed over time (see §2.3.3). The recommendation formulated by the European

[193] That was a specific risk of the RLAI, whereby the regime set forth by the regulation would prevail over conflicting MS's rules, please allow reference to Bertolini, A. (2022). "Artificial Intelligence does not exist! Defying the technology-neutrality narrative in the regulation of civil liability for advanced technologies." Europa e diritto privato(2): 369.

[194] Si consenta il rinvio ad Bertolini, A. (2013). "Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules." Law Innovation and Technology 5(2): 214–247.; Palmerini, E. and A. Bertolini (2016). Liability and Risk Management in Robotics. Digital Revolution: Challenges for Contract Law in Practice. R. Schulze and D. Staudenmayer. Baden-Baden, Nomos: 225-259.; Bertolini, A. (2020). Artificial Intelligence and Civil Liability. Bruxelles, European Parliament - Committee on Legal Affairs: 1-132.; similarly Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission. ,34 (4).

[195] Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission., 57-58.

[196] Ibid.

[197] Cfr. Bertolini, A. (2013). "Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules." Law Innovation and Technology 5(2): 214–247. and Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission..

Parliament for a Regulation on civil liability regime for artificial intelligence (hereafter RLAI) represents the sole example, until today, of a legislative text embedding such an approach and taking into account the recommendations formulated by the experts[198].

Before moving on to depict the essential aspects that should characterise such a liability framework (see §§4.2-4.3.8) a brief analysis of the RLAI will allow to discuss both the strongpoints of that proposal (see §§4.3.3 and 4.3.4), and those aspects that ought, instead, be reconsidered (see §§4.3.6-4.3.8).

4.3.1. The operator's liability example: an overview

On 20 October 2020, the European Parliament adopted a resolution calling on the Commission to intervene with a regulation—to achieve full harmonisation and maximum certainty[199]— establishing a "horizontal and harmonised legal framework based on common principles [as] necessary to ensure legal clarity", while agreeing that sector-specific regulations are "preferable [given] the broad range of possible applications"[200].

In order to design such a "common liability framework for AI-systems", the Parliament deemed necessary to add a second pillar, next to producers' liability[201], holding the "operator" liable, for he "exercises a degree of control over a risk connected with the operation and functioning of an AI-system, which is comparable to that of an owner of a car [...]" and in many cases will be the first visible point of contact of the affected person[202].

The notion of operator includes "both the frontend and the backend operator as long as the latter's liability is not already covered by Directive 85/374/EEC" (art. 3(d) RLAI). While "frontend operator" means "any natural or legal person who exercises a degree of control over a risk connected with the operation and functioning of the AI-system and benefits from its operation" (art. 3(e) RLAI), "backend operator" means "any natural or legal person who, on a continuous basis, defines the features of the technology and provides data and an essential backend support service and therefore also exercises a degree of control over the risk connected with the operation and functioning of the AI-system" (art. 3(f) RLAI).

Where there is more than one operator, they are held jointly and severally liable (art. 11 RLAI), with reciprocal right of recourse for compensation in proportion to the liability of each (art. 12 RLAI).

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198 Also those appointed by the European Commission Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission. and Bertolini, A. (2020). Artificial Intelligence and Civil Liability. Bruxelles, European Parliament - Committee on Legal Affairs: 1-132.

199 European Parliament (2020). Civil liability regime for artificial intelligence. European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL)). Brussels, European Parliament., 13.

200 Ibid., 7 no 2.

201 Ibid., 13 no 6.

202 Ibid., 16 no 10.

4.3.2. The liability rule(s)

The proposal identified two distinct liability regimes. With respect to h-AIS— determined by reason of their inclusion in an annex that the Commission would undertake to update progressively, inserting or eliminating certain applications (art. 4(2) RLAI) –[203], the strict liability of the operator is established (art. 4(1) RLAI), from which the operator cannot be exonerated by demonstrating that he acted diligently or that the damage was caused by the autonomous operation of the system.

The only limit to the operator's liability would then be represented by force majeure (art. 4(3) RLAI). Liability is then associated with a corresponding insurance obligation (art. 4(4) RLAI) within the limits established by art. 5 for the maximum amounts that may be compensated, namely two million in the event of the death of, or in the event of harm caused to the health or physical integrity of, an affected person, resulting from an operation of a high-risk AI-system (art. 5(1) let (a) RLAI) one million in the event of significant immaterial harm that results in a verifiable economic loss or of damage caused to property, including when several items of property of an affected person were damaged as a result of a single operation of a single high-risk AI-system (art. 5(1) let (b) RLAI). These limits are left unchanged also in the case of a plurality of injured parties as a consequence of a single event—*rectius* of the same operation involving the use of the same AIS—imposing a *pro rata* reduction of the amount due to each injured party (art. 5(2) RLAI). The statute of limitations for the claim is 30 years, starting from the time of the accident (art. 7(1) RLAI).

For non-high-risk AIS, i.e. identified residually with respect to the others, a fault-based liability rule applies, holding the operator responsible for any harm or damage resulting from the physical or virtual activity of the system (art. 8(1) RLAI). The subjective element is, however, presumed and the operator is only freed if he can prove that the system was activated without his knowledge—having taken sufficient precautions to prevent it (art. 8(2)(a) RLAI)— or that an appropriate degree of diligence was observed—respectively, in the choice of a system appropriate to the function it was called upon to perform, as well as in its activation and monitoring of its activity, regular maintenance and updating (art. 8(2)(b) RLAI). No other evidence would be admitted to release the operator, who is held liable also for the damage caused by a third party who interfered with the operation of the machine, if that party is untraceable or impecunious (art. 8(3) RLAI).

The proposal also establishes the obligation of the producer to cooperate, at the request of the operator or the victim, by providing the information necessary to establish the various responsibilities. This profile is also particularly important in the reform of the Product Liability Directive.

[203] The proposal was presented several months before the AIA and could not thence consider the definitions advanced by the regulation, including that of h-AIS. In agreement with the experts' opinion, it distinguished liability regimes pursuant to the different levels of risk. Eventually, the proposed approach to classify h-AIS—by reference to an explicit list, contained in an Annex, periodically updated by the Commission—could have ensured higher degrees of *ex ante* certainty, compared to the current formulation of art. 6 AIA, that requires complex evaluations, and yields greater uncertainty (see §2.3).

4.3.3. The efficient aspects of the proposal: a truly strict liability rule, corresponding to a compensatory rationale, achieving clarity and foreseeability of outcomes

The proposal seemed preferable an alternative to the AILD, even in the framing of a civil liability rule for non-h-AIS (see §5.2).

Most importantly, however, the idea of holding another entity other than the producer strictly liable is advantageous in that it makes it possible to overcome those limitations of the PLD already discussed with respect to the defect[204], compensable damages, and the burden of proof that plaintiffs must still satisfy (see §2.3.5).

The operator is, indeed, a natural or legal person, not responsible for the design and construction of the AIS, but for its professional use, or for the offering of services through it or even for it, such as maintenance and updating.
The rationale for the imposition of such liability is analogous to that underlying product liability, and even more so to all truly strict liability rules, emphasizing the dual dimension of (i) the ability to control and influence the characteristics, operation and use of the system, on the one hand, and (ii) the ability to derive an economic benefit from it, on the other. By virtue of *sub* (i) the operator is deemed to control a 'risk factor', by virtue of *sub* (ii) he is in a position to 'benefit' from it, either directly or through his own professional and/or business activity.

The idea that subjects other than the producer can be made responsible for the functioning of the autonomous machine, insofar as they are in control of a risk factor, and insofar as they are able to take advantage—economically—of the system and its operation, is coherent with a risk management approach[205], and implements one of the fundamental ideas advanced by the Expert Group on Civil Liability, appointed in 2018 by the European Commission[206].

The most important advantage of such an approach would have been to conceive a true strict liability, with no possibility of avoiding the obligation to compensate damage - beyond *force majeur* - overcoming the conceptual limitations of the notion of defect - as the lack of safety one is entitled to expect -, capturing automation in both products and services. A truly strict rule, that does not attempt—and fail—to balance contradictory rationales (such as the PLD and its revision, see Chapter 2, §§2.3.3 and 2.3.4) — that does not rely on procedural artifices and the creativity of courts to ensure

[204] In this sense also Scognamiglio, C. (2023). "Responsabilità civile ed intelligenza artificiale: quali soluzioni per quali problemi?" Responsabilità civile e previdenza(4): 1073-1089., 1084; Cioni, A. Ibid."Nuovi pregi e vecchi difetti della Proposta di Direttiva sulla responsabilità da prodotto difettoso, con particolare riferimento all'onere della prova." (2): 656 - 684.

