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REASONABLE AI AND OTHER CREATURES. WHAT ROLE FOR AI STANDARDS IN LIABILITY LITIGATION?

Abstract

Standards play a vital role in supporting policies and legislation of the European Union. The regulation of artificial intelligence (AI) makes no exception as made clear by the AI Act proposal. Particularly, Articles 40 and 41 defer to harmonised standards and common specifications the concrete definition of safety and trustworthiness requirements, including risk management, data quality, transparency, human oversight, accuracy, robustness, and cybersecurity. Besides, other types of standards and professional norms are also relevant to the governance of AI. These include European non-harmonised standards, international and national standards, professional codes and guidelines, and uncodified best practices. This contribution casts light on the relationship between standards and private law in the context of liability litigation for damage caused by AI systems. Despite literature's commitment to the issue of liability for AI, the role of standardisation in this regard has been largely overlooked hitherto. Furthermore, while much research has been undertaken on the regulation of AI, comparatively little has dealt with its standardisation. This paper aims to fill this gap.

Building on previous scholarship, the contribution demonstrates that standards and professional norms are substantially normative in spite of their private and voluntary nature. In fact, they shape private relationships due to normative and economic reasons. Indeed, these private norms enter the courtrooms by explicit or implicit incorporation into contracts as well as by informing general clauses such as reasonableness and duty of care. Therefore, they represent the yardstick against which professionals' performance and conduct are evaluated. Hence, a link between standards, safety, and liability can be established. Against this backdrop, the role of AI standards in private law is assessed. To set the scene, the article provides a bird's-eye view of AI standardisation. The European AI standardisation initiative is analysed along with other institutional and non-institutional instruments. Finally, it is argued that AI standards contribute to defining the duty of care expected from developers and professional operators of AI systems. Hence, they might represent a valuable instrument for tackling the challenges posed by AI technology to extracontractual and contractual liability.

JEL CLASSIFICATION: D82, F23, K12, K13, K24, K41, L15

SUMMARY

[*] Ph.D. Candidate in Comparative Legal Disciplines at Roma Tre University. I am grateful to the anonymous reviewers for their valuable comments and to the participants in the DynamInt Doctoral Forum 'Markets, Governance and European Law in the Algorithmic Era' at Humboldt-University of Berlin for the fruitful discussion.

1 Introduction

Standardisation is the codification of professional knowledge and expertise in a particular field or with regard to specific products and services. Hence, standards are technical specifications and recommendations addressed to professionals. Standards can be issued by international, regional, and national organisations.

Standardisation is a strategic instrument for the governance of highly technical issues. The standardisation process is more agile than law-making procedures, which makes it particularly suited to regulating technologies that evolve at a rapid pace. Moreover, it is market-driven since standards are adopted by qualified experts in the field with the participation of businesses and representatives of non-industrial interests. Notably, standards stand as trade facilitators by creating a level playing field, promoting interoperability,[1] and favouring cost optimisation. At the same time, standardisation is essential to quality assurance in the interest of society as a whole.[2] In fact, standards provide objective and comparable measures of quality and safety. As a result, standards are meant to increase consumer confidence too.[3]

However, standardisation is a double-edged sword. Whereas in principle it is a catalyst for trade, it can also obstruct it.[4] Once standards take root in a given market they might act as a barrier against traders who do not comply with them. Furthermore, standardisation have both negative and positive impacts on innovation.[5] Whilst standardisation attracts investments and encourages the development of specific

[1] Commission, 'An EU Strategy on Standardisation – Setting global standards in support of a resilient, green and digital EU single market' COM (2022) 31 final, 1. See also Regulation (EU) No 1025/2012 of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council [2012] OJ L316/12, Recital 6; Case C-160/20 *Stichting Rookpreventie Jeugd and Others v Staatssecretaris van Volksgezondheid, Welzijn en Sport*, Opinion of AG Saugmandsgaard Øe, para 79.

[2] Marta Cantero Gamito, 'Europeanization through Standardization: ICT and Telecommunications' (2018) 37 YEL 395, 421-422.

[3] Commission, 'An EU Strategy on Standardisation - Setting global standards in support of a resilient, green and digital EU single market' COM (2022) 31 final, 1.

[4] Marta Cantero Gamito, 'Europeanization through Standardization: ICT and Telecommunications' (2018) 37 YEL 395, 398 ff.

[5] GM Peter Swann, 'The Economics of Standardization: An Update' (Innovative Economics Limited 2010) Report for the UK Department of Business, Innovation and Skills (BIS) <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/32444/10-1135-economics-of-standardization-update.pdf>, 9-12; Knut Blind, 'The Impact of Standardisation and Standards on Innovation' in Jakob Edler and others (eds), *Handbook of Innovation Policy Impact* (Edward Elgar 2016).

technologies, it risks promoting lock-in in outdated technologies,[6] especially in the case of strong network externalities, that is, customers benefitting from the existence of a large network of many other users of the same standard or technology.[7] Finally, it may be challenging to ensure that all goals of are sufficiently achieved. For instance, cost optimisation and interoperability may conflict with quality assurance in some cases. Hence, standardisation must be handled with care.

In addition to standards on goods and services that are formally adopted by standardisation organisations, technical specifications and rules of conduct can be established by stakeholders outside of typical standardisation fora.[8] Professional associations and companies often lay down guidelines and codes of conduct or adopt private certification schemes for goods and services. Furthermore, private contracts, particularly standard form contracts, perform a regulatory function.[9] These guidelines, codes, certifications schemes, and contracts can incorporate standards set by standardisation organisations and/or set different criteria. Therefore, 'formal' and 'informal' standards coexist, and they both contribute to shaping the choices and the behaviour of manufacturers and professionals.

At the European level, standardisation is at the core of the internal market of the European Union ('EU').[10] In the EU framework, standardisation means a mechanism of co-regulation that brings together private and public parties at different stages of decision-making so as to balance different interests.[11] Hence, it refers to the adoption of standards by recognised standardisation organisations. Standards play a vital role in supporting EU policies and legislation and particularly in the context of emerging technologies. The regulation of artificial intelligence (AI) makes no exception.

In its proposal for a regulation on AI (hereinafter, 'AI Act'),[12] the Commission has made it clear that it envisions a prominent role for standards. The AI Act seeks to introduce a complex patchwork of safety and trustworthiness requirements for 'high-risk' AI systems[13] concerning risk management, data quality, transparency, human

[6] ibid.
[7] GM Peter Swann, *The Economics of Innovation: An Introduction* (Edward Elgar 2009), 82 ff.
[8] Marta Cantero Gamito and Hans-W Micklitz (eds), *The Role of the EU in Transnational Legal Ordering* (Elgar 2020).
[9] Dan Wielsch, 'Global Law's Toolbox: How Standards Form Contracts' in Horst Eidenmüller (ed), *Regulatory Competition in Contract Law and Dispute Resolution* (Beck/Hart/Nomos 2013).
[10] Commission, 'An EU Strategy on Standardisation Setting global standards in support of a resilient, green and digital EU single market' COM (2022) 31 final, 1. See also Standardisation Regulation, Recital 5.
[11] Mariolina Eliantonio and Megi Medzmariashvili, 'Hybridity Under Scrutiny: How European Standardization Shakes the Foundations of EU Constitutional and Internal Market Law' (2017) 44 Legal Issues of Economic Integration 323, 324.
[12] Commission, '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 (hereinafter, 'AI Act').
[13] Pursuant to Article 6 of the AI Act, high risk AI systems include: i) systems that are intended to be used as safety components of a product, or are themselves a product, covered by listed Union harmonisation legislation and

oversight, accuracy, robustness, and cybersecurity. With a view to lowering compliance costs for providers of high-risk AI systems,[14] Articles 40 and 41 establish a presumption of conformity with said requirements for systems that comply with harmonised standards and common specifications.[15] The presumption should incentivise the adoption of these standards and therefore create a virtuous circle.[16] Hence, standards will have a crucial role in providing technical and operational details for the design, development, and deployment of AI technology. Whilst much research has been undertaken on the regulation of AI, comparatively little has dealt with its standardisation.[17] Hence, the focus of the present contribution is on AI standardisation.

Furthermore, the paper deals with the role of AI standards in private law, specifically in liability litigation. Liability for damage caused by AI systems is a mainstream topic for scholarly and policy debate. In particular, the futureproofing of the Directive on liability for defective products[18] (hereinafter, 'PLD') has been questioned.[19] Moreover, the

required by that legislation to undergo a third-party conformity assessment (eg machinery, toys, radio equipment, medical devices, aviation equipment, motor vehicles); ii) applications of AI technologies listed in Annex III to the Regulation, that pose a risk of harm to health and safety, or a risk of adverse impact on fundamental rights (eg biometric identification, creditworthiness assessments, immigration assessments, access to education or employment, law enforcement, safety components for critical infrastructure). By Article 7, the Commission, following stipulated criteria, may add similar systems to the list in Annex III if they pose an equivalent or greater risk of harm to health and safety, or of adverse impact on fundamental rights, than the systems already listed in the Appendix.

[14] Pursuant to Article 3, 'provider' means a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed with a view to placing it on the market or putting it into service under its own name or trademark, whether for payment or free of charge.' As pointed out by Edwards, the definition of provider does not encompass businesses that deploy AI systems that are developed by a third party. As a result, most safety and trustworthiness obligations do not apply to professional users of AI systems according to the Proposal. This differential treatment is not justified though. Moreover, it has negative repercussions for those affected by the operation of an AI system. See Lilian Edwards, 'Regulating AI in Europe: Four Problems and Four Solutions' (Ada Lovelace Institute 2022) <https://www.adalovelaceinstitute.org/report/regulatingai-in-europe/>.

[15] 'Harmonised standards and supporting guidance and compliance tools will assist providers and users in complying with the requirements laid down by the proposal and minimise their costs' (AI Act, Explanatory Memorandum, 6-7).

[16] Mark McFadden and others, 'Harmonising Artificial Intelligence: The Role of Standards in the EU Regulation' (Oxford Commission on AI & Good Governance 2021).

[17] Martin Ebers, 'Standardizing AI: The Case of the European Commission's Proposal for an "Artificial Intelligence Act"' in Larry DiMatteo, Michel Cannarsa and Cristina Poncibò (eds), *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics* (CUP 2022); Mark McFadden and others, 'Harmonising Artificial Intelligence: The Role of Standards in the EU Regulation' (Oxford Commission on AI & Good Governance 2021); Alessia Monica, 'Regulating AI and the Key-Role of Standard in the Co-Regulation of ICT: EU, Members States and Private Entities' [2021] MediaLaws 145; Michael Veale and Frederik Zuiderveen Borgesius, 'Demystifying the Draft EU Artificial Intelligence Act. Analysing the Good, the Bad, and the Unclear Elements of the Proposed Approach' (2021) 22 Computer L Rev Int'l 97, 104-107. See also Florian Möslein and Roberto V. Zicari, 'Certifying Artificial Intelligence Systems' in Roland Vogl (ed), *Research Handbook on Big Data Law* (Edward Elgar 2021).

[18] 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 [1985] OJ L210/29.

[19] See Expert Group on Liability and New Technologies – New Technologies Formation, 'Liability for Artificial Intelligence and Other Emerging Technologies' (Commission 2019) <https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeetingDoc&docid=36608>; Commission, 'Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics' COM (2020) 64 final. In European scholarship see eg Jean-Sébastien Borghetti, 'How can Artificial Intelligence be Defective?' in

application of established tort law is not straightforward.[20] Notably, it is challenging to determine if, and under what conditions, human operators are liable for damage caused by autonomous[21] AI systems over which they retain little to no control. Suggestively, it has been proposed to replace the 'reasonable person' standard of conduct with a 'reasonable algorithm' standard.[22] In a similar vein, contract liability is not clear-cut when obligations are performed with the support of AI systems.[23]

Ultimately, these concerns triggered two recent legislative initiatives at an EU level in the context of extra-contractual liability. Following a public consultation,[24] the Commission adopted a proposal for an 'AI Liability Directive'[25] and a proposal for a revised 'PLD II.'[26] Specifically, the proposed AI Liability Directive does not aim to establish a full-fledged liability regime for AI-related damage, but it eases the burden of

Sebastian Lohsse, Reiner Schulze and Dirk Staudenmayer (eds), *Liability for Artificial Intelligence and the Internet of Things* (Hart/Nomos 2019); Tiago Sérgio Cabral, 'Liability and Artificial Intelligence in the EU: Assessing the Adequacy of the Current Product Liability Directive' (2020) 27 MJ 615; Martin Ebers, 'Liability for Artificial Intelligence and EU Consumer Law' (2021) 12 JIPITEC 204, 214 ff; Bernhard A Koch, 'Product Liability 2.0 – Mere Update or New Version?', in *Liability for Artificial Intelligence and the Internet of Things*, *cit.*; Piotr Machinowski (ed), *European Product Liability. An Analysis of the State of the Art in the Era of New Technologies* (Intersentia 2016); Daniel Schönberger, 'Artificial Intelligence in Healthcare: A Critical Analysis of the Legal and Ethical Implications' (2019) 27 IJLIT 171; Christian Twigg-Flesner, 'Guiding Principles for Updating the Product Liability Directive for the Digital Age' (European Law Institute 2021); Gerhard Wagner, 'Produkthaftung für autonome Systeme' (2017) 217 AcP 707; *id.*, 'Robot Liability', in *Liability for Artificial Intelligence and the Internet of Things*, *cit.*; Herbert Zech, 'Liability for Autonomous Systems: Tackling Specific Risks of Modern IT', in *Liability for Artificial Intelligence and the Internet of Things*, *cit.*

[20] Cf *ex multis* Jaap Hage, 'Theoretical Foundations for the Responsibility of Autonomous Agents' (2017) 25 Artificial Intelligence and Law 255; Joseph A Cannataci, 'Law, Liability and Expert Systems' (1989) 3 AI & Society 169; Alberto Galasso and Hong Luo, 'Punishing Robots. Issues in the Economics of Tort Liability and Innovation in Artificial Intelligence' in Ajay Agrawal, Joshua Gans and Avi Goldfarb (eds), *The Economics of Artificial Intelligence: An Agenda* (University of Chicago Press 2019); Andrew D Selbst, 'Negligence and AI's Human Users' (2020) 100 B U L Rev 1315; Christiane Wendehorst, 'Strict Liability for AI and Other Emerging Technologies' (2020) 11 JETL 150; Zhao Yan Lee, Mohammad Ershadul Karim and Kevin Ngui, 'Deep Learning Artificial Intelligence and the Law of Causation: Application, Challenges and Solutions' (2021) 30 Information & Communications Technology Law 255; Martin Ebers, 'Civil Liability for Autonomous Vehicles in Germany' (2022) <https://ssrn.com/abstract=4027594> accessed 30 July 2022; David C Vladeck, 'Machines without Principals: Liability Rules and Artificial Intelligence' (2014) 89 Wash L Rev 117.

[21] Cf Simon Chesterman, 'Artificial Intelligence and the Problem of Autonomy' (2020) 210 Notre Dame Journal on Emerging Technologies 210.

[22] Cf Woodrow Barfield, 'Liability for Autonomous and Artificially Intelligent Robots' (2018) 9 Paladyn, Journal of Behavioral Robotics 193; Mark A Lemley and Bryan Casey, 'Remedies for Robots' (2019) 86 U Chi L Rev 1311.

[23] See André Janssen, 'AI and Contract Performance' in Larry DiMatteo, Michel Cannarsa and Cristina Poncibò (eds), *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics* (CUP 2022); Tycho J de Graaf and Iris S Wuisman, 'Contractual Liability for the Use of AI under Dutch Law and EU Legislative Proposals' in Bart Custers and Eduard Fosch-Villaronga (eds), *Law and Artificial Intelligence: Regulating AI and Applying AI in Legal Practice* (Springer 2022).

[24] 'Civil Liability – Adapting Liability Rules to the Digital Age and Artificial Intelligence' (Have your say) <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-adapting-liability-rules-to-the-digital-age-and-artificial-intelligence_en> accessed 4 November 2022. Cf Bernhard A Koch and others, 'Public Consultation on Civil Liability. Adapting Liability Rules to the Digital Age and Artificial Intelligence' (European Law Institute 2022).

[25] Commission, '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 (hereinafter, 'AI Liability Directive').

[26] Commission, 'Proposal for a Directive of the European Parliament and of the Council on liability for defective products' COM (2022) 495 final (hereinafter, 'PLD II').

proof on plaintiffs by introducing a right to request a court order of disclosure of relevant evidence about high-risk AI systems[27] and rebuttable presumptions of fault[28] and causation.[29] Similar to the AI Liability Directive, the PLD II introduces a duty to disclose relevant evidence[30] and rebuttable presumptions of defectiveness and causation.[31] Furthermore, the PLD II extends the scope of application of EU product liability law to software, such as operating systems, computer programs, and AI systems.[32]

In this regard, courts play a pivotal role in applying tort law to AI-related damage.[33] Indeed, the issuance of an order of disclosure and the application of a presumption depend on the discretionary appreciation of contextual factors, in relation to the technical and scientific complexity of the single case. Moreover, courts will have to set a standard of conduct as a yardstick against which the behaviour of providers, producers, operators, and other actors must be assessed.[34]

Against this backdrop, standards might help deal with uncertainty. Indeed, judges and experts rely on standards for assessing negligence and causation in highly technical cases. Standards also inform general clauses like due diligence. Furthermore, standards enter the courtrooms through contracts. In fact, contractual clauses might refer explicitly to standards that therefore acquire binding force between parties. Moreover, because of their pervasiveness, standards shape private relationships and the expectations of private parties. Hence, they represent the main yardstick against which professionals' behaviour is measured. Accordingly, deviation from standards can constitute evidence of negligence. Notwithstanding their non-binding nature, standards are therefore a precious tool in the hands of stakeholders and courts to mitigate the unclarity of the liability regime of AI. And yet, the role of standards in the context of liability for AI-related damage has been overlooked hitherto. Therefore, the present contribution aims to fill this gap.

The reasoning proceeds in four steps. First, Sections 2 and 3 set the scene with a brief overview of the European standardisation framework and a discussion of the legal nature of standards. Second, Section 4 highlights the relationship between standards and private law. Particularly, it casts light on the link between standards, safety, and liability. Third, Section 5 analyses the role of AI standardisation for AI governance in

[27] AI Liability Directive, Article 3.
[28] AI Liability Directive, Article 3(5). See also Recital 21.
[29] AI Liability Directive, Article 4.
[30] PLD II, Article 8.
[31] PLD II, Article 9. See also Recitals 33 and 34.
[32] PLD II, Article 4, No. 1 and Recitals 12 and 13.
[33] Orian Dheu, Jan De Bruyne and Charlotte Ducuing, 'The European Commission's Approach to Extra-Contractual Liability and AI – A First Analysis and Evaluation of the Two Proposals' (2022) CiTiP Working Paper 2022 <https://ssrn.com/abstract=4239792>, 42.
[34] ibid.

light of the AI Act. Fourth, building on the findings of the previous sections, Section 6 pinpoints the role of AI standards in the context of liability litigation, with a focus on negligence and conformity. Section 7 concludes.

The aim of this paper is twofold. It aims to encourage further research on AI standardisation. Furthermore, it provides motivation for reconsidering the European approach to standardisation. Indeed, the shortcomings of private standards-making in terms of democracy, legitimacy, and transparency are under the spotlight.[35] These concerns are shared by scholars and the Commission. Arguably, they are even more persuasive if standards influence the outcome of private disputes.

2 The European way' to standardisation in a nutshell

Regulation (EU) No 1025/2012 on standardisation (hereinafter, 'Standardisation Regulation')[36] defines standards as written documents adopted by recognised standardisation bodies containing technical specifications on the characteristics of products and services,[37] with which compliance is not mandatory.[38] Depending on the issuing body, the Standardisation Regulation divides them into international, European, and national standards.[39] European standards can be harmonised and non-harmonised standards. Harmonised standards are adopted by European standardisation organisations following a request made by the European Commission.[40] They provide harmonisation insofar as all conflicting national standards ought to be withdrawn after their publication.[41]

[35] Cf Commission, 'Standardisation Package – Report from the Commission to the European Parliament and the Council on the implementation of the Regulation (EU) No 1025/2012 from 2016 to 2020' COM (2022) 30 final; Commission, 'Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 1025/2012 as regards the decisions of European standardisation organisations concerning European standards and European standardisation deliverables' COM (2022) 32 final. In the literature cf Pierluigi Cuccuru, 'Regulating by Request: On the Role and Status of the Standardisation Mandate under the New Approach' in Mariolina Eliantonio and Caroline Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique* (Edward Elgar 2020); Harm Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Hart 2005), 257; Rob van Gestel and Peter van Lochem, 'Private Standards as a Replacement for Public Lawmaking?' in Marta Cantero Gamito and Hans-W Micklitz (eds), *The Role of the EU in Transnational Legal Ordering: Standards, Contracts and Codes* (Edward Elgar 2020); Raymund Werle and Eric J Iversen, 'Promoting Legitimacy in Technical Standardisation' (2006) 2 Science, Technology and Innovation Studies 19, 21.

[36] Regulation (EU) No 1025/2012 of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council [2012] OJ L316/12 [Standardisation Regulation].

[37] Standardisation Regulation, Article 2(4).

[38] Standardisation Regulation, Article 2(1).

[39] ibid.

[40] ibid.

[41] Standardisation Regulation, Article 3(6).