[205] This approach aligns with a risk management strategy that involves allocating financial losses to the entity or individual best positioned to avert and oversee potential hazards, even if said entity or individual was not the direct cause of the initial risk. Consequently, if a product exhibits a conformity defect, it is likely attributable to its manufacturing or transport process, rather than to its handling by the final retailer. For additional information, please refer to Bertolini, A. (2016). "Insurance and Risk Management for Robotic Devices: Identifying the Problems." Global Jurist 16(3): 291-314.

[206] Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission., 36.

compensation to the victim, achieves clarity, simplicity of application[207] and subsequent foreseeability of outcomes.

The clear compensatory rationale underpinning the solution aims to ensure that those who benefit economically from the operation of a technically advanced system internalize its costs, at least prima facie (see §§ 3.5 and 3.7), without leaving them to the injured party or the other party least able to defend itself in a costly trial[208].

4.3.4. The multiplicity of operators and the insufficiency of joint and several liability as a solution to causal uncertainty

The main criticism that may be brought against the proposal has to do with the failure to identify a clear and single—at least prima facie— responsible party. The definition of operator is, in fact, ambiguous and capable of encompassing a plurality of subjects[209] that may be deemed in control of a risk factor and benefiting from the use of the AIS.

As discussed above (see §2.3.6 and §3.3.4), increasing human-machine cooperation in the performance of complex tasks leads to the potential overlap of different civil liability rules as a consequence of causal uncertainty. Indeed, the complex nature of the technology and its opacity make it difficult to identify the specific risk factor(s) that materialized among the many potential alternatives.

Disentangling the causal nexus is, in fact, possibly the most complex factor in solving a civil liability claim revolving around the use of AIS.

This complexity and subsequent uncertainty as per whom needs to bear—at least *prima facie*—the economic consequences of the accident may not, however, be solved through joint and several liability.

[207] Dissenting opinion is that of Wagner, G. (2022). "Liability Rules for the Digital Age. Aiming for the Brussels Effect." Journal of European Tort Law 13(3): 191.-197.

[208] Ibid.. Castronovo, C. (2006). La nuova responsabilità civile. Milano, Giuffrè., 704 e Owen, D. G. (2008). Products Liability Law. St. Paul (MN), Thompson West. D.G. Owen.

[209] In the case of a vehicle with increasing automation, the manufacturer of the vehicle, the mechanic responsible for its maintenance, the person responsible for the autonomous system's updates, the owner and the user/driver, the possible provider of network services, the provider of an intelligent and connected road system, all may qualify as operators, in various capacities, for the reasons stated.

The technical issue is not that of alternative causation[210], nor of hypothetical alternative causation[211], but truly of causal uncertainty.

To understand the difference, which does not possess a mere theoretical bearing one may consider the following example.

> Example 3
>
> A bilateral upper-limb amputee has a bionic prosthesis implanted that uses an AIS[212]. Thanks to this solution the quality of life of the wearer increases and he resumes daily activities he could,

[210] Indeed so it was defined by Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission., 22 and 57, where it is stated

> "It is already difficult to prove that some conduct or activity was the cause of harm, but it gets even more complex if other alternative causes come into play. This is nothing new, but it will become much more of an issue in the future, given the interconnectedness of emerging digital technologies and their increased dependency on external input and data, making it increasingly doubtful whether the damage at stake was triggered by a single original cause or by the interplay of multiple (actual or potential) causes" "A patient's artery is cut by an AI-driven surgical robot either due to a failure of the surgeon operating the robot, or due to the wrong execution of the surgeon's movements by the robot. If so, neither of the two potential causes satisfies the conditio sine qua non test ('but for' test), because if either one of them is hypothetically disregarded, the damage may still have been caused by the remaining respective other event(s). The consequence would be that neither of these suspected reasons why the victim was harmed could trigger liability, so the victim could—at least in some legal systems—end up without a claim for compensation, despite the known certainty that one of the two or more events was indeed the cause of damage".

The scenario described does not appear to be correctly qualified with reference to alternative causality. The final clause could be interpreted as a hypothetical causal alternative. A more accurate assessment would be to categorize it as a simple case of causal uncertainty, a condition marked by significant difficulty in accurately reconstructing the events that occurred. It is not necessarily the case that the robot performed the movement incorrectly, nor is it necessarily the case that the human being made a mistake in using the machine; it may very well be that only one of these events occurred. It has been observed that numerous authors appear to encounter a similar form of intellectual impasse, which can be exemplified by the following cases:, see Geistfeld, M. A., E. Karner, B. A. Koch and C. Wendehorst, Eds. (2023). Civil Liability for Artificial Intelligence and Software. Berlin-Boston, De Gruyter.,42 ff.

Alternative causation entails that a given outcome may result from a plurality of etiological chains, independent of each other, and yet each sufficient to cause the same harm as is also the case in German and Austrian law, with respect to which Koziol, H. (2009). Grundfragen des Schadenersatzrechts. Wien, Jan Sramek Verlag., 141 ff, recalls Wilburg's mobile system theory Wilburg, W. (1950). Das bewegliche System. Wien., *passim*; Larenz, K. (1987). Lehrbuch des Schuldrechts. Allgemeiner Teil. München., 42 and fn 72. The typical schoolbook example being that of two hunters who, with weapons of the same caliber, shoot simultaneously in the same direction, mistakenly hitting another hunter and not the animal. In the model case, only one bullet reaches the unfortunate hunter, yet it cannot be established from which weapon it was fired. Both men engaged in the same potentially damaging conduct, and each of the conducts alone would have been capable of producing the harmful result, yet only one caused it. The problem obviously takes on a different dimension if what is at issue is criminal or civil liability. Most would not doubt, in fact, that the injured person should be compensated in full for the damage, while many would doubt that one of the hunters should be deprived of his or her personal freedom in the face of such uncertainty.

[211] See Castronovo, C. (2018). Responsabilità civile. Milano, Giuffrè., 382, in hypothetical alternative causality one is the efficient cause because the other, the alternative cause, would in turn have been capable of producing the event, but only at a later time than that at which the historical cause caused it. On this issue see also Trimarchi, P. (1964). "Condizione sine qua non, causalità alternativa ipotetica e danno." Rivista trimestrale di diritto e procedura civile.1434 ff.; Rizzo, N. (2010). "Momento della determinazione del danno e mora del debitore." Rivista di diritto civile: 245-279.; Rizzo, N. (2022). La causalità civile. Torino, Giappichelli., 57 ff.

[212] A human-machine interface that interprets the biological signal of the nervous system to control the motors, actuators and sensors of the artificial limb.

otherwise, no longer perform, such as driving a car, adapted to his needs[213]. If an accident occurs, where the wearer drives off-road into an obstacle and gets killed, it might be extremely complex to determine whether the accident was due to a mere human error in driving, to a miss-interpretation of the biological signal by the human-machine interface, or some other failure, in the AIS. Moreover, even a failure in the AIS could, under certain conditions, be remedied by a prompt reaction of the wearer, who will most likely be trained to counter most typical scenarios. In such a perspective, under certain conditions, failure to do so could be perceived as a non-excusable fault on the side of the implantee. Finally, the malfunctioning of the AIS could depend upon erroneous maintenance performed over the system by the party responsible for it, or the very omission of timely intervention because the wearer missed an appointment.

The example shown, similar to the one considered above (see Example 1), demonstrates that unraveling the etiology that led to the accident is neither simple nor inexpensive. Multiple conducts and elements could have either contributed or directly caused the accident, pointing to different individuals as potentially responsible parties, on the grounds of distinct liability rules. Unlike the case of the hunters (see fn. 210), where two identical conducts were put in place, in more realistic cases involving advanced technologies it is not always possible to determine the causal series, among multiple distinct ones, that led to harm. It could very well be the case that only human error led the wearer to steer into a wall or, instead, that only a malfunctioning in the AIS prevented him from moving the wheel timely and appropriately. Still, it is possible that the maintenance performed was faulty, and yet the prosthesis should be designed to allow the user to react quickly under these circumstances to counteract the malfunction. These speculations show how the alternative causal series that led to the accident may be completely independent of each other, or they may partially coexist. However, it is complex to determine which of these abstract risks actually materialized into a damaging event, and while some risks may coexist, others may be radically excluded by the concrete factual development that took place. To take the example of the hunters, it is as if we were uncertain whether the person's death depended on being shot, attacked by a wolf, or struck by a branch falling from a nearby tree.

The purpose of the example is not to showcase the possible application of the RLAI, rather the difference between alternative causation problems and pure causal uncertainty. While some incidents involving AIS could also trigger concerns of the former kind, many more will elicit discussion about the latter. Opacity and complexity lead primarily to pure uncertainty.