The Standardisation Regulation follows the principles of the New Approach to technical harmonisation and of the New Legislative Framework ('NLF') for the marketing of products. The New Approach was launched by the Council in 1985.[42] It consists of a new regulatory strategy in which legislative instruments and European standards interact to foster the free movement of goods. The core idea is that of complementing top-down legislation with bottom-up regulation.[43] Accordingly, legislative harmonisation is limited to the formulation of 'essential safety requirements' that a product must satisfy to be put on the market.[44] Instead, the definition of detailed technical specifications is entrusted to standardisation organisations by virtue of specific mandates conferred by the Commission.[45] This is in stark contrast to the previous Old Approach to the marketing of goods which was characterised by detailed texts containing all the necessary technical and administrative requirements. The NLF for the marketing of products, adopted in July 2008,[46] builds on the New Approach and completes the overall legislative framework with provisions on conformity assessment, accreditation, and market surveillance.[47] Recently, the responses to the Commission's consultation on the standardisation strategy have revealed that there is overwhelming support for the NLF approach.[48]

Although harmonised standards are not binding on individuals, normative and economic incentives push businesses toward compliance with them. Notably, products that are manufactured in conformity to harmonised standards are presumed to fulfil the essential requirements imposed by EU law.[49] The presumption of conformity performs a twofold function. It promotes the quality and the safety of products in the interest of consumers. At the same time, it provides legal certainty and a level playing field that fosters the free movement of goods since national authorities cannot restrict the trade of products that are in conformity with harmonised standards,[50] in application of the principle of mutual recognition.[51]

[42] Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards [1985] OJ C136/01.
[43] Cf Marta Cantero Gamito, 'Europeanization through Standardization: ICT and Telecommunications' (2018) 37 YEL 395, 400.
[44] ibid.
[45] ibid.
[46] Regulation (EC) No 764/2008 of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC [2008] OJ L218/21; Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC [2008] OJ L218/82.
[47] Commission, Notice — The 'Blue Guide' on the implementation of EU products rules 2016 [2016] OJ C272.
[48] Cf Mark McFadden and others, 'Harmonising Artificial Intelligence: The Role of Standards in the EU Regulation' (Oxford Commission on AI & Good Governance 2021), 14 and references therein.
[49] ibid.
[50] ibid.
[51] Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C326/47, Articles 34-36; Regulation (EU) No 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 [2019]

Notably, the Standardisation Regulation extended the New Approach to services. Article 1 states clearly that the Standardisation Regulation disciplines the establishment of European standards and of European standardisation deliverables[52] 'for products and for services,' thus providing a legal basis for standardisation of services.[53] Standards for services are substantially different from standards for goods though.[54] Whereas standards for goods consist of highly technical specifications on sizes and materials, standards for services concern contractual obligations and social interaction between the provider and the customer.[55] Therefore, the intertwinement between technical standards and private law is even tighter for services than for products.[56] Indeed, considering that service standards touch upon contractual obligations, non-compliance with them can easily trigger contractual remedies such as contract termination.[57]

Focusing on European standards, they are developed by private international non-profit organisations, the European Standardisation Organisations (ESOs), namely the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI). Amidst European standards, those that have been formally requested and validated by the Commission are also harmonised standards.[58] References to harmonised standards are published in the Official Journal of the European Union ('OJ') by the Commission after verifying their compliance with EU law.[59] From this moment on, the Member States and national standardisation bodies are obliged to withdraw all conflicting national standards for the sake of harmonisation.[60]

In theory, compliance with harmonised standards is voluntary. Whilst compliance with legal essential requirements is presumed in case of conformity to harmonised

OJ L91/1. See Case C-120/78 *Rewe-Zentral v Bundesmonopolverwaltung für Branntwein* [1979] ECR 649 [Cassis de Dijon]. On the potentially quantitative restrictive effect of national standardisation and certification activities see Case C-171/11 *Fra.bo SpA v Deutsche Vereinigung des Gas- und Wasserfaches eV (DVGW) — Technisch-Wissenschaftlicher Verein* [2012] ECR I-176, paras 27-32.

[52] 'European standardisation deliverable' means any other technical specification than a European standard, adopted by an ESO for repeated or continuous application. Like European standards, European standardisation deliverables are voluntary. Cf Standardisation Regulation, Article 2(2).

[53] Barend van Leeuwen, *European Standardisation of Services and Its Impact on Private Law: Paradoxes of Convergence* (Bloomsbury Publishing 2017), 49.

[54] Cf Standardisation Regulation, Recital 10, stating that the distinction between goods and services is blurred nowadays so 'it is not always possible to clearly distinguish standards for products from standards for services'.

[55] See Christoph Busch and Simon Reinhold, 'Standardisation of Online Dispute Resolution Services: Towards a More Technological Approach' (2015) 4 EuCML, 50-58; Hans-W. Micklitz, 'The Service Directive: Consumer Contract Law Making via Standardisation', in Aurelia Colombi Ciacchi and others (eds), *Haftungsrecht im dritten Millennium – Liability in the Third Millennium (Liber Amicorum Gert Brüggemeier)* (Nomos 2009), 454.

[56] Cf Marta Cantero Gamito, 'Europeanization through Standardization: ICT and Telecommunications' (2018) 37 YEL 395, 421-422.

[57] ibid.

[58] Proposals for harmonised standards can also be submitted to ESOs by national standardisation organisations.

[59] Standardisation Regulation, Article 10.

[60] Standardisation Regulation, Article 3(6).

standards, manufacturers and providers are always free to deviate from said standards, as long as they dispose of alternative means to demonstrate compliance with EU law. The facts tell a different story though. Providing alternative evidence of compliance with EU law is so expensive and time-consuming that professionals cannot 'opt out' of harmonised standards without incurring significant further costs.[61] In some cases, market access is even contingent on compliance with a certain standard.[62]

While harmonised standards are drafted by private entities, they must adhere to the essential safety requirements laid down by EU law.[63] Furthermore, the ESOs are under tight control and supervision by the Commission, which initiates, manages, and monitors the entire procedure, and finally decides on the publication in the OJ.[64] Hence, the European approach to standardisation embraces the paradigm of 'proceduralization'[65] and establishes a dialectical relation between private autonomy and public rules. The State recognizes the potential of private standards-making. At the same time, it frames the exercise of this normative power within procedural rules and requirements that force private rule makers to consider public interest.[66] However, it is worth noting that the supervisory role of the Commission is contested[67] both in terms of efficacy, due to its lack of sector-specific expertise, and in terms of efficiency, due to the increased complexity brought in the standards-making process by tight control mechanisms.[68] Furthermore, scholars have denounced the constitutional

[61] Rob van Gestel and Peter van Lochem, 'Private Standards as a Replacement for Public Lawmaking?' in Marta Cantero Gamito and Hans-W Micklitz (eds), *The Role of the EU in Transnational Legal Ordering: Standards, Contracts and Codes* (Edward Elgar 2020), 31-32; Raymund Werle and Eric J Iversen, 'Promoting Legitimacy in Technical Standardisation' (2006) 2 Science, Technology and Innovation Studies 19, 21.
[62] Marta Cantero Gamito, 'Europeanization through Standardization: ICT and Telecommunications' (2018) 37 YEL 395, 421-422.
[63] Case C-613/14 *James Elliott Construction Limited vs Irish Asphalt Limited* [2016] ECR I-821, para 43.
[64] ibid.
[65] The expression is borrowed from Wielsch who adopts it in the context of regulatory competition between public and private norms in the regulation of contracts: Dan Wielsch, 'Global Law's Toolbox: How Standards Form Contracts' in Horst Eidenmüller (ed), *Regulatory Competition in Contract Law and Dispute Resolution* (Bloomsbury 2013), 104.
[66] ibid.
[67] For a critique and a suggestion of alternative rule-making and certification schemes, see Rob van Gestel and Peter van Lochem, 'Private Standards as a Replacement for Public Lawmaking?' in Marta Cantero Gamito and Hans-W Micklitz (eds), *The Role of the EU in Transnational Legal Ordering: Standards, Contracts and Codes* (Elgar 2020).
[68] Cf Pierluigi Cuccuru, 'Regulating by Request: On the Role and Status of the Standardisation Mandate under the New Approach' in Mariolina Eliantonio and Caroline Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique* (Edward Elgar 2020). Cuccuru makes the point that the Commission lacks technical expertise and proximity to industry comparable to those of ESOs. This seriously undermines its ability to substantially contest ESOs' standards. Moreover, Cuccuru contends that the ESOs have a pervasive influence on the drafting of the very same Commission's mandates which are meant to set a framework for their activity.

shortcomings[69] of standardisation as well as the limits of judicial oversight,[70] sometimes proposing alternative regulatory models.[71]

As to the legal nature of harmonised standards, the Standardisation Regulation is silent. Indeed, it does not clarify whether harmonised standards are part of EU law or not. Their legal nature has been puzzled by the ruling of the Court of Justice (hereinafter, 'CJEU' or 'the Court') in the landmark case *James Elliott Construction Ltd. and Irish Asphalt Ltd.*[72] ('*James Elliott*') of 2016. In *James Elliott*, the CJEU stated that harmonised standards are part of EU law and thus fall within the interpretative jurisdiction of the Court under Article 267 TFEU. Subjection to the Court's jurisdiction has been affirmed not to jeopardise the uniformity of EU law. Notwithstanding the fact that harmonised standards are not acts of the EU *per se*, they produce legal effects in the internal market since compliance with them permits the circulation of products and services.[73] Therefore, harmonised standards are 'necessary implementation measures' of provisions of EU law on essential requirements.[74] Hence, the need to prevent different national authorities from attributing dissimilar meanings to harmonised standards.[75] Furthermore, the standards-making power of ESOs is substantially and formally

[69] See Case C-9/56 *Meroni & Co., Industrie Metallurgiche, SpA v High Authority of the European Coal and Steel Community* [1958] ECR 133. According to the *Meroni* formula, in the EU system delegation of rule-making powers is allowed only if they are of a purely executive nature, if appropriate procedural guarantees are in place, and if judicial review of delegates' decisions is ensured. For a critique of the New Approach framework in light of the Meroni doctrine see Takis Tridimas, 'Community Agencies, Competition Law, and ECSB Initiatives on Securities Clearing and Settlement' (2009) 28 YEL 216. See also Eric J Iversen, Thierry Vedel and Raymund Werle, 'Standardization and the Democratic Design of Information and Communication Technology' (2004) 17 Knowledge, Technology & Policy 104; Olia Kanevskaia, 'ICT Standards Bodies and International Trade: What Role for the WTO?' (2022) 56 JWT 429. For proposals of alternative regulatory models see Rob van Gestel and Hans-W Micklitz, 'European Integration through Standardization: How Judicial Review Is Breaking down the Club House of Private Standardization Bodies' (2013) 50 CML Rev 145.

[70] See Pierluigi Cuccuru, 'The Public and Private Sides of Harmonized Standards: *James Elliott Construction v. Irish Asphalt*' (2018) 19 German LJ 1399.

[71] Harm Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Hart 2005), 257; Rob van Gestel and Peter van Lochem, 'Private Standards as a Replacement for Public Lawmaking?' in Marta Cantero Gamito and Hans-W Micklitz (eds), *The Role of the EU in Transnational Legal Ordering: Standards, Contracts and Codes* (Edward Elgar 2020).

[72] Case C-613/14 *James Elliott Construction Limited vs Irish Asphalt Limited* [2016] ECR I-821 (hereinafter, 'James Elliott'). For comments on the decision see eg Pierluigi Cuccuru, 'The Public and Private Sides of Harmonized Standards: *James Elliott Construction v. Irish Asphalt*' (2018) 19 German LJ 1399; Mariolina Eliantonio, 'Judicial Control of the EU Harmonized Standards: Entering a Black Hole?' (2017) 44 Legal Issues of Economic Integration 399; Mariolina Eliantonio and Carlo Colombo, 'Harmonized Technical Standards as Part of EU Law: Juridification with a Number of Unresolved Legitimacy Concerns?' (2017) 24 MJ 323; Kai P Purnhagen, 'Voluntary "New Approach" Technical Standards are Subject to Judicial Scrutiny by the CJEU! – The Remarkable CJEU judgment "Elliott" On Private Standards' (2017) 8 EJRR 586; Carlo Tovo, 'Judicial Review of Harmonised Standards: Changing the Paradigms of Legality and Legitimacy of Private Rulemaking under EU Law' (2018) 55 CML Rev 1187; Arnaud van Waeyenberge and David Restrepo Amariles, '*James Elliot Construction*: A "New(ish) Approach" to Judicial Review of Standardisation' (2017) 42 EL Rev 882; Annalisa Volpato, 'The Harmonized Standards before the ECJ: *James Elliott Construction*' (2017) 54 CML Rev 591.

[73] *James Elliott*, paras 38-42; Case C-613/14 *James Elliott Construction Limited vs Irish Asphalt Limited* [2016] ECR I-821, Opinion of AG Campos Sánchez-Bordona EU:C:2016:63, para 61.