By completing the analysis, we may then understand that the problem of causal uncertainty could not be solved through their joint and several liability. Indeed, not al the different parties potentially involved in the accident described (wearer, producer of the prostheses, the party responsible for the maintenance of the AIS, the manufacturer of the vehicle) could be deemed liable in the first place. If the accident was entirely due to human error the producer and operator responsible for the

[213] The case is losely inspired by the accident that involved Christian Kandlbauer, on which see Christian Kandlbauer – Wikipedia. The inspiration was necessary only to derive a realistic example but none of the analysis conducted in and through the example ought to be considered realistic nor attributing liabilities to the parties involved in the case.

maintenance could not be called in to compensate. Similarly, if the accident was due to the malfunctioning of the traditional vehicle. But even if it were sufficiently clear that the events leading to the incident may be traced back to the functioning of the AIS, it is disputable that the wearer—who could also qualify as operator—, producer and back-end operator, are all to be deemed liable. What happened could have nothing to do with the maintenance of the system, and in that case the back-end operator could not be held liable because the risk factor over which he had control did not ultimately materialize in the accident.

In other words, joint and several liability presupposes that those obliged to compensate for the damage are actually liable, at least in part, and that the uncertainty of causation has thus been resolved, at least in part[214].

The merit of the proposal, namely that of elaborating a single clear, truly strict liability rule is somewhat impaired by this choice that could, instead, be reconsidered.

The only condition under which multiple operators could be held jointly and severally liable under causal uncertainty is if their liability depended only on the fact that they were merely qualified as operators, had control over a risk factor, and benefited - in some way - from the use of the AIS.

However, while this interpretation appears to conflict with the proposed text[215], and its rationale, it would also produce an overdeterrence effect, leading all parties to acquire insurance to cover all damages related to the use of AIS, even for accidents that would not depend on the risk factor they are in control of. The multiplication of insurance costs would, however, lead to overdeterrence and a reduction in the efficiency of the norm, unnecessarily increasing administrative costs.

Ultimately, a preferable solution would be that of holding one single party liable—a single operator—pursuant to a one-stop-shop approach (see §4.3.5), eventually leaving the decision and the possibility with him to sue in recourse other parties, along the value chain, who might share in the responsibility for the accident (see §4.3.7).

4.3.5. A one-stop-shop approach and a risk management perspective

An ideal regulatory framework for h-AIS, based on a truly strict liability rule, embedding a risk management perspective aimed at ensuring victim compensation, foreseeability of outcomes, and the

[214] That is also the main problem with advanced technologies, see Expert Group on Liability and New Technologies (2019). Report on Liability for Artificial Intelligence and other emerging digital technologies. Brussels, European Commission., 1 ff.

[215] Indeed art. 3(g) RLIA defines control as "any action [...] that affects the functioning of an artificial intelligence system [...] at any stage by determining the inputs, outputs or results, or may modify specific functions or processes", and art. 3(e) RLIA defines the operator as someone in control of *a* risk, thence admitting to the existence of a plurality of risks. A systematic interpretation leads to the conclusion that the operator is held liable not because he is an operator in the abstract, but because he was in control of the risk that materialized. If this were the correct interpretation, however, joint and several liability would not resolve the causal uncertainty, since some operators might not be responsible for the specific incident and therefore could not be successfully sued by the victim. As a result, and to avoid a judgment denying compensation, the plaintiff should sue all potential operators involved in order to avoid a partial judgment denying compensation because the specific operator the plaintiff sued was not the one truly responsible for the incident.

minimization of litigation and other administrative costs, ought to have a clear, single entry-point for litigation.

Said otherwise, the ideal liability rule should point at one single subject, held clearly responsible not on the grounds of a—direct or reversed (such as in the PLD, see §2.4.1)—judgment of fault, but on the circumstance that, above all others, that party is best positioned to (i) minimize risks and (ii) manage costs associated to the harm that nonetheless materializes[216].

The rationale would be identical to that underlined by the proposal of the Parliament presented above (see §3.1), but rather than burdening a multiplicity of parties (see §3.3), it would identify one single respondent, at least *prima facie*. Such a principle is not foreign to European law[217], as well as MS's experiences where truly strict liability rules[218] are evenly disseminated.

From a substantive law perspective holding the party liable that is in control of risks and benefits from the use of the AIS is certainly admissible, abiding by the principle *cuius commoda eius et incommoda*[219]. Liability so intended would not necessarily entail blameworthiness, rather the need to force an internalization of costs by the party that benefits from the use of the AIS, and who could manage the risks on the one hand as well as the costs associated therewith on the other hand (see §3.4.7).
The notion of operator was sufficiently clear and well-defined. Yet, it allowed for the identification of a multiplicity of operators for each AIS, causing the framework to preserve a high degree of complexity that did not help with the issue of causal uncertainty.

Each AIS used as a product or service ought to allow for the identification of a single operator, in the same way as there is a single producer[220]. It could be defined as the "natural or legal person who controls

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[216] In this same sense, Commission, E. (2022). Commission Staff Working Document. AI Subsidiarity Grid Accompanying the document Proposal for a Directive of the European Parliament and of the Council on adapting non contractual civil liability rules to artificial intelligence (AI Liability Directive) {COM(2022) 496 final} - {SEC(2022) 344 final} - {SWD(2022) 319 final} - {SWD(2022) 320 final}. and Commission, E. (2021). Commission Staff Working Document - Impact Assessment Accompanying the Proposal for a Regulation of the European Parliament and of the Council Laying down harmonised rules on AI.

[217] A similar rationale, despite not in the field of liability, is also present in the European Parliament and Council (2019). 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, OJ L 136, 22/05/2019, p. 28–50. Under this directive, the seller is liable to the consumer for any lack of conformity in the purchased goods, regardless of the cause, provided specific circumstances are met (artt. 10(1) and 10(2)).

[218] For a comparative perspective among MS regimes, see Werro, F. and E. Büyüksagis (2021). The bounds between negligence and strict liability. Comparative Tort Law, Global Perspectives, Research Handbooks in Comparative Law series. M. Bussani and A. J. Sebok. Cheltenham, Edward Elgar Publishing.; Koziol, H., Ed. (2015). Basic Questions of Tort Law from a Comparative Perspective. Wien, Jan Sramek Verlag KG.; Van Dam, C. (2013). European Tort Law. Oxford, Oxford University Press.

[219] Please refer Gentili, A. (2024). "Regole per l'intelligenza artificiale." Contr. impr., 1043 ff; Izzo, U. (2024). "Profili storici dell'imputazione dei danni cagionati dagli animali e del principio cuius commoda, eius et incommoda." Giustizia civile., 481 ff; Comporti, M. (2009). Fatti illeciti: le responsabilità oggettive. Milano, Giuffré., 60 ff; Scognamiglio, R. (1967). Responsabilità civile per fatto altrui. Noviss. dig. it. Torino., 27 ff; Comporti, M. (1965). Esposizione al pericolo e responsabilità civile. Napoli, Morano. Trimarchi, M. (1961). Rischio e responsabilità oggettiva. Milano, Giuffré.

[220] In the same way as the PLD and its revision allow for the identification of a single producer, even when the latter incorporates other elements and products into his own, see art. 8 PLDr.

the operation and functioning of the AIS and who benefits from its operation, offering products or services to the public through it".

The fundamental idea is that the last party entering into contact with the victim, who controlled the AIS to provide a product or service through it should be held to compensate for all damage suffered (see §3.4.7).

The definition of "operator" so simplified appears encompassing both of the notions of "provider" and "deployer", put forth by art. 3 AIA, as:

> "(3) 'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge;
>
> (4) 'deployer' means a natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of a personal non-professional activity;"

If, for the purpose of achieving highest consistency and coordination within European technology regulation, the legislator wanted to do away with an additional concept, the liability could be channelled towards both (preferably), or one of them.

Indeed, even if both were held liable the reasons for concern of potential overlap would be minimized, since the provider is the party that "puts on the market [...] or into service under its own name or trademark", while the deployer uses the AIS "under its authority" in a professional activity.

Both parties satisfy the conditions implied by the rationale described above, in as much as they operate in a professional context, bring the technology to the market or offering a professional service through it, respectively, and therefore benefit—directly or indirectly—from the AIS.

At the same time, if someone suffered damage, it would be possible to determine whether they were interacting with a provider or a deployer, and there would be no risk of causal uncertainty and overlapping liability, and consequently no doubt as to who should compensate the damage. This would not depend on disentangling a complex causal nexus, but on whether the party was using a product or service offered under a particular name or trademark or, instead, whether the AIS was being used in a professional context by another entity when the damage occurred. A simple assessment of the factual elements would suffice, potentially leaving no uncertainty.