[74] *James Elliott*, para 43. Cf Case C-192/89 *Sevince v Staatssecretaris van Justitie* [1990] ECR I-3461, para 10; Case C-188/91 *Deutsche Shell AG v Hauptzollamt Hamburg-Harburg* [1993] ECR I-363, para 17.

[75] Cf *James Elliott*, para 34.

limited. Indeed, the content of standards is framed by legal essential requirements.[76] Moreover, from an institutional angle, the adoption of harmonised standards is required and strictly monitored by the Commission.[77] Hence, the exercise of private standards-making power is subject to substantial and procedural constraints. In light of the above, harmonised standards are substantially part of EU law and thus subject to the interpretative jurisdiction of the Court.

However, it must be noted that the Court did not deny that harmonised standards are voluntary private rules. On the contrary, they are private rules by virtue of their issuing institutions, the ESOs, that are private organisations and not institutions, bodies, offices, or agencies of the Union.[78] The fact that ESOs act under the mandate and the supervision of the Commission does not alter their private nature. This is especially true in light of the limited role of public oversight over ESOs, which is largely replaced by private third-party monitoring. Moreover, no sanctions under public law are inflicted on ESOs in case of non-compliance with standardisation requests issued by the Commission.[79] Finally, harmonised standards are voluntary rules since they are not binding.[80] Arguably, harmonised standards should be regarded as part of EU law only for the purposes of Article 267 of the Treaty on the Functioning of the European Union[81] ('TFEU').[82] In the *James Elliott* ruling, the CJEU equated harmonised standards to acts of the EU to establish its interpretative jurisdiction under Article 267 on them. Yet, the Court has not clarified whether it is entitled to rule on their validity too. For instance, the Court may rule on the validity of the Commission's Implementing Decision, that authorises their publication in the OJ, as a means of indirectly controlling the validity of harmonised standards.[83] Indeed, the Court did not push it to state that harmonised standards are acts of the Union.[84] Instead, the CJEU ruled out this possibility due to the

[76] *James Elliott*, paras 33 and 43.
[77] *James Elliott*, paras 36-37 and 43-47.
[78] *James Elliott*, para 34.
[79] Cf Commission, 'Vademecum on European standardisation in support of Union legislation and policies' SWD (2015) 205 final, Part I, 10; Pierluigi Cuccuru, 'Regulating by Request: On the Role and Status of the Standardisation Mandate under the New Approach' in Mariolina Eliantonio and Caroline Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique. A Cross-disciplinary and Multi-level Analysis* (Edward Elgar 2020), 57.
[80] Standardisation Regulation, Article 2(1).
[81] Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C326/47 [TFEU].
[82] In the words of AG Campos Sánchez-Bordona: 'harmonised technical standards [...] should be regarded as 'acts of the institutions, bodies, offices or agencies of the Union' for the purposes of Article 267 TFEU' (*James Elliott*, *cit.*, Opinion of AG Campos Sánchez-Bordona, para 40). This argument is also made in a report commissioned by the German Federal Ministry for Economic Affairs and Energy (BMWi): Kathrin Dingemann and Matthias Kottmann, 'Legal Opinion on the European System of Harmonised Standards' (BMWi 2020) <https://www.bmwi.de/Redaktion/EN/Downloads/L/legal-opinion-on-the-european-system-of-harmonised-standards.pdf?__blob=publicationFile&v=3>.
[83] Cf Arnaud van Waeyenberge and David Restrepo Amariles, '*James Elliot Construction*: A "New(ish) Approach" to Judicial Review of Standardisation' (2017) 42 European Law Review 882, 891 f. The Authors suggest adopting a similar approach to the one used for preliminary rulings on international treaties.
[84] Cf Pierluigi Cuccuru, 'The Public and Private Sides of Harmonized Standards: *James Elliott Construction v. Irish Asphalt*' (2018) 19 German LJ 1399, 1403-1405.

private nature of their issuing institutions. While Advocate General Campos Sánchez-Bordona did say that harmonised standards are acts of the Union in his opinion, he also specified that the equation was 'for the purposes of Article 267 TFEU.'[85] Such a statement might open to the possibility of the Court's scrutiny over the validity of harmonised standards too. Instead, the CJEU adopted a more cautious approach by stressing that the case at hand concerned only its interpretative jurisdiction. Whereas such an issue deserves in-depth analysis, for the purposes of this study it suffices to reaffirm that harmonised standards are voluntary private rules that have legal effects in the EU internal market.

It must be stressed that standards other than harmonised standards are also vital to European standardisation. Only conformity to harmonised standards, ie standards mandated by the Commission and published in the OJ, triggers the presumption of compliance with essential safety requirements. However, all types of European standards have an impact on private law. For instance, European standards acquire legal force between parties if they are explicitly or implicitly incorporated into contracts, regardless of their harmonised or non-harmonised character. Furthermore, they inform general clauses like due diligence. Contracts and case-law thus contribute to the diffusion of European standards. Therefore, harmonisation via European standards can occur top-down by means of an act of the Commission—namely, publication of harmonised standards in the OJ—or bottom-up by virtue of private autonomy or judicial interpretation.[86]

Finally, it is worth noting that EU law can incorporate standards, including non-European standards, and make them mandatory. Accordingly, in the recent *Stichting Rookpreventie* case,[87] the Court upheld a provision of EU law that obliged manufacturers of tobacco products to comply with international standards on the measurement of tar, nicotine, and carbon monoxide emissions. The Court, therefore, stated that references to international standards are valid insofar as their addressees have access to the official and authentic version of the referred standards.[88]

3 The legal nature of standars

[85] *James Elliott*, Opinion of AG Campos Sánchez-Bordona, para 40 as quoted in fn 82. Cf Pierluigi Cuccuru, 'The Public and Private Sides of Harmonized Standards: *James Elliott Construction v. Irish Asphalt*' (2018) 19 German LJ 1399, 1403-1405.
[86] Marta Cantero Gamito, 'The Role of the EU in the Transnational Governance of Standards, Contracts and Codes' in Hans-W Micklitz and Marta Cantero Gamito (eds), *The Role of the EU in Transnational Legal Ordering* (Edward Elgar Publishing 2020); Mariolina Eliantonio and Annalisa Volpato, 'The Contradictory Approach of the CJEU to the Judicial Review of Standards: A Love–Hate Relationship?' in Mariolina Eliantonio and Caroline Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique. A Cross-disciplinary and Multi-level Analysis* (Edward Elgar 2020).
[87] Case C-160/20 *Stichting Rookpreventie Jeugd and Others v Staatssecretaris van Volksgezondheid, Welzijn en Sport* [2022] EU:C:2022:101 [Stichting Rookpreventie].
[88] *Ivi*, para 52.

Professional knowledge and expertise shape a variety of written and unwritten rules of conduct, including standards. In a nutshell, standards are protocols that contain technical specifications and practical recommendations around which significant consensus has been reached in the relevant professional community. They are delivered by private organisations in the form of documents concerning best practices, guidance for deployment, or specifications for interoperability at the physical, network, or application level.[89] In addition to these 'formal' standards, technical know-how and behavioural rules are also provided by guidelines and codes of conduct laid down by professional associations and companies or embedded into private certification schemes.

Standards are not mandatory. They are issued by private entities and thus they do not represent State-made laws. Rather, they are voluntary private rules from an institutional standpoint. However, there is more than meets the eye. Notably, the distinction between 'institutional' technical regulation and private norms is blurred when voluntary standards and good practices are converted into mandatory requirements, either by virtue of law or by reason of market forces.[90] Indeed, market preferences might compel traders to conform to standards in order to be competitive.[91] Furthermore, law provisions can refer to standards when imposing obligations on individuals and thus make them binding.[92] For instance, Article 4(1) of Directive 2014/40/EU[93] prescribes that cigarettes' emissions must be measured in accordance with the methods arising from given ISO standards. As recently confirmed by the CJEU in the above-mentioned *Stichting Rookpreventie* case, referred standards are binding on undertakings by virtue of their incorporation into an act of EU law.[94]

In other cases, State law refers to standards and good practices without making them mandatory. For instance, several provisions of EU law establish presumptions of legal conformity for products and services in conformity with harmonised standards. This saves businesses time and resources that they would otherwise spend on conformity assessments. Hence, they tend to comply with standards spontaneously in order to benefit from said presumptions. Moreover, the law can assign standards an evidential

[89] Mark McFadden and others, 'Harmonising Artificial Intelligence: The Role of Standards in the EU Regulation' (Oxford Commission on AI & Good Governance 2021), 10.
[90] Olia Kanevskaia, 'ICT Standards Bodies and International Trade: What Role for the WTO?' (2022) 56 JWT 429, 436 and references therein.
[91] Fabrizio Cafaggi, 'New Foundations of Transnational Private Regulation' (2011) 38 JL & Soc'y 20, 22.
[92] Cf *James Elliott*; *Stichting Rookpreventie*, para 44.
[93] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC [2014] OJ 2014 L127/1.
[94] *Stichting Rookpreventie*, para 52. However, since said standards have not been published in the OJ, they are not binding on the public generally, but only on undertaking that have access to them: see *ivi*, para 51 and CJEU, 'Judgment of the Court of Justice in Case C-160/20 *Stichting Rookpreventie Jeugd and Others*' (22 February 2022) Press Release No 29/22 <https://curia.europa.eu/jcms/upload/docs/application/pdf/2022-02/cp220029en.pdf>.

role. For instance, Italian Law No. 24/2017 on the liability of healthcare professionals[95] states that doctors can invoke their compliance with guidelines and best practices in their defence pleas. Vice versa, if they deviate from said recommendations, they need to demonstrate that their choice was justified by the specific circumstances of the case, according to a 'comply or explain' approach.[96]

Besides, bottom-up processes contribute to attributing normative force to standards and professional norms. Indeed, compliance with these private rules is often imposed by market participants, such as customers demanding certain product specifications.[97] More importantly, standards and professional norms can be incorporated into contracts and thus be binding on parties. In the exercise of their freedom of contract, parties can in fact agree that performance must fulfil certain requirements laid down by the referred private norms. Absent any explicit reference in the text of the contract, standards and good practices can still play an evidential role in contractual cases.[98] If the defendant is a professional then the plaintiff can argue that abiding by relevant standards is implicitly part of the obligation assumed with the contract. Moreover, standards and good practices inform general clauses like the duty of care and reasonableness. For instance, the above-mentioned Italian law on healthcare has done nothing but codify established case law on the relevance of professional norms in the assessment of medical liability.[99] Furthermore, domestic courts even recognise standards and professional norms as customary law.[100]

In some cases, standardisation is 'procedimentalised' by the law and thus represents a hybrid between public and private rule-making. For instance, EU law disciplines

[95] *Legge 8 marzo 2017 n. 24* 'Disposizioni in materia di sicurezza delle cure e della persona assistita, nonché in materia di responsabilità professionale degli esercenti le professioni sanitarie' in *Gazzetta Ufficiale* n. 64/2017. Law No. 24/2017 is usually referred to as 'Legge Gelli-Bianco.'

[96] For comments on the Italian Law No. 24/2017 see eg Francesca Di Lella, '*Leges artis* e responsabilità civile sanitaria' [2018] NGCC 264; Laura Maria Franciosi, 'The New Italian Regime for Healthcare Liability and the Role of Clinical Practice Guidelines: A Dialogue among Legal Formants' (2018) 11 Journal of Civil Law Studies 371.

[97] On the influence of market forces on the diffusion of international standards see Tim Büthe, 'Engineering Uncontestedness? The Origins and Institutional Development of the International Electrotechnical Commission (IEC)' (2010) 12 Business and Politics 1, 2.