Joint and several liability could also be considered to further ensure protection to the potential victim.

4.3.6. Defences and exclusions

One of the reasons for praise in the European Parliament's proposal was the exclusion of all defences for the operator, besides *force majeure*. Such a solution clearly abides by a clear compensatory rationale and excludes all attempts at mitigating that purpose with a desire for *ex ante* deterrence.

The limited effect of liability rules in ensuring adequate incentives to minimize harm in an *ex ante* perspective were already discussed, and the superiority of both market mechanisms on the one hand, and product safety regulation on the other hand was commented upon (see §2.3).

Any attempt at balancing ex ante incentives and ex post compensation, leading to the adoption of numerous and potentially complex liability exemptions is inevitably destined to increase uncertainty and litigation, together with its associated costs for the parties and the legal system overall, while the economic concern of not burdening one party disproportionately are best tackled otherwise (see §3.4.7).

Finally, it could be considered to provide for an exemption from liability in cases where it can be argued that the victim is primarily responsible for the accident due to her totally reckless behaviour. Such an option, which could be explored, would balance a very strict liability rule with a component of self-responsibility of the claimant, at least countering the major risks of moral hazard.

4.3.7. Rights to sue in recourse along the value chain

In a functional perspective, the defendants, being certain of their liability exposure, could better quantify the legal risk, and both adopt measures to prevent the damage and structure adequate mechanisms to manage associated costs, most commonly through insurance mechanisms.

Such an approach would radically avoid any need for complex causal assessments and would render litigation almost entirely superfluous, except in the most ambiguous cases or in those where a predominant responsibility of the victim could be observed and proven.

Moreover, when litigation was actually needed, plaintiffs would have no uncertainty as per whom to sue, since only one party would be liable towards them.

To limit the economic consequences of liability ultimately borne, the responsible party could resort to two alternative strategies that may well coexist and be combined one with the other.

First, the defendant could decide to sue in recourse other parties, along the value chain. Such right should be expressly granted. If providers were held responsible for an AIS someone else designed and delivered upon their request, they could apply product liability, as well as contract law to pursue restoration of the loss suffered. Moreover, if they were held liable in a multiplicity of instances, for a similar malfunction, by numerous plaintiffs, they could combine the claims and sue unitarily. Indeed, while pursuing legal action against the manufacturer would be excessively costly for the individual plaintiffs, due to the limited euro amount of damages they would be entitled to claim, the same would not be true for a provider who aggregated a multiplicity of judgments where he was found responsible for an identical defect in the design of the AIS. In other instances, the provider could decide to resort to contractual remedies or even mere negotiations in the prosecution of the business relationship with the parties that contribute to the creation of the AIS-based product or service offered under its name or trademark. Analogous considerations may then be drawn with respect to the deployer.

Second, the defendant could quantify the overall liability exposure faced, insure itself against it, most likely exploiting economies of scale[221], and then distribute insurance costs to technology users through price mechanisms. Indeed, the insurance premium paid would become part of the cost function of the business, and its ability to transfer it onto users would be dependent on the elasticity of the demand curve for that specific good or service. The more rigid the demand, the simpler it is to transfer the whole or a substantial part of the cost. In those latter cases, the defendant would minimize all administrative and insurance costs, pooling them, and then transfer them to those that by purchasing the service or good benefit from it.

Finally, both mechanisms would minimize litigation costs, including those associated with the need to access and elaborate information, eventually provided through disclosure obligations, and even such measures would become for the most part unnecessary (see §2.5 and §3.4).

4.3.8. Compensable damages

Compensable damages should not be limited neither as per the categories deemed admissible nor per the amounts. Indeed, MS have different doctrines about what damages may be compensated and restricting the possibility to obtain certain kind of damages (e.g. non-pecuniary losses) could prove a strong limitation to the diffusion even of a dedicated liability rule.

Damage caps, instead, are most problematic whenever a rule is conceived that could apply to profoundly different applications. A two-million-euro maximum amount may appear excessively high for the damages that could arise from the use of a smart-home device, and absolutely inadequate for a driverless car accident involving multiple parties, or the malfunctioning of an AIS used for smart frequency trading, or that of a medical device.

Finally, in no way should the possibility be excluded to claim damage suffered to the AIS itself, should that be purchased by the victim in the form of a product or service from the defendant, so as to avoid the need to sue on multiple grounds, with distinct legal actions. This, in fact, could both increase litigation costs, and discourage the application of the dedicated liability rule, to the advantage of other remedies, as observed with respect to the PLD (see §2.3)

[221] If the individual technology user were to purchase first party insurance to cover identical losses, she would most likely face higher costs than a business insuring against the same risks in an aggregate fashion, taking into account all the potential users of its products and services.

5. POLICY OPTIONS

KEY FINDINGS

1. The withdrawal of the AILD (OPTION 1), would foster the proliferation of national rules and solutions, leading to legal fragmentation and the creation of path-dependency across MS. In the absence of a harmonised European framework, civil liability for AI will likely be governed by divergent national rules—be they general fault-based regimes or strict liability standards for hazardous activities. This fragmentation will produce dissimilar outcomes, hinder regulatory coherence, and increase compliance costs for cross-border operators. Over time, entrenched national solutions will make subsequent harmonisation increasingly unattainable, replicating the failures in integration encountered in other domains of private law, such as commercial contracts. The scenario would thus entail a high risk of legal uncertainty and regulatory inefficiency, deterring innovation.

2. The adoption of the AILD in its current form, without structural amendments (OPTION 2), is not a viable alternative, as it will neither provide substantive harmonisation nor enhance legal certainty. Given that the AILD merely introduces procedural presumptions and does not replace national fault-based liability rules, it fails to displace the primacy of national frameworks. Moreover, its coordination with diverse national rules—each operating under distinct doctrinal assumptions concerning fault and causality—renders its practical application both uncertain and inefficient. The evidentiary burdens it imposes are likely to increase, rather than reduce, litigation costs. Most importantly, the mere presence of a European directive—however inadequate—would obstruct the adoption of more meaningful regulatory solutions in the future, thereby crystallising a fragmented and suboptimal legal landscape.

3. The introduction of a dedicated fault-based liability rule for high-risk AI systems (h-AIS), through a revised AILD (OPTION 3), would constitute a marked improvement by narrowing the scope of application and clarifying a substantive standard of liability. This approach would mitigate the difficulties of coordinating fragmented national regimes and the procedural uncertainties of the current proposal, by creating a specialized single liability rule. By embedding a strongly objective notion of fault—defined through reference to verifiable compliance obligations for providers and deployers—the revised directive would increase foreseeability and facilitate risk management through insurance and pricing mechanisms. While not as efficient as strict liability in compensating victims or reducing litigation, the revised AILD would significantly improve upon the status quo by enhancing uniformity, legal clarity, and innovation uptake.

4. The most desirable and coherent regulatory solution (OPTION 4) consists in the revision of the AILD to introduce a strict liability regime for h-AIS. Such a framework would embody the recommendations of expert scholarship and European Parliament resolutions, providing clear and uniform rules across the Union. By identifying the responsible parties as providers and deployers—consistent with the AI Act's definitions—this solution would maximise harmonisation while supporting a risk-management approach. A strict liability model would reduce litigation, enhance compensatory effectiveness, internalise risks, and prevent the proliferation of divergent national norms. It would thus foster the emergence of a unified European market for AI applications and services, free from legal barriers and regulatory uncertainty.

5. The absence of a coherent European liability framework constitutes a case of regulatory failure, undermining user protection, legal certainty, and the internal market. Both OPTION 1 and OPTION 2 are to be rejected: the former for leaving the field unregulated, the latter for institutionalising inefficiency, both for leading to the proliferation of fragmented MS solutions and the creation of path-dependencies. OPTION 3, while suboptimal, represents an acceptable compromise where political will precludes a stricter model. Nonetheless, only OPTION 4 aligns with the fundamental goals of a human-centric, innovation-friendly, and economically efficient AI regulatory architecture. It ensures foreseeability for users and operators alike, facilitates cross-border technological deployment, and ultimately promotes Europe's global competitiveness in the AI sector.

5.1. Introduction

To conclude the analysis four policy options are described, that build upon the considerations drawn on the debate around the regulation of civil liability rules for AI, and the concerns of over-regulation, the assessment of the existent regulatory framework—taking into account the PLDr — of the proposal whose withdrawal is currently being considered—AILD—as well as of alternative—and preferable—regulatory approaches.

Each option will be separately assessed to (i) anticipate potential consequences at European and MS level, in particular in terms of adoption of regulation, (ii) discuss the expected efficiency in granting compensation to the victim, reducing litigation and its associated costs, and (iii) favouring innovation.

5.2. OPTION 1 – Withdrawal of the AILD

The first scenario to be considered is that of the possible withdrawal of the AILD without any alternative piece of regulation being proposed, primarily argued on the basis of a risk of over-regulation.

5.2.1. The balance between European and MS law

In such a case we may expect the issue of the regulation of civil liability to be put aside for a long time at European level, in particular considering the complexity of the enactment of the AIA, and the years that will be required to provide a first assessment of a very complex piece of legislation.

At MS level, as soon as cases will start to emerge solutions will be elaborated, either through the application of dedicated norms—some of which were already passed[222], some may be adopted at a future date—or by resorting to general civil liability rules, primarily fault-based ones, but also strict, such as those that some MS possess for hazardous activities or traffic accidents. As a consequence, the field of civil liability of AI will grow as another domain of national tort law, leading to path dependencies that will increase divergences over time.

Such a tendency is at the basis of all difficulties in achieving a greater level of uniformity across MS in the most traditional fields of private law, in particular torts, contracts and the law of obligations. Indeed, the numerous comparative law studies, and attempts at harmonization have repeatedly failed to ensure the development of a truly European private law, leading to particularly detrimental results in specific instances. A case in point is offered by the failure of European commercial contract law to establish itself as the governing rule in international business transactions[223].

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[222] Consider, for instance, the German "Law on Autonomous Driving" (*Gesetz zum autonomen Fahren*), formally known as the "Act to Amend the Road Traffic Act and the Compulsory Insurance Act" (*Gesetz zur Änderung des Straßenverkehrsgesetzes und des Pflichtversicherungsgesetzes*) and entered into force on July 28, 2021. This law allows the regular use of Level 4 autonomous vehicles (according to the SAE classification) on public roads in defined operational areas, without a human driver physically present in the vehicle, as well as the numerous national laws on civil liability for accidents involving drones, on which please allow reference to Hartmann, J., A. Masutti, A. Bertolini, S. Truxal and B. I. Scott, Eds. (2024). Civil Regulation of Autonomous Unmanned Aircraft Systems in Europe. Cheltenham, Glos, UK - Northampton, Massachussets, USA, Edward Elgar.

[223] Please allow reference to Bertolini, A. (2020). Artificial Intelligence and Civil Liability. Bruxelles, European Parliament - Committee on Legal Affairs: 1-132.

Attempts to regulate at a later date will have to overcome the fragmentations established, resistances to repeal existing norms and paradigms to replace them with solutions that may abide by a different rationale. Indeed, some MS will convincingly attempt to pursue greater protection for potential victims, while others will be more concerned with favouring businesses attempting to innovate. Forcing the adoption of a common logic and rationale at a subsequent stage may prove even more complex a task.

5.2.2. The regulatory framework and its anticipated efficiency

The efficiency of such a solution seems minimal. At European level the PLDr will most likely maintain a trend of application comparable to that of its previous formulation. The notion of defect, the exclusion of the possibility to compensate damages to the defective product itself, the complexity and subsequent cost of litigation will relegate the directive to a residual application of the kind witnessed until today. Said otherwise, there are no reasons to believe the PLDr will become the primary source of liability arising from the use of advanced technologies. It is also clear that this was never the intention of European policymakers, since the reformed text was always presented as part of a broader reform. The PLDr may allow higher success rates if the presumptions will be effectively applied by courts, but those provisions merely transposed solutions that had already been elaborated, in a scattered fashion, by caselaw (see Chapter 2). Broader success could be achieved if class actions became more diffused over time.

Day to day litigation will most likely be primarily based on national law, with very different outcomes achieved in different MS as well as before different courts. Moreover, in the absence of a structured intervention, or the adoption of dedicated norms, judges will inevitably pursue justice in the single case over systemic coherence and the creation of optimal incentives. As a result, maximum fragmentation in both legislation and its outcomes will result.

As clarified above (see §1.5), lack of normative intervention at European level, leading to the proliferation of alternative solutions in different MS, will ultimately lead to overregulation. Businesses will, in fact, have to acknowledge the different characteristics of all legal system and abide by them. Such a concern is deemed to increase in relevance in as much as increasing automation will inevitably shift consequences of accidents towards them, considering how tasks that were performed by humans only, until today, will see increase collaboration with machines and eventually overall replacement.

5.2.3. The impact on innovation

Uncertainty and unpredictability of legal outcomes will prevent the efficient internalization of risks and costs and their management by firms, including through insurance and pricing mechanisms. Losses will remain where they occur or where a single decision by a judge decides that they should remain.

Most likely regulatory uncertainty will discourage the early adoption of technologies that could expose their users to additional liabilities, arising from the autonomous nature of the system[224]. This might substantially delay technological uptake.

In many instances liability rules will provide incentives that influence which technological solutions prevails[225]. Different norms, especially if divergent as per the underlaying rationale, might also lead to a direct fragmentation of the technological market.

In any case, even if such a more extreme scenario was avoided, and that of advanced technologies evolved as other industrial fields, in the absence of dedicated and uniform European liability norms, the solution achieved would still be less optimal than what could have otherwise been pursued. Indeed, European policymakers would not have learned from previous experiences, overcoming path-dependency and fragmentation of solutions developed at MS level in all other domains where no initiative was taken. This is after all the cost of non-Europe[226].

5.3. OPTION 2 – Maintaining the AILD without substantive structural modifications

If the AILD were ultimately not withdrawn and the text was approved without substantial changes, in the form it was commented upon (see Chapter 3), a number of concerns would arise, that cause this option not to be substantially preferable to the pervious, rather the contrary.

5.3.1. The balance between European and MS law

The European regulatory framework would consist of the PLDr and AILD, as per the intention of the Commission, when it presented both texts. However, while the PLDr would not become the primary piece of European legislation addressing the liability arising form the use of AIS, due to the reasons discussed above (see §2.5), the AILD would still leave primacy to MS's fragmented and differentiated framework, rooted in a multiplicity of fault-based rules.

Indeed, since the AILD—theoretically—contains only two provisions that influence evidentiary and procedural aspects (see §3.3) that need then be coordinated with pre-existing and potentially even newly adopted fault-based liability rules present in the legal ordering of each MS, the focus will be on the latter. Each MS has, indeed multiple fault-based rules, some applicable as general clauses—to all sorts of incidents—some specific for a given domain (e.g. medical malpractice). In some cases, doctrinal and judicial debates occur to discuss whether a given provision is truly fault-based or, instead, strict,

[224] Please allow reference to Bertolini, A. and M. Riccaboni (2020). "Grounding the case for a European approach to the regulation of automated driving: the technology-selection effect of liability rules." European Journal of Law and Economics: 243-285.

[225] A case in point is offered by driverless cars, where the choice of a liability rule that holds the producer always liable for all damages arising from the circulation of its vehicle could lead to a different form of full automation (no steering wheel) than the rule holding the owner liable even for accidents dependent on the autonomous function, for a detailed discussion, please allow reference to ibid.

[226] The expression was coined by Evas, T. (2020). Civil Liability Regime for Artificial Intelligence. Brussel, European Union.

and that uncertainty would extend to the definition of the scope of application of the AILD itself (see §3.4.5).

The overall effect appears then as problematic as the previous (see §2.5) in terms of allowing for a similar degree of fragmentation and proliferation of a multiplicity of distinct national regulatory frameworks, causing that of advanced technologies to evolve into another domain of national tort law, with its path-dependencies that will prevent later harmonization. All the criticism drawn above in this respect should be considered here fully recalled (see §2.4.3).

At the same time, however, fragmentation will also depend on the difficult coordination between those procedural norms contained in the AILD, which embedded specific notions of fault and causal nexus (see §3.3.2), and MS's fault-based tort rules, that may profoundly differ in that respect (see also §5.3.2). Finally, the adoption of the AILD, even more than in the previous case, will prevent any other alternative normative intervention to be considered at European level in this domain. Therefore a piece of legislation that has very limited positive impact in terms of efficiency (see §3.4.7) and harmonization will harm the chances of future regulatory interventions, creating an even harder obstacle to overcome than the no-intervention option discussed above (see Chapter 2).

5.3.2. The regulatory framework and its anticipated efficiency

The considerations about the limited potential role of the PLDr in governing daily accidents depending on the use of AI, and increasing automation is here entirely recalled (see §2.3.5).
At the same time, the AILD will not affect the primacy of national fault-based liability regimes, also leading to the proliferation of a multiplicity of different, and possibly divergent—as per the underlying rationale—solutions at MS level, causing the identical concerns described above (see §1.5) in terms of overregulation, and creation of path-dependencies.