[98] Barend van Leeuwen, *European Standardisation of Services and Its Impact on Private Law : Paradoxes of Convergence* (Bloomsbury Publishing 2017), 154 f., 169.

[99] Massimo Franzoni, 'Colpa e linee guida' [2016] *Danno e responsabilità* 801, 805. The Author makes the point that medical guidelines and *leges artis* have always entered the courtrooms through experts' opinions.

[100] Fabrizio Cafaggi, 'New Foundations of Transnational Private Regulation' (2011) 38 J L & Soc'y 20, 22. Cf Jorge L Contreras, 'Private Law, Conflict of Laws, and a *Lex Mercatoria* of Standards-Development Organizations' (2019) 27 ERPL 245, who stresses the lack of uniformity among judicial interpretation of standards by domestic courts. Customary law, particularly international customary law, is considered part of *lex mercatoria* in the literature. *Lex mercatoria* has been the object of lively scholarly discussion. Particularly, it is debated whether *lex mercatoria* constitutes an autonomous legal order or not. Additionally, scholars who answer this question in the positive have different opinions about what counts as *lex mercatoria* and what its sources are. For an introductory overview see Phillip Hellwege, '*Lex Mercatoria*' in Jürgen Basedow, Klaus J Hopt and Reinhard Zimmermann (eds), *Max Planck Encyclopedia of European Private Law* (Oxford University Press 2012) 1086. Cf Ralf Michaels, 'The True Lex Mercatoria: Law Beyond the State' (2007) 14 Ind J Global Legal Studies 447.

composition, representation, and voting rights of standards makers with a view to ensuring democracy, legitimacy, authority, independence, and reliability. Besides, consultation with stakeholders can be required to guarantee that their interests are taken into account. Standardisation might also be constrained *ex ante* by limits set in formal standards requests and/or subject to *ex post* validation by public authorities. In turn, the institutional facets of standards makers provide further justification for the normative character of standards.[101] Finally, standards are highly authoritative as standards-making bodies are composed of qualified experts in their field. Hence, they have a strong persuasive force.

In light of the foregoing, it can be argued that standards and good practices have strong normative power. In spite of being soft law,[102] they are akin to State-made law from a functional perspective.[103] Albeit standards and good practices are umbrella terms for a heterogeneous group of sources, it can be safely affirmed that altogether they shape national and cross-border relationships between private parties. Notably, they influence significantly the behaviour of private parties.[104] As a consequence, they are deeply intertwined with private law.[105] In light of the above, standards and professional norms constitute a transnational[106] legal order according to Halliday's and Shaffer's definition, which is a collection of formalized legal norms and associated organisations and actors, including any social formation and network, that authoritatively order the understanding and practice of law across national jurisdictions.[107]

[101] Olia Kanevskaia, 'ICT Standards Bodies and International Trade: What Role for the WTO?' (2022) 56 JWT 429, 432.
[102] In its broadest scope, soft law encompasses 'all regulatory instruments and mechanisms of governance that, while implicating some kind of normative commitment, do not rely on binding rules or on a regime of formal sanctions' (Anna Di Robilant, 'Genealogies of Soft Law' (2006) 54 Am J Comp L 299, 299).
[103] See Marta Cantero Gamito, 'The Role of the EU in the Transnational Governance of Standards, Contracts and Codes' in Hans-W Micklitz and Marta Cantero Gamito (eds), *The Role of the EU in Transnational Legal Ordering* (Edward Elgar Publishing 2020); Rob van Gestel and Peter van Lochem, 'Private Standards as a Replacement for Public Lawmaking?' in *id.*
[104] Dan Wielsch, 'Global Law's Toolbox: How Standards Form Contracts' in Horst Eidenmüller (ed), *Regulatory Competition in Contract Law and Dispute Resolution* (Beck/Hart/Nomos 2013), 76.
[105] Cf Eduard Fosch Villaronga and Angelo Jr Golia, 'Robots, standards and the law: Rivalries between private standards and public policymaking for robot governance' (2019) 35 CLSRV 129, 129-133.
[106] For an excellent overview of the different theories on transnational law see Gregory Shaffer, 'Theorizing Transnational Legal Ordering' (2016) 12 Annual Review of Law and Social Science 231 and references therein. In his seminal work 'Transnational Law', Jessup gave a broad definition of transnational law as including traditional public and international public law: Philip C Jessup, *Transnational Law* (Yale University Press 1956). Cf Fabrizio Cafaggi, 'The Many Features of Transnational Private Rulemaking: Unexplored Relationships between Custom, *jura mercatorum* and Global Private Regulation' (2015) 36 U Pa J Int'l L 101; Gralf-Peter Calliess and Peer Zumbansen, *Rough Consensus and Running Code: A Theory of Transnational Private Law* (Hart 2010); Roger Cotterell, 'What Is Transnational Law?' (2012) 37 Law & Social Inquiry 500; Terence C Halliday and Gregory Shaffer (eds), *Transnational Legal Orders* (Cambridge University Press 2015); Ralf Michaels, 'The True *lex mercatoria*: Law beyond the State' (2007) 14 Ind J Global Legal Studies 447; Peer Zumbansen, 'Transnational law, evolving' in Jan Smits (ed), *Elgar Encyclopedia of Comparative Law* (2nd edn, Edward Elgar 2012).
[107] Terence C Halliday and Gregory Shaffer, 'Transnational Legal Orders' in *id.*, *Transnational Legal Orders* (CUP 2015).

As repeatedly pointed out by scholars, modern legal systems are composed of plural normative systems.[108] Particularly, public institutions and norms co-exist with private and mixed ones.[109] Therefore, next to State-made law there are sector-specific normative orders 'crafted' by private entities and tailored to identified businesses and industries.[110] Key actors of these private orders are non-governmental organisations, multinational corporations, consulting firms, law firms, and financial institutions.[111] The expertise of these private regulators stands as a guarantee of the quality of rule-making.

The downside is that standardisation is largely dominated by industry and thus might not take sufficiently into account societal needs.[112] This is of utmost relevance to our analysis. Indeed, private regulation is likely to affect the governance of AI with particular intensity. Similar to other regulated technologies, its governance requires a high level of technical expertise. However, what makes the governance of AI unique is perhaps the ubiquity of the technology in the public and private spheres and its impact

[108] See eg Paul Schiff Berman, 'The New Legal Pluralism' (2009) 5 Annual Review of Law and Social Science 225; Ralf Michaels, 'Global Legal Pluralism' (2009) 5 Annual Review of Law and Social Science 243; Rodolfo Sacco, 'Legal Formants: A Dynamic Approach to Comparative Law' (1991) 39 Am J Comp L 1. According to Teubner's theory of 'global law without a State', today's legal systems are not hierarchical but heterarchical. It stems from this that decentralised law, including *lex mercatoria*, standards, and professional self-regulation, is not only normative but amounts also to positive law. See eg, Gunther Teubner, 'Global Bukowina: Legal Pluralism in the World Society', in *id.* (ed), *Global Law Without a State* (Dartmouth Gower 1997); *id.*, 'The King's Many Bodies: The Self-Deconstruction of Law's Hierarchy' (1997) 31 L & Soc'y Rev 763; *id.*, 'Breaking Frames. Economic Globalization and the Emergence of *lex mercatoria*' (2002) 5 European Journal of Social Theory 199, 206-208. For a different view of private normative rules as 'law beyond the State' and not 'law without the State' see Ralf Michaels, 'The True *lex mercatoria*: Law beyond the State' (2007) 14 Ind J Global Legal Studies 447.

[109] Kenneth W Abbott & Duncan Snidal, 'International Regulation without International Government: Improving IO Performance through Orchestration' (2010) 5 The Review of International Organizations 315. Cf Fabrizio Cafaggi, 'New Foundations of Transnational Private Regulation' (2011) 38 J L & Soc'y 20.

[110] Dan Wielsch, 'Global Law's Toolbox: How Standards Form Contracts' in Horst Eidenmüller (ed), *Regulatory Competition in Contract Law and Dispute Resolution* (Beck/Hart/Nomos 2013), 72 f.

[111] ibid. See also See eg, Anna Beckers, 'Regulating Corporate Regulators through Contract Law? The Case of Corporate Social Responsibility Codes of Conduct' (2016) EUI Working Paper MWP 2016/12; Florian Möslein, 'Legal Innovation in European Contract Law: Within and Beyond the (Draft) Common Frame of Reference' (2009) EUI Working Paper RSCAS 2009/07; *id.*, 'Regulatory Competition between Public and Private Rules' in Horst Eidenmüller (ed), *Regulatory Competition in Contract Law and Dispute Resolution* (Bloomsbury Publishing 2013)

[112] See eg Marta Cantero Gamito, 'Europeanization through Standardization: ICT and Telecommunications' (2018) 37 YEL 395, 399; Rob van Gestel and Peter van Lochem, 'Private Standards as a Replacement for Public Lawmaking?' in Marta Cantero Gamito and Hans-W Micklitz (eds), *The Role of the EU in Transnational Legal Ordering: Standards, Contracts and Codes* (Edward Elgar 2020). These concerns are shared by the Commission that recently put forward a proposal to limit the voting rights of members of ESOs who are not representatives of competent national standardisation bodies: Commission, 'Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 1025/2012 as regards the decisions of European standardisation organisations concerning European standards and European standardisation deliverables' COM (2022) 32 final.

on fundamental rights.[113] In the era of the 'race to AI'[114] it is essential that all interests at stake are duly considered by both public and private rule-makers alike. However, it is not sure that standards makers are in the best position to make certain ethical and legal decisions.[115] Rather, the regulation of AI requires cooperation between scientists, developers, policymakers, and ethicists.[116] On the other hand, in the AI sector reactivity to fast scientific advancements and to changes in market needs is fundamental not to stifle competition. From this pragmatic angle, standardisation is superior to law-making due to its flexibility and due to the sector-specific expertise of standards makers. Hence, there might be a trade-off between constitutionalisation and efficiency of rule-making.[117]

4 The role of standards in private law

Building on the findings in the previous section, it is hereby demonstrated that extracontractual and contractual liability are deeply intertwined with standardisation, for the expertise encoded in standards is used as a yardstick against which a professional's behaviour is evaluated.

Notably, tort law is highly fragmented in Europe.[118] Absent a comprehensive body of EU tort law,[119] only specific hypotheses of liability are harmonised, such as liability for defective products. Nonetheless, fundamental tenets of extracontractual liability are shared by national tort laws. There are three main bases of liability, namely fault, strict,

[113] For instance, see our study on disability discrimination in AI-powered recruiting: Maarten Buyl and others, 'Tackling Algorithmic Disability Discrimination in the Hiring Process: An Ethical, Legal and Technical Analysis', *2022 ACM Conference on Fairness, Accountability, and Transparency* (Association for Computing Machinery 2022) <https://dl.acm.org/doi/pdf/10.1145/3531146.3533169>, available at arXiv <https://arxiv.org/abs/2206.06149v1>. In the context of eHealth, see *ex multis* Hannah van Kolfschooten, 'EU Regulation of Artificial Intelligence: Challenges for Patients' Rights' (2021) 59 CMLR 81.

[114] Nathalie A Smuha, 'From a 'Race to AI' to a 'Race to AI Regulation': Regulatory Competition for Artificial Intelligence' (2021) 13 Law, Innovation and Technology 57.