More specifically, due to the complex coordination of the procedural norms contained in the AILD with the national fault-based rules (see §3.2.1), both relevant discrepancies in the application of the Directive will potentially arise and, in many cases, it will simply be disregarded in favor of alternative - eventually strict - solutions applicable at the MS level. What has been witnessed in the application of the PLD, namely the persistence of both general (tort and contract based) and specific normative solutions at the MS level, preferred by the courts to the European Directive in cases of defective products litigation (see §2.3.3), is likely to happen in this case as well.

The results in terms of user protection and minimization of litigation and associated costs will be minimal, if positive at all. The evidentiary solutions proposed are, in fact, going to increase litigation costs (in particular disclosure obligations, see §3.3.1) and will not provide real advantages over the existent framework due to the complexity of applying presumptions (see Chapter 3, §3.3.2).

5.3.3. The impact on innovation

All concerns in terms of uncertainty, *ex ante* unforeseeability of judicial outcomes, lack of internalization of risks and costs by businesses operating with AIS, as well as uncertainty and discouragement of early technological adoption, as described above (see §2.3), should be deemed here entirely recalled.

5.4. OPTION 3 – Maintaining the AILD, introducing a fault-based liability rule for h-AIS

If the proposal for an AILD was maintained, but its structure was open to a revision, the content could be profoundly improved. In particular, the proposal should be shaped to introduce a special, fault-based liability rule—similar to that advanced by the Parliament in the RLA for non-high-risk systems (see §4.1)—only applicable to h-AIS.

A special, well-defined liability rule would overcome the need of complex coordination between MS's fault-based frameworks, with their respective underlying concepts (see §3.2), and procedural norms that embed potentially different if not conflicting notions of fault and causal nexus that would be hard to harmonize (see §4.1).

The scope of applications and the cases that should fall under those provisions would be clearly identifiable ex ante, especially if the rule applied only to h-AIS. While the adoption of ad hoc liability rules for specific categories of applications might be a preferable solution (see § 4.2.2), reasons of uniformity of the European regulatory framework for AI would suggest coordinating the proposal with the already adopted AIA (see § 4.3.2). Indeed, the AIA has already created path dependencies in the European regulatory framework by opting for a horizontal approach, partially mitigated by a risk-based categorization. Such a solution is not necessarily optimal and there are reasons why it could be criticized. However, if liability rules were to take a radically different approach to the identification of regulated objects, coordination between the different pieces of regulation could become highly problematic, leading to ex ante uncertainty and fragmented application across jurisdictions. Moreover, a revision of art. 6 AIA – identifying h-AIS – is possible, and considerations about the need to shape the liability regime for specific AIS could play a role in the future policy debate in that regard.

In such a perspective restricting the application to h-AIS would serve two purposes. First, only higher-risk applications seem to deserve a dedicated regulatory intervention, as agreed upon by most experts (see §2.3.3). This way a risk of over-regulation for less problematic AIS would be curtailed. Second, the ambiguity provided for by the existence of under-defined residual categories would be prevented. Indeed, on the one hand the notion of AIS is so broad as to possibly encompass any product ranging from a smart toothbrush to a large language model (see §4.2.3)[227], and the proliferation of AI-based solution is deemed to further increase, expanding and further blurring the borders of this potential category. On the other hand, only the notion of h-AIS is well defined[228], through specifically applicable criteria. A non-high-risk residual category would thence encounter only a clear upper limit (h-AIS) but would be extremely broad and almost impossible to distinguish in its lower one, since the very notion of AIS is intentionally underdetermined to accommodate all foreseeable innovation. Both perspectives and, most importantly, considerations of appropriateness and proportionality, suggest that only high-

[227] Please allow reference to Bertolini, A. (2020). Artificial Intelligence and Civil Liability. Bruxelles, European Parliament - Committee on Legal Affairs: 1-132.; Bertolini, A. (2024). Intelligenza Artificiale e responsabilità civile. Problema, sistema, funzioni. Bologna, Il Mulino. 88-95.

[228] Despite the reasons of concern that the application of art. 6 AIA gives rise to, please allow reference to Bertolini, A., F. Fedorczyk, M. M. Mollicone and G. Migliora (forthcoming, 2025). "The Brussels Sphinx's Riddle. What is a high-risk AI System?" Working Paper., *passim*.

risk application should be governed at European level with a dedicated civil liability framework. Moreover, the way the h-AIS category is defined allows for evolution, adaptation and expansion of the category, as well as its revision (see art. 6 (6) AIA), and if other needs emerged or insufficiencies with respect to specific applications further reform could be considered.

In such a perspective, corrections to art. 6 AIA should be considered, in the sense already clarified (see §4.2.3) in particular to ensure mechanisms that "certify" the qualification of a given AIS as high-risk, ensuring uniformity across MS and preventing divergent interpretations by single courts.

The provision currently contained in art. 4 AILD should, instead, be replaced by a fault-based liability rule, abiding a similar rationale to the provision of art. 8 RLAI, whereby

> "1. The operator of an AI-system [...] shall be subject to fault-based liability for any harm or damage that was caused by a physical or virtual activity, device or process driven by the AI-system.
>
> 2. The operator shall not be liable if he or she can prove that the harm or damage was caused without his or her fault, relying on either of the following grounds: (a) the AI-system was activated without his or her knowledge while all reasonable and necessary measures to avoid such activation outside of the operator's control were taken, or (b) due diligence was observed by performing all the following actions: selecting a suitable AI-system for the right task and skills, putting the AI-system duly into operation, monitoring the activities and maintaining the operational reliability by regularly installing all available updates. The operator shall not be able to escape liability by arguing that the harm or damage was caused by an autonomous activity, device or process driven by his or her AI-system. The operator shall not be liable if the harm or damage was caused by force majeure.
>
> 3. Where the harm or damage was caused by a third party that interfered with the AI-system by modifying its functioning or its effects, the operator shall nonetheless be liable for the payment of compensation if such third party is untraceable or impecunious. [...]"

Such a liability rule presupposes the fault of the defendant, which can only be excluded by demonstrating compliance with the specific obligations the responsible party is subject to. The latter could be identified either in a single operator (see §4.3) or, for reasons of internal coordination with the emergent European regulatory framework for AI, in both the provider and deployer, without risks of causal uncertainty or potential overlap of liability rules as already clarified (see §4.3.3). The latter option is preferable.

Coherently, liability is excluded in cases of force majeure but not when a third party intervenes, modifying the AIS. In such hypotheses the defendant assumes a warranty position in the interest of the claimant, and is forced to internalize, prima facie the loss. This provision, particularly beneficial in a risk-management perspective could, however, be deemed optional, if causing excessive contrast.

The notion of fault, so defined, is still objective, determined in light of the violation of specific obligations to maintain a given conduct. If the responsible parties were identified in the provider and deployer, those obligations (in particular those contained in let (b) art. 8(2) RLAI) ought to be

determined through reference to the corresponding provisions of the AIA that determine their respective duties.

The duty of the producer to cooperate (art. 8(4) RLAI), despite commendable, may not be strictly necessary to define the deployer's and provider's liability and may thence be omitted.

The overall substantive rule that would emerge from such a system would be clear, well defined both with respect to its contents and scope of application, leaving limited room for uncertainty and divergent applications (see §4.3.4) and would offer greater protection to users of AIS, achieving higher efficiency (see §4.3.7). Indeed, unlike the current formulation of the AILD, which provides only evidentiary norms that must then be interpreted in coordination with a variety of different national tort rules, some of which may be based on different conceptualizations of the notions of fault and causal nexus, the text modified as described here would provide a self-contained rule of responsibility. All the elements of the tort would be defined by the AILD itself, and the interpreter would not need to coordinate it with other pieces of national law. In other words, the judge would only have to determine whether the case at hand falls within the scope of the Directive and apply the special rule, which is well and completely defined by the Directive itself. The risk of fragmented interpretation is therefore much more limited and falls within the reasonable and unavoidable uncertainty typical of any judicial application of any norm. So conceived, the AILD would become a single special liability rule, similar to the numerous special torts that determine the liability of teachers, parents, owners, manufacturers, practitioners, and the like, rather than adding a European horizontal layer over most – if not all – of said instances, on top of all the general fault-based rules present in each MS's civil code (see fn. 175).

With such a framework, the complex and largely inefficient provision of art. 4 AILD would become radically superfluous, and should be struck. Instead, the disclosure obligation provided for by art. 3 AILD may be maintained, possibly addressing the concerns about the complexity of its application already discussed (see §3.3). In particular, the need to demonstrate attempts to obtain information directly asking the defendant ought to be reconsidered, and clearer indication to judges ought to be provided about what constitutes *fumus boni iuris* and an adequate balance of the opposing interests of the parties. Ultimately, however, even the current formulation of the provision would not cause too much concern if a clear liability rule of the kind depicted were to be enacted, for that would ensure sufficient clarity and possibly cause disclosure obligations to become altogether superfluous. Indeed, even in the current framework of the AILD the greatest risk of that provision is for it to become mostly irrelevant and seldomly applied by national courts.