[115] Martin Ebers, 'Standardizing AI: The Case of the European Commission's Proposal for an "Artificial Intelligence Act"' in Larry A DiMatteo, Cristina Poncibò and Michel Cannarsa (eds), *The Cambridge Handbook of Artificial Intelligence* (CUP 2022), 342; Clothilde Goujard and Gian Volpicelli, 'Harmful AI Rules: Now Brought to You by Europe & Co., Inc.' Politico (31 October 2022) <https://www.politico.eu/article/harmful-ai-rules-european-union-corporate-influence/> accessed 4 November 2022.

[116] Virginia Dignum, *Responsible Artificial Intelligence: How to Develop and Use AI in a Responsible Way* (Springer 2019), 97-98.

[117] Marta Cantero Gamito, 'The Role of the EU in the Transnational Governance of Standards, Contracts and Codes' in Marta Cantero Gamito and Hans-W Micklitz (eds), *The Role of the EU in Transnational Legal Ordering: Standards, Contracts and Codes* (Edward Elgar 2020), 22.

[118] See Ernst Karner, Bernhard A Koch and Mark A Geistfeld, 'Comparative Law Study on Civil Liability for Artificial Intelligence' (European Commission – Directorate-General for Justice and Consumers 2021).

[119] Cf Marta Infantino, 'Making European Tort Law: The Game and Its Players' (2010) 18 Cardozo J Int'l & Comp L 45; Helmut Koziol, 'Harmonising Tort Law in the EU: Advantages and Disadvantages' [2013] ELTE LJ - Separatum 73.

and vicarious liability.[120] Particularly, in addition to causation[121] and damage,[122] fault-based liability requires the assessment of fault on behalf of the alleged tortfeasor. In a nutshell, fault is generally understood as the (intentional or negligent) objective deviation from the required standard of conduct, which is that of a 'reasonable person.'[123] Hence, the question is what conduct the law requires to meet this standard.

Like tort law, the general law of contract is not harmonised in Europe, even though there is a comprehensive body of EU primary and secondary law in the context of different areas (the so-called *acquis communautaire*).[124] Nonetheless, comparative studies have revealed the existence of a set of shared rules and principles in national provisions of general contract law as well.[125] Remedies against non-performance in national contract law usually do not depend on fault. However, parties' conduct is taken into account in apportioning liability when a breach of contract occurs. First, performance needs to be satisfactory. Several provisions of domestic law obligate parties to execute contracts in good faith and with due diligence. Moreover, non-performance is generally excused in the event of impediments that were not reasonably foreseeable or avoidable.[126] Finally, in the case of gross negligence, contractual liability is extended to unforeseeable damage.[127] The questions are what conduct constitutes satisfactory performance, and which circumstances are considered as being beyond any reasonable control and therefore excuse non-performance and exclude liability for damages.

Markedly, general clauses like the reasonable person standard and due diligence are abstract legal concepts that can be imbued with different content.[128] In concrete cases,

[120] European Group on Tort Law, *Principles of European Tort Law: Text and Commentary* (Springer 2005), Articles 4:101 to 6:102, 64-119. Fault is the criterion of imputation for damage caused by personal misconduct. Strict liability might include no-fault liability for risks involving animals or objects as well as cases involving dangerous human activity. Finally, vicarious liability means liability for others. Namely, the person in charge of a minor or of an incapacitated person is responsible for the damage they cause. Moreover, the principal is responsible for the tortious acts of his or her agents and employees. Under some doctrines, vicarious liability may be qualified as strict liability.

[121] Cf Christian von Bar, Eric Clive and Hans Schulte-Nölke (eds), *Principles, Definitions and Model Rules of European Private Law. Draft Common Frame of Reference* (European Law Publishers 2009), Comment A to Article VI-4:101. For a comparative study on causation see Jaap Spier (ed), *Unification of Tort Law: Causation* (Kluwer Law International 2000).

[122] For a comparative study on damage see Ulrich Magnus (ed), *Unification of Tort Law: Damages* (Kluwer Law International 2001).

[123] See European Group on Tort Law, *Principles of European Tort Law: Text and Commentary* (Springer 2005), 64-100.

[124] For a complete overview see *ex multis* Reiner Schulze and Fryderyk Zoll, *European Contract Law* (3rd edn, Bloomsbury Publishing 2021).

[125] As a result of these comparative studies, two main soft law instruments have been built on this common core of general contract law, namely the Principles of European Contract Law (PECL) and the UNIDROIT's Principles of International Commercial Contracts (PICC).

[126] Article 8:108(1) PECL and Article 7.1.7 PICC.

[127] Article 9:503 PECL.

[128] Alan D Miller and Ronen Perry, 'The Reasonable Person' (2012) 87 NYUL Rev 323, 325.

these standards of conduct are adjusted to account for individual characteristics.[129] Indeed, skills or knowledge that exceed those possessed by most others influence what can be reasonably expected of an individual. The benchmark that must be met thus corresponds to that of a reasonable person of comparable education and expertise. It is precisely in this respect that standards come into play. As they supposedly encode best practices, parties and courts invoke them to substantiate general clauses in deciding on professionals' liability and performance. Hence, the interplay between standards, safety, and liability deserves further investigation.

4.1 Standards, safety, and liability: connecting the dots

To unveil the role of standards in liability litigation, different normative frameworks need to be considered. Starting from the manufacturing of goods, EU product safety law defines under which conditions a product can be released onto the market. Such conditions are laid down in the General Product Safety Directive[130] ('GPSD'), according to which a product is deemed safe if, under normal or reasonably foreseeable conditions of use, it does not pose unacceptable risks for the safety and health of persons.[131] Interestingly, safety requirements are not limited to technical features. Pursuant to the GPSD, 'the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product' must also be taken into account when assessing a product's safety.[132] In addition to that, product-specific safety legislation sets out distinctive requirements. Examples include safety rules relating to machinery,[133] toys,[134] drones,[135] medical

[129] For instance, this principle is enshrined in the American Restatement (Third) of Torts: Liability for Physical and Emotional Harm (American Law Institute 2010), § 12. From an American perspective, see Omri Ben-Shahar and Ariel Porat, 'Personalizing Negligence Law' (2016) 91 NYUL Rev 627, 641-644.
[130] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety [2001] OJ L11/4 [GPSD].
[131] GPSD, Article 2(b).
[132] ibid.
[133] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) [2006] OJ L157/24 (hereinafter, 'Machinery Directive'). The directive covers a wide range of products, consumer and industrial, going from lawnmowers to sophisticated industrial robots.
[134] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys [2009] OJ L170/1.
[135] Commission Delegated Regulation (EU) 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems [2019] OJ L152/1 (hereinafter, 'Drones Regulation').

devices,[136] pharmaceuticals.[137] Where present, specific safety provisions take precedence over the GPSD.[138]

Pursuant to the NLF, statutory requirements under EU law are complemented by standards.[139] In the absence of specific EU law provisions, national product safety law applies.[140] Products are presumed safe when they conform to European harmonised standards that have been transposed by national standards.[141] In the lack of such standards, product safety is assessed by taking into account other standards, Commission guidelines, codes of good practices, state-of-the-art, and reasonable consumer's expectations.[142] In addition to these general safety requirements, several products must also undergo conformity assessment to obtain the CE mark. In this regard, compliance with technical standards makes these assessments significantly smoother. However, manufacturers can always choose not to comply with said standards and demonstrate that essential safety requirements are satisfied by alternative means.

Once the product is deemed safe and placed on the market, the producer can still be liable for damages caused to consumers by their product under the PLD. In fact, the GPSD is without prejudice to the application of the PLD.[143] Indeed, a product that is deemed safe may still be defective and cause damage. This is because product safety rules and product liability rules operate at essentially different levels.[144] For instance, even though a product is certified as safe, one specific item can still be defective, or defects can emerge with the use of the product, after its placement on the market. Therefore, legislation on product safety and on product liability are complementary.[145] Pursuant to the PLD, the producer is strictly liable for physical harm[146] caused to persons or property by a defect in their product. Instead, immaterial harm and pure economic

[136] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [2017] OJ L117/1 (hereinafter, 'Medical Devices Regulation'); Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU [2017] OJ L117/176.
[137] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67.
[138] GPSD, Article 1(2).
[139] See *supra* at Section 2.
[140] GPSD, Article 3(2), first subparagraph.
[141] GPSD, Article 3(2), second subparagraph.
[142] GPSD, Article 5. Similar presumptions of conformity are provided by specific safety legislation, such as Article 7(2) Machinery Directive, Article 12 Drones Regulation, Article 8 Medical Devices Regulation.
[143] GPSD, Article 17.
[144] Andrea Bertolini, 'Artificial Intelligence and Civil Liability' (European Parliament, Directorate-General for Internal Policies of the Union 2020) <https://data.europa.eu/doi/10.2861/220466>, 50-51.
[145] ibid.
[146] PLD, Article 9.

loss fall outside the scope of the PLD[147] and can therefore be compensated only under national law remedies. A product is defective if it does not provide the safety that a person is entitled to expect having regard to the use to which the product could reasonably be put.[148] As for safety, the presentation of the product must also be taken into account when assessing whether the product is defective.[149]

Hence, compliance of products with harmonised standards is verified *ex ante* when releasing the CE mark, unless the manufacturer chooses to demonstrate that the product is safe by other means. Nonetheless, standards can play a role *ex post* too, namely in liability litigation. Other standards that were not relevant for the purposes of the CE marking can be considered to assess whether the product is defective. Moreover, for goods and damage that fall outside the scope of application of the PLD, aggrieved parties can seek restoration under national tort law. Hence, plaintiffs might have to prove fault on behalf of the producers, or that they failed to take reasonable precautions. In this regard, deviation from standards and best practices might serve as evidence of negligence.

The PLD does not apply to services[150] nor to stand-alone software. However, this might soon change in light of the proposed PLD II.[151] Furthermore, pursuant to the Directives on Sale of Goods[152] ('SGD') and on Digital Content and Digital Services[153] ('DCSD'), sellers of digital goods and traders of digital content and services, including stand-alone software, are contractually liable[154] to consumers for lack of conformity with the contract or with the legal requirements set out in the directives.[155] In the event

[147] However, the proposed PLD II extends compensation to the case of loss or corruption of data, including cost of recovering or restoring data (Article 4, No 6, letter c, read in conjunction with Recital 16).
[148] PLD, Article 6(1).
[149] ibid.
[150] Case C-495/11 *Centre hospitalier universitaire de Besançon v Thomas Dutreux and Caisse primaire d'assurance maladie du Jura* [2011] EU:C:2011:869. More recently, Case C-65/20 *VI v KRONE – Verlag Gesellschaft mbH & Co KG.* [2021] EU:C:2021:471, paras 24-32.
[151] PLD II, Article 4, No 1 and 4.
[152] Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC [2019] OJ L136/28.
[153] Directive (EU) 2019/770 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the supply of digital content and digital services [2019] OJ L 136/1.
[154] SGD, Article 10 and DCSD, Article 11.
[155] For comments on the directives see eg Ignacio Fernández Chacón, 'Some Considerations on the Material Scope of the New Digital Content Directive: Too Much to Work Out for a Common European Framework' (2021) 29 ERPL 517; Dirk Staudenmayer, 'The Directives on Digital Contracts: First Steps Towards the Private Law of the Digital Economy' (2020) 28 ERPL 219; Christian Twigg-Flesner, 'Conformity of Goods and Digital Content/Digital Services' in Esther-Cámara Arroyo Amayuelas and Sergio Lapuente (eds), *El Derecho privado en el nuevo paradigma digital* (Marcial Pons 2020), available in preprint version at SSRN <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3526228>. For a preliminary comment on the directive proposals cf Christina Ramberg, 'Digital Content – A Digital CESL II – A Paradigm for Contract Law via the Backdoor?' in Stefan Grundmann (ed), *European Contract Law in the Digital Age* (Intersentia 2018). Cf Martin Ebers, 'Liability for Artificial Intelligence and EU Consumer Law' (2021) 12 JIPITEC 204. For a critical analysis with a focus on AI products and services see Raphaël Gellert, 'The EU's New Directives on Digital Contracts, and Artificial Intelligence: Really Future Proof?' (2021) 21 ERPL 403.

of a lack of conformity, consumers are entitled to have their goods or services brought into conformity by means of repair or replacement, to receive a proportionate reduction in the price, or to terminate the contract. Moreover, sellers and traders of digital products and services, including stand-alone software, are contractually liable to consumers. Whilst the SGD and the DCSD apply to sellers and traders, not to producers,[156] the former ones are entitled to seek redress from other persons involved in the chain of transactions if they are responsible, including producers.[157] Hence, producers are indirectly liable for the lack of conformity of digital products.

In this regard, standards and professional norms might be relevant in assessing whether the content or service is affected by a lack of conformity. As shown in Section 3, they can make their way before courts by reference in legal provisions, or as explicit or implicit contractual clauses, criteria for the interpretation of general clauses, or customary law. The same is true for national contract law remedies against non-performance and contractual damage.

Pursuant to the Standardisation Regulation, European standardisation concerns products as well as services alike.[158] Already in 2006, the Services Directive encouraged the development of European standards regarding interoperability between services, information, and quality of service.[159] Unlike products, there is no CE marking for services. However, service providers undertake third-party certification or assessment of their activities.[160]

Arguably, the implications of standards for private law are particularly penetrating in the field of services.[161] As remarked by Busch and Reinhold,[162] standards for services are different from standards for products in that they are not so much of a technical nature, but rather of a legal nature. Service standards resemble general terms and conditions as they set out requirements for the pre-contractual phase like information duties and, most importantly, they define the duties of the service provider and the

[156] Unless the producer offers to the consumer a commercial guarantee of durability for certain goods for a certain period of time. In this case, pursuant to Article 17 SGD, the producer is liable directly to the consumer, during the entire period of the commercial guarantee of durability for repair or replacement of the goods in accordance with Article 14.
[157] SGD, Article 18 and DCSD, Article 20.
[158] See *supra* at Section 2.
[159] Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market [2006] OJ L376/36, Article 26(5).
[160] ibid, Article 26(1).
[161] Marta Cantero Gamito, 'Europeanization through Standardization: ICT and Telecommunications' (2018) 37 YEL 395, 421 -422; Hans-W Micklitz, 'Services Standards: Defining the Core Consumer Elements and their Minimum Requirements' (ANEC 2007) <http://www.anec.eu/attachments/ANEC-R&T-2006-SERV-004final.pdf>, 21: 'At the very least [...] standardisation of services affects the rights and duties of the contracting partners, that is standards may give shape to legal rights in European and national contract law, for example, they may give shape to an already existing legal right to information.'
[162] Christoph Busch and Simon Reinhold, 'Standardisation of Online Dispute Resolution Services: Towards a More Technological Approach' (2015) 4 EuCML 50, 53. See *supra* at Section 2.

applicable standards of care.[163] Compliance with service standards is thus ensured via contractual obligations and remedies, such as termination of the contract.[164] Here, standards and professional norms are as relevant as for the evaluation of a lack of conformity.

Finally, for situations not covered by EU law, national law applies. For instance, this is the case with extracontractual liability other than product liability. In this regard, standards and professional norms are pivotal to establishing whether professionals fulfilled their duties of care or vice versa were negligent. Notoriously, in highly technical cases courts rely on experts' opinions. The findings of experts are based on standards, professional norms, and best practices. Hence, the role of private rules in extracontractual liability litigation.

Of course, non-professionals, ie consumers, can cause damage to other persons too. However, laymen are held to a lower standard of conduct than professionals since what can be reasonably expected from a person carrying out an activity depends on his or her expertise.[165] Hence, standards and professional norms are not really relevant in such cases. The importance of distinguishing between professional and non-professional users of AI systems is recognised by the Commission in its proposal for an AI Liability Directive. In fact, Article 4(6) takes a stand against a generalised application of the proposed presumption of causation in national tort cases. As clarified by Recital 29, it is not appropriate to aggrieve the position of defendants who are not professional users of AI systems, unless they interfered with its operation or failed to take the required precautions. Hence, the Commission acknowledges that non-professional users of AI systems are not required to abide by the same standard of care as professionals.

In conclusion, standards can substantiate technical requirements, contractual obligations, and general clauses. In particular, requirements or obligations may be drafted so vaguely that they are a mere 'empty shell' to fill with content.[166] General clauses instead are vague by definition. Hence, the key role of standards in shaping their concrete meaning. Particularly, standards inform general clauses such as the reasonable person standard in tort law, or due diligence in contract performance. Hence, in spite of the voluntary nature of standards, they have strong normative power.[167] Besides, standards may be invoked by courts when interpreting statutory

[163] See Standardisation Regulation, Article 2(4)(c).
[164] Marta Cantero Gamito, 'Europeanization through Standardization: ICT and Telecommunications' (2018) 37 YEL 395, 421-422.
[165] European Group on Tort Law, *Principles of European Tort Law: Text and Commentary* (Springer 2005), Article 4:102.
[166] Pierluigi Cuccuru, 'Regulating by Request: On the Role and Status of the Standardisation Mandate under the New Approach' in Mariolina Eliantonio and Caroline Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique. A Cross-disciplinary and Multi-level Analysis* (Edward Elgar 2020) 57.
[167] See *supra* at Section 3.

norms, even if perhaps more rarely.[168] Therefore, regardless of their voluntary nature, standards establish a benchmark for evaluating conduct, conformity, and performance.[169] Finally, they can be explicitly referred to by contracts and statutory norms and thus be mandatory. This is true with regard to both situations governed by EU law and situations covered by national law, as well as to both commercial and consumer contracts.

The importance of standards in liability claims should not come as a surprise. Ultimately, this issue points to the increasingly decisive role of scientific and technical knowledge in courtrooms.[170] Although this phenomenon is to some extent unavoidable in modern industrial society, it comes with significant challenges in terms of democracy and legitimacy due to the constitutional shortcomings of standardisation.[171]

5 AI standardisation in the AI Act framework and beyond

The landscape of AI governance is a complex patchwork of State-made law and other norms coined by institutional and non-institutional private actors. In essence, an AI system is an information technology ('IT') system for which a multitude of standards from various industries and fields of application already exist[172] and more are to come. The analysis of AI standardisation is particularly compelling in the aftermath of the AI Act which ascribes a pivotal role to standards.

Following the NLF approach,[173] legal requirements enshrined in the AI Act are intended to be specified by standards and common specifications.[174] Specifically, the AI Act lays down legal requirements for the design, development, and deployment of high-

[168] Dan Wielsch, 'Global Law's Toolbox: How Standards Form Contracts' in Horst Eidenmüller (ed), *Regulatory Competition in Contract Law and Dispute Resolution* (Beck/Hart Publishing/Nomos 2013), 83. The Author makes the example of a judgment of the German Supreme Court (BGH NJW 2008, 511 (514); NJW 1987, 643) in which the VOB/B, ie the general conditions of contract relating to the execution of construction work, was invoked by courts when construing the meaning of statutory norms. The VOB/B was established by the DAV (*Deutscher Vergabe- und Vertragsausschuss für Bauleistungen*), an association within which public authorities and head organizations of the construction industry participate.

[169] Pierluigi Cuccuru, 'The Public and Private Sides of Harmonized Standards: *James Elliott Construction v. Irish Asphalt*' (2018) 19 German LJ 1399, 1413.

[170] Cf Sheila Jasanoff and Dorothy Nelkin, 'Science, Technology, and the Limits of Judicial Competence' (1982) 22 Jurimetrics 266; Etienne Vergès and Lara Khoury, 'Le traitement judiciaire de la preuve scientifique: une modélisation des attitudes du juge face à la connaissance scientifique en droit de la responsabilité civile' (2017) 58 Les Cahiers de Droit 517. Cf in the context of environmental litigation Christina Eckes, 'Tackling the Climate Crisis with Counter-Majoritarian Instruments: Judges Between Political Paralysis, Science, and International Law' (2021) 6 *European Papers* 1307.

[171] See *supra* at Section 3.

[172] DIN-DKE, 'German Standardization Roadmap on Artificial Intelligence' (November 2020) <https://www.din.de/resource/blob/772610/8bfea3055c03aa1e2563afc16001b06f/normungsroadmap-en-data.pdf>, 24; Stefano Nativi and Sarah De Nigris, 'AI Watch, AI Standardisation Landscape State of Play and Link to the EC Proposal for an AI Regulatory Framework' (European Commission – Joint Research Centre 2021).

[173] See *supra* at Section 3.

[174] Cf AI Act, Explanatory Memorandum, 13 and AI Act, Recital 61.

risk AI systems.[175] Such requirements deal with data and data governance, documentation and record keeping, transparency and provision of information to users, human oversight, robustness, accuracy and security.[176] In the words of the Commission, common mandatory requirements are intended to be 'further operationalised through harmonised technical standards [...] [which] will assist providers and users in complying with the requirements laid down by the proposal and minimise their costs.'[177] Therefore, AI standardisation aims to foster legal certainty and lower compliance costs for providers of high-risk AI systems.

For this, a key instrument is the presumption of compliance established by Article 40. Accordingly, high-risk AI systems which conform to harmonised standards shall be presumed to be compliant with legal requirements. Similarly, a presumption of compliance is set out in Article 41 for high-risk AI systems in conformity to common specifications[178] put forward by the Commission. Moreover, providers must justify the adoption of different measures other than the Commission's specifications, which must be equivalent to said specifications (Article 41(4)).