Finally, as per damages the considerations drawn above (see §4.3) should apply. No limitation of compensable damages should be provided for at European level, leaving that aspect to MS and their overall liability framework, to avoid making dedicated provisions less appealing to claimants, thence favouring the proliferation of national alternative that ensure broader compensation.

Instead, the possibility to recover damages suffered by the AIS itself, even when purchased by the plaintiff as a product should be expressly allowed (see §2.3 and §4.3.8).

5.4.1. The balance between European and MS law

The considerations about the application of the PLDr drawn above (see §2.5) remain unchanged and should be deemed here entirely recalled.

However, by introducing a special liability rule with a well-defined scope of application, the ambiguity of overlapping MS's multiple and divergent fault-based systems and the AILD would be entirely avoided.

Indeed, by creating a special liability rule greater homogeneity and uniformity of application are ensured, and a greater role could be played by the European Court of Justice in harmonizing the application of the directive. In fact, despite the AILD being a directive a not a regulation—unlike the RLAI—a liability rule so clearly formulated would allow for a high degree of harmonization among MS, despite the need to enact it at national level.

Moreover, unlike the uncertain and complex procedural provisions—in particular art. 4 AILD—the proposed solution would introduce a special liability rule, would not conflict with national tort law systems and their most general provisions contained in general purpose fault-based rules. This should reduce also political conflicts and resistances in approving the proposal (see §3.4.1). A vertical approach—identifying a specific, well-defined and constrained scope of application—as opposed to a horizontal one proves certainly preferable in such a perspective.

The adoption of a dedicated liability rule would reduce the possibility for MS to adopt a multiplicity of alternative and conflicting solutions and generate path-dependencies later impossible to overcome. At the same time, at European level it would provide a substantive solution that would prevent the possibility of future proliferation of other normative interventions in the same domain. Unlike the current formulation of the AILD, however, this could come with a benefit in terms of overall efficiency of the system (see, by contrast, the considerations made under §3.4, and §4.3).

Over time, the series of applications governed by this provision would vary thanks to the application of art. 6 AIA, that should be further specified and partially corrected as indicated above (see references to Chapter 4). Eventually, European policy makers could decide to adapt the definition describing the applications encompassed by the directive, extending it though analogical reasoning or restricting it as deemed fit, still maintaining a well-defined scope of application. Indeed, it is preferable to leave some potentially relevant applications out than creating radical uncertainty about what exactly ought to be deemed regulated by the specific provisions.

Overall, as system so conceived, discouraging the adoption of national solution, would prevent fragmentation of outcomes, and would ensure that over-regulation does not take place, providing a coherent regulatory framework at EU level.

5.4.2. The regulatory framework and its anticipated efficiency

While fault-based rules are less efficient than strict ones in ensuring victim compensation and, even more, the minimization of litigation and associated costs, the proposed approach achieves almost comparable results.

The liability rule, embedding a strongly objective notion of fault, and reversing the evidentiary burden, certainly favours claimants in achieving compensation, and is most likely preferable to standard fault-based rules applicable across MS. Similarly, the possibility to hold the defendant liable also for the actions of third parties who interfered, provides further protection to the user. Both these aspects certainly favour technological uptake (see §4.3). The greater efficiency of such a provision when compared to mere presumptions of the kind formulated by art. 4 AILD is evident.

At the same time, the definition of fault in terms of violation of sufficiently specified conducts also allows potentially responsible parties (providers and deployers) to determine the exact conditions of their exposure and adopt adequate ex ante measures to minimize those risks and manage them, eventually through insurance mechanisms.

Litigation will not be altogether avoided by a similar solution, but the sufficient clarity of legal rules will reduce its costs and the potential uncertainty leading outcomes to be more homogeneous and altogether foreseeable.

Unless truly strict liability rules are applied at MS level, it is difficult to anticipate that national solutions would be preferred to such a framework, both by plaintiffs and defendants.

5.4.3. The impact on innovation

Greater protection for plaintiffs will encourage the adoption of the technology, as users will not fear being left with the harmful consequences of potential accidents involving the use of advanced technologies. At the same time, a simpler application of the less complex norms will improve the predictability of outcomes and thus the management of associated costs by companies offering AI-based services and products. Foreseeability is a prerequisite for insurability, and therefore for effective risk and cost management.

The risks of market fragmentation and over-regulation are minimized, though not radically eliminated, by the introduction of a specific European liability regime, applicable in well-identified cases, without the need for complex coordination with national rules. Moreover, adopting the same categorization criteria as the AIA (regulating only h-AIS) would result in a more coherent European regulatory framework for advanced technologies.

5.5. OPTION 4 – Maintaining the AILD, introducing a strict liability rule

If the AILD was profoundly revised to consider the unanimous recommendations issued by the experts (see §2.3.3), it could accommodate a strict liability framework for damages arising from the use of h-AIS. Eventually the possibility of adopting a regulation, rather than a directive, could be considered, even if that entailed revising the legal basis for intervention.

The reason why a strict liability rule is preferable was already discussed (see §2.5 and §4.3) and the shortcomings of the PLD and its revision, in such a perspective, were already explained (See §2.4).

The opinion of experts was unanimous (see §2.3.3) and encountered the approval of the European Parliament[229] in considering the adoption of a distinct strict liability rule, parallel to the PLD, necessary. As per the previous policy option (n. 3), there would be a need to clearly define the scope of application by reference to h-AIS for the reasons already discussed, which should be considered here entirely recalled (see §4.2).

Similarly, the responsible party should either be one single operator or both the provider and deployer, as per the reasoning already conducted above (see §4.3). Indeed, while a plurality of operators could cause concerns of causal uncertainty (see §4.3.4), a definition of operator such as the one presented above (see §4.3.1), or the choice to hold both providers and deployers responsible, whenever they respectively intervene, would abide by a "one-stop-shop" rationale and embed a risk management perspective (see §4.3.5). The latter option—holding both the provider and the deployer strictly liable, in their respective activities, identified by the very definitions provided by art. 3 AIA (see §4.3.5)—is preferable for reasons of coordination with the AIA.

This, in particular, would help minimize litigation and its associated costs, together with uncertainty of outcomes (see §5.2).

The liability rule should mirror that of art. 4 RLAI, whereby

> "(1) The operator of a high-risk AI-system shall be strictly liable for any harm or damage that was caused by a physical or virtual activity, device or process driven by that AI-system.
>
> […]
> (3) Operators of high-risk AI-systems shall not be able to exonerate themselves from liability by arguing that they acted with due diligence or that the harm or damage was caused by an autonomous activity, device or process driven by their AI-system. Operators shall not be held liable if the harm or damage was caused by force majeure."

While the indication of the responsible party ought to be adapted, the structure of the liability rule is perfect in achieving a true strict liability provision, allowing exemptions solely for acts of God (unlike the PLD and its revised version). The superiority of such a choice was already discussed above (see §§4.3.3 and 4.3.5).

The liable parties should then be allowed to sue in recourse any party, along the value chain, that may be deemed responsible for the malfunctioning of the AIS, ranging from the producer to any other contractual party (see §4.3.7). Existing norms, including the PLDr, would most likely suffice in ensuring such a right, absent any dedicated provision. However, some redundancy would definitely not harm interpreters and, at the same time, it would underline the risk management perspective embedded in the entire framework.

A structure similar to that of the Consumer Sales Directive (see fn. 205 and 217) could be replicated here, according to which sellers are prima facie liable to the buyer for all defects of the sold good,

[229] European Parliament (2020). Civil liability regime for artificial intelligence. European Parliament resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL)). Brussels, European Parliament., 21 no 23.

irrespective of any consideration of their fault, and can later claim in recourse along the value chain for the damages they had to compensate.

To illustrate how such a rule could work, we can consider that both the supplier and the user - each in their own case - would be able to calculate ex ante their exposure in terms of civil liability, thanks to the objective and well-defined liability rule. Most likely, as rational agents, they will insure themselves and the premium paid will be included in their cost function and then passed on to the users of the technology by increasing the price of the good or service provided. Users will pay for this insurance through the price of the good or service they purchase. Safer solutions will be more competitive, and markets will ideally favour their selection.