Common specifications are adopted by the Commission in case harmonised standards are absent or deemed insufficient (Article 41 and Recital 61). Hence, common specifications represent 'a safety net or backstop.'[179] When preparing common specifications, the Commission is required to consult relevant bodies or expert groups. Moreover, common specifications ought to be approved by a committee composed of representatives of the member States (Article 74). Whilst common specifications surely represent a flexible governance instrument, it has been observed that they might give too much discretion to the Commission, in spite of its less expertise if compared to ESOs, who adopt harmonised standards.[180]

Whilst compliance with harmonised standards and common specifications is not mandatory, it is reasonably foreseeable that most providers will follow them. Indeed, it would be very costly to demonstrate compliance with all requirements enshrined in the AI Act without benefitting from the presumption of conformity.[181] Moreover,

[175] For the definition of high-risk AI system see fn 13.
[176] AI Act, Title V, Chapter 2.
[177] AI Act, Explanatory Memorandum, 6-7. See also AI Act, Recital 61.
[178] Common specifications were first introduced in the health sector in 2017 by Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In-Vitro Diagnostic Devices. In this context, the use of common specifications was criticized by some stakeholders. See Mark McFadden and others, 'Harmonising Artificial Intelligence: The Role of Standards in the EU Regulation' (Oxford Commission on AI & Good Governance 2021), 8 and references therein.
[179] Mark McFadden and others, 'Harmonising Artificial Intelligence: The Role of Standards in the EU Regulation' (Oxford Commission on AI & Good Governance 2021), 9.
[180] ibid.
[181] High-risk AI systems that are not in conformity to harmonised standards or common specifications shall undergo the third-party conformity assessment set out in Annex VII (Article 43(1), second subparagraph). Moreover, in case of non-compliance with harmonised standards, providers of high-risk AI systems are also subject to further documentation burdens with regard to quality management systems (Article 17(1)(e)).

harmonised standards and common specifications will guide the interpretation of said requirements. Finally, in spite of the fact that standards are voluntary rules, several provisions of the AI Act explicitly require providers to take into account the state of the art as formalised in standards.[182] For all these reasons, the normative framework for high-risk AI systems will be consistently shaped by AI standards.[183]

In the AI Act framework, the main actors of AI standardisation are the three ESOs, that are in charge of enacting harmonised standards. The CEN and the CENELEC established a Focus Group on AI already in 2019 and then the Joint Technical Committee 21 'Artificial Intelligence' ('JTC 21') in 2021.[184] JTC 21 is currently drafting standards on conformity assessment and natural language processing technologies.[185] Besides developing its own standards, JTC 21 aims to provide guidance to other technical committees involved in AI standardisation with a view to promoting consistency in values and terminology between different standards that bear relevance to AI,[186] such as those on smart manufacturing,[187] electrical equipment in medical practice,[188] cybersecurity and data protection,[189] ICT professionalism and digital competences,[190] railway applications,[191] intelligent transport systems,[192] road vehicles.[193]

Furthermore, information communication technology ('ICT') standards are also crucial for AI technology since they govern technical interoperability. Indeed, interconnectivity and interoperability are key features of many AI ecosystems and particularly AI-driven Internet of Things ('IoT') systems.[194] ICT standards stem from the third ESO, the ETSI. ETSI's technical bodies are already addressing numerous aspects of using AI in ICT systems. These include 5G systems, network planning and optimization,

[182] AI Act, Articles 9(3), 12(1), 17(1).
[183] Cf Michael Veale and Frederik Zuiderveen Borgesius, 'Demystifying the Draft EU Artificial Intelligence Act. Analysing the Good, the Bad, and the Unclear Elements of the Proposed Approach' (2021) 22 Computer L Rev Int'l 97, 105; Martin Ebers, 'Standardizing AI: The Case of the European Commission's Proposal for an "Artificial Intelligence Act"' in Larry DiMatteo, Michel Cannarsa and Cristina Poncibò (eds), *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics* (CUP 2022), 338.
[184] 'CEN and CENELEC Launched a New Joint TC on Artificial Intelligence' (CEN-CENELEC, 3 March 2021) <https://www.cencenelec.eu/news-and-events/news/2021/briefnews/2021-03-03-new-joint-tc-on-artificial-intelligence/> accessed 4 November 2022.
[185] 'CEN/CLC/JTC 21 Work Programme' <https://standards.cencenelec.eu/dyn/www/f?p=205:22:0::::FSP_ORG_ID,FSP_LANG_ID:2916257,25&cs=1827B89DA69577BF3631EE2B6070F207D> accessed 4 November 2022.
[186] CEN-CENELEC JTC 21, 'Business Plan for JTC 21, Version 1.0' <https://standards.cencenelec.eu/BPCEN/2916257.pdf> accessed 4 November 2022.
[187] CLC/SR SM Smart Manufacturing.
[188] CLC/TC 62 Electrical equipment in medical practice.
[189] CEN/CLC/JTC 13 Cybersecurity and Data Protection.
[190] CEN/TC 428 ICT Professionalism and Digital Competences.
[191] CEN/TC 256 Railway applications.
[192] CEN/TC 278 Intelligent transport systems.
[193] CEN/TC 30 Road Vehicles.
[194] Geraint Howells and Christian Twigg-Flesner, 'Interconnectivity and Liability: AI and the Internet of Things' in Larry A DiMatteo, Cristina Poncibò and Michel Cannarsa (eds), *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law & Ethics* (CUP 2022).

service provisioning and assurance, operator experience, security, IoT, data management, and testing.[195] However, it is worth noting that ETSI is considered less inclusive of small and medium-sized enterprises (SMEs) and of other non-industrial stakeholders[196] than CEN and CENELEC. Different from the other two ESOs, ETSI does not allow non-industrial organisations to submit formal opinions on draft standards (the so-called 'right of opinion').[197] Moreover, the ETSI differs in its membership structure and participation rules from the other two ESOs. Unlike them, the ETSI is an association of industry and national governments who work closely, 'sitting at the same table', and who adopt standards collaboratively by means of a consensus-based decision-making process based on direct member participation, not national representation.[198] Additionally, the voting rights of industrial stakeholders are higher than the combined voting rights of any other category of stakeholders or Authority.[199] These democratic concerns should not be underestimated because ICT standards have potentially trade-restrictive effects.[200] Hence, it is of utmost importance that adequate consideration is devoted to the interests of SMEs and other non-industrial stakeholders.[201] The Commission seems willing to take steps in this direction as it recently submitted a regulatory proposal that strips industrial stakeholders of their right to vote on paramount decisions in ESOs, such as the acceptance and refusal of standardisation requests or the adoption and revision of European standards.[202]

[195] Lindsay Frost and others, 'Artificial Intelligence and Future Directions for ETSI' (2020) ETSI White Paper No. 34 <https://www.etsi.org/images/files/ETSIWhitePapers/etsi_wp34_Artificial_Intellignce_and_future_directions_for_ETSI.pdf>, 4.
[196] Cf Standardisation Regulation, Article 5 which requires the ESOs to encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders, including SMEs, consumer organisations, and environmental and societal stakeholders in their standardisation activities. The identified stakeholder organisations currently receiving EU financing (also known as the 'Annex III organisations') are Small Business Standards (SBS), the European consumer voice in standardisation (ANEC), the Environmental Coalition on Standards European Environmental Citizens Organisation for Standardisation (ECOS) and the European Trade Union Confederation (ETUC), respectively representing SMEs, consumers, environmental and workers' interests. Cf Commission, 'Standardisation package – Report from the Commission to the European Parliament and the Council on the implementation of the Regulation (EU) No 1025/2012 from 2016 to 2020' COM (2022) 30 final, 2.
[197] Commission, 'Standardisation package – Report from the Commission to the European Parliament and the Council on the implementation of the Regulation (EU) No 1025/2012 from 2016 to 2020' COM (2022) 30 final, 3 (hereinafter, 'Standardisation Package').
[198] Marta Cantero Gamito, 'Europeanization through Standardization: ICT and Telecommunications' (2018) 37 YEL 395, 413 f.
[199] Commission, Standardisation Package, 3.
[200] See Olia Kanevskaia, 'ICT Standards Bodies and International Trade: What Role for the WTO?' (2022) 56 JWT 429. See also Marta Cantero Gamito, 'Europeanization through Standardization: ICT and Telecommunications' (2018) 37 YEL 395, 421-422, arguing that differential switching costs of ensuring interoperability between networks and systems discourage the adoption of non-European ICT standards.
[201] See Fabrizio Cafaggi, 'New Foundations of Transnational Private Regulation' (2011) 38 J L & Soc'y 50: 'It is difficult, if not impossible, for small suppliers to afford the costs of private regulation rendering it impossible to gain or maintain market access.'
[202] Commission, 'Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 1025/2012 as regards the decisions of European standardisation organisations concerning European standards and European standardisation deliverables' COM (2022) 32 final, Article 1(2).

Whereas the proposed AI Act pointed at ESOs and at the Commission as the main regulators of AI, harmonised standards and common specifications will overlap with other standards[203] and professional norms. In the framework of AI governance, private rules stem from a variety of institutional and non-institutional actors. They include the design of technology architecture by private standards bodies[204] and by the many professionals along the AI pipeline.

Moreover, the approval of the AI Act, its entry into force, and the adoption and validation of harmonised standards will require some time. Accordingly, the Commission itself foresees that harmonised standards for AI will not be available before three to four years.[205] It is even doubtful whether the envisioned time would be sufficient since AI standardisation entails additional practical difficulties if compared to other sectors,[206] such as the risk of rapid obsolescence, the manifold interests involved, the diversity among the possible field of applications of AI technology.[207] Hence, European standardisation of AI will likely move at a much slower pace than the development of the technology itself.[208] In the meantime, existing and upcoming standards other than harmonised standards and common specifications gain ground.

At an international level, the main actor of AI standardisation is ISO/IEC JTC 1/SC 42, which is the joint committee on AI established by the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC). The JTC 1/SC 42 has already published fifteen standards to date,[209] including standards on machine learning,[210] big data,[211] bias,[212] trustworthiness,[213] and robustness.[214] Furthermore, it is currently working on fundamental topics such as the controllability

[203] For a mapping of the AI standards onto the requirements introduced by the AI Act see Stefano Nativi and Sarah De Nigris, 'AI Watch, AI Standardisation Landscape State of Play and Link to the EC Proposal for an AI Regulatory Framework' (European Commission – Joint Research Centre 2021).
[204] Olia Kanevskaia, 'ICT Standards Bodies and International Trade: What Role for the WTO?' (2022) 56 JWT 429, 444.
[205] Commission, 'Impact Assessment Accompanying the 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', part 1/2, 57.
[206] Martin Ebers, 'Standardizing AI: The Case of the European Commission's Proposal for an "Artificial Intelligence Act"' in Larry DiMatteo, Michel Cannarsa and Cristina Poncibò (eds), *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics* (CUP 2022), 332-333.
[207] Cf DIN-DKE, 'German Standardization Roadmap on Artificial Intelligence' (November 2020) <https://www.din.de/resource/blob/772610/8bfea3055c03aa1e2563afc16001b06f/normungsroadmap-en-data.pdf>, 25.
[208] Mark McFadden and others, 'Harmonising Artificial Intelligence: The Role of Standards in the EU Regulation' (Oxford Commission on AI & Good Governance 2021), 18.
[209] As of 4 November 2022.
[210] ISO/IEC TS 4213:2022, ISO/IEC 23053:2022.
[211] ISO/IEC 20546:2019, ISO/IEC TR 20547-1:2020, ISO/IEC TR 20547-2:2018, ISO/IEC 20547-3:2020, ISO/IEC TR 20547-5:2018.
[212] ISO/IEC TR 24027:2021.
[213] ISO/IEC TR 24028:2020.
[214] ISO/IEC TR 24029-1:2021.

of automated AI systems, testing, data quality, and performance assessment.[215] Remarkably, it is developing a quality model for AI systems, the 'Systems and software Quality Requirements and Evaluation (SQuaRE)'.[216] Moreover, essential standards are being developed by other ISO/IEC joint committees as well as by ISO and IEC separately.[217]

Besides, other consortia like professional associations also work on AI and ICT standardisation, such as the Institute of Electrical and Electronics Engineers (IEEE),[218] which launched its Global Initiative on Ethics of Autonomous and Intelligent Systems', the Internet Engineering Task Force (IETF), the International Telecommunication Union (ITU), the Open Geospatial Consortium (OGC), the World Wide Web Consortium (W3C), the Connectivity Standards Alliance (CSA), the Object Management Group (OGM), OASIS Open. It has been critically observed that some of them may lack impartiality as their experts tend to be affiliated with industries rather than independent researchers.[219] This notwithstanding, standards developed by these informal groups can become more widespread than those created within an internationally recognised standards body due to market preferences.[220]

At a national level, AI standards are developed by standards organisations. However, once harmonised standards are approved, all conflicting national standards will have to be withdrawn.[221] Notably, the German Institute for Standardization (DIN), together with DKE (German Commission for Electrical, Electronic & Information Technologies of DIN and VDE), put forward a Roadmap on AI Standardisation including recommendations

[215] 'Standards by ISO/IEC