In the event of an accident, the supplier or provider will pay for the damage, most likely with limited or no litigation. Since both the provider and the deployer are professional parties who are likely to offer similar products and services to a wider audience, it is likely that if a problem arises with an AIS they use in their business, as part of a product or service, they will be called upon to compensate similar damages to similar users. Therefore, they will be in a much better position than the latter to investigate and understand the technical mechanisms that led to the incident(s) and be able to address them in a unified manner. On the one hand, they may decide to address a recurring problem (e.g., the same AI-based product or service has caused several analogous incidents for which they were prima facie required to compensate) through contractual remedies and negotiations with their business partners, obtaining price reductions, choosing to replace their services with those of competitors who appear to offer better quality solutions, and all sorts of market dynamics capable of minimizing transaction costs. On the other hand, they may aggregate claims that appear to depend on an identical technological feature (e.g. a specific design flaw) and sue the manufacturer under the PLDr, still reducing the number of lawsuits (instead of having multiple lawsuits from multiple injured user, there would be one from a provider or supplier) and being in the economic position and possessing the technological knowledge to decide to sue more successfully and even to exploit the remedies (including disclosure obligations) that the reformed text grants to the plaintiff.

Instead, dedicated rules on disclosure put forth by the AILD itself may be superfluous, as well as presumptions, considering the strict nature of liability. However, while the latter should radically be omitted as completely unnecessary, the former could still be considered, in particular to further ease the position of the defendant to later sue in recourse. Towards that end, an obligation to cooperate of the kind advanced by art. 8(4) RLAI would be preferable to the disclosure obligation put forth by art. 3 AILD.

Liability exemptions could be explored for cases of reckless behaviour of the plaintiff (see §4.3.6).
Finally, as per compensable damages, the considerations drawn above (see Chapter 4) should be deemed here entirely recalled.

5.5.1. The balance between European and MS law

Such a policy option would entail a return to the original conclusions of the political debate around the regulation of advanced technologies (see §1.4) and would minimize risks of fragmentation at MS level.

A strict liability rule, better if adopted with a regulation—but a maximum-harmonisation directive, with a very well-defined liability rule, limiting the possibility of great variations in implementation at MS level, would still prevent relevant discrepancies in implementation— would ensure the highest degree of harmonization. Being a special rule, it would not maintain a horizontal approach, overlapping with MS's general fault-based rules, eliminating both risks of divergent applications and political resistance to its adoption. Moreover, the European Court of Justice, like in the case described under OPTION 3, would certainly contribute to making harmonization more profound and coherent. Indeed, with a clear liability regime fully governed by EU law, the Court will be able to ensure harmonization in its interpretation. Instead, in the case described under OPTION 1, the role of the Court will be minimal, if any, while in the case considered under OPTION 2, harmonization will be radically more complex, since it would only reach the procedural dimension.

Embedding the vertical approach of conceiving a liability rule dedicated to a well-defined domain, it would also prevent the proliferation of alternative solutions at MS level, and the subsequent path-dependencies those entail. Ultimately, it would attract the regulation of civil liability for advanced technologies into a more coherent European regulatory framework companies would more easily navigate. As a result, it would also prevent the risk of over-regulation through the development of multiple, alternative and potentially conflicting regulatory frameworks at MS level.

Indeed, a clear strict liability rule would ease application and courts and claimants will hardly prefer alternative liability rules, already existing in single MS or ad-hoc adopted. This would mark a relevant distinction with the PLD and its application until today, which, instead, will most likely continue to characterize also the PLDr for the reasons discussed above (see Chapter 2).

Uniformity of outcomes in the domain of advanced technologies would favour the proliferation of a European market without barriers for products, manufacturers and innovators, and contribute to create that human-centric regulatory framework, the Commission declared to be interested in pursuing from the start[230].

5.5.2. The regulatory framework and its anticipated efficiency

The policy option here considered is the one that would favour technology users the most in obtaining compensation for harm suffered in the use of AIS (see §2.3.3 and §§4.2 and 4.3), this would also positively impact the development of innovation and its industry (see §5.5.3).

A clear strict liability rule would ensure prima facie compensation for most claimants, potentially without requiring litigation, but for limited cases where exemptions could play a role (see §4.3.6). That would minimize administrative costs.

[230] European Commission (2018). 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. Artificial Intelligence for Europe. COM(2018) 237 final. Brussels, European Commission.

At the same time, clear cut liability would ensure foreseeability of outcome and the possibility for businesses to identify the legal risk associated, calculate it and manage it, both through insurance and price mechanisms (see §4.3.7).

That, together with the possibility to sue in recourse along the value chain and negotiate contractual agreements within business partnerships—of the kind providers and deployers will establish with manufacturers and AIS designers—ensures costs will be efficiently distributed along the value chain, preventing the excessive burdening of defendants (see §4.3.7).

5.5.3. The impact on innovation

A uniform, unambiguous rule, leading to foreseeable and consistent outcomes, applicable across European MS, is of paramount importance in terms of economic efficiency and effective user protection.

This, in turn, provides for two major advantages. First, users increase their confidence in the early adoption of technology, since they perceive protection. Second, risks become manageable and distributable through pooling and spreading mechanisms, and businesses can factor them in their development and production costs, ultimately transferring them to the users of technology (see §4.3.7).

This effective internalization and increased foreseeability, if ensured Europe-wide, will strongly benefit businesses operating on the European market, and help the proliferation of innovation—in a technology transfer perspective—also among professional users, whose obligations will be clearly laid down.

CONCLUSIONS

The design of a clear regulatory framework for damages arising from the use of AIS is of paramount importance in order to create a well-defined, efficient and human-centered regulatory framework at the European level, benefiting both users and developers of the technology.

It is a strategic component to ensure that administrative costs are minimized, that users are protected, that incentives are provided for early adoption of technological solutions, and that companies are able to easily calculate potential risks and exposure. This reduces litigation, ensures efficient management, achieves economies of scale and radical simplification.

In such a perspective, it is clearly contradictory to address through European law detailed ex-ante compliance obligations while avoiding ex-post liability rules with the aim of reducing over-regulation and costs for developers and innovators.

Rather, the costs of non-Europe, of not adopting a coherent and consistent regulatory framework across all Member States, are clear and certain. Indeed, the absence of regulation at the European level will proliferate multiple, potentially contradictory legal solutions at the MS level, which will likely be the expression of conflicting policy options. This will create path dependencies that will later be very difficult, if not impossible, to overcome, and over-regulation will result. Ultimately, this could also lead to profound market fragmentation. Liability rules have a major impact on the way technology is designed and the solutions that prevail. Divergent solutions at Member State level could prevent identical AIS and AI-based services from being deployed across Europe. This would certainly be to the detriment of European professional and non-professional users, businesses and ultimately Europe's global competitiveness. To prevent such outcomes, the reform of the PLDr is certainly insufficient. The revision of the text from 1985 did not alter its structure, the filter represented by the notion of defect, the limitations to compensable damages, as well as the relevant litigation costs it requires to successfully carry out a claim. The PLDr will remain a rule of residual application, that may only benefit from the increase in class-actions and economically conspicuous litigation.

In such a perspective the first two policy options are the least desirable ones. Merely withdrawing the AILD (OPTION 1) or, worse, approving it in its current form, without profound revision (OPTION 2) will both ensure the proliferation of MS's alternative regulatory frameworks, as already clarified.

OPTION 2 is possibly worse than OPTION 1 in that the adoption of the current version of the AILD will raise relevant problems of coordination with national rules. This, in turn, will neither prevent the creation of specific liability frameworks at MS level, nor reduce the potential fragmentation of outcomes and discrepancies in the application of European procedural norms. Most likely, national courts will disregard European norms and apply preferable national alternatives, in particular strict liability rules. In other words, the result will be identical, if not worse, than rejecting a European framework. Overregulation will be the inevitable result. At the same time, however, the circumstance that a European regulatory initiative was already enacted, will seriously prevent or at least delay the adoption of alternative norms and solutions, crystallizing a fragmented, conflicting, and altogether inefficient outcome.

Therefore, despite being OPTION 1 largely undesirable, OPTION 2 is certainly less, and should be radically discarded.

Finally, for the reason largely discussed in this chapter and in the previous analysis, OPTION 4 is certainly the ideal one, consistent with the findings of the very experts that the European institutions have listened to over a decade of debate.

However, in the absence of the political will to present an alternative strict liability proposal at the time of the withdrawal of the AILD, the current proposal for a Directive could be reshaped along the lines of the proposals formulated under OPTION 3 and still achieve a commendable, albeit not ideal, result.

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This study, commissioned by the European Parliament's Policy Department for Justice, Civil Liberties and Institutional Affairs at the request of the Committee on Legal Affairs, critically analyses the EU's evolving approach to regulating civil liability for artificial intelligence systems. In order to avoid regulatory fragmentation between Member States, the study advocates for a strict liability regime targeting high-risk systems, structured around a single responsible operator and grounded in legal certainty, efficiency, and harmonisation.

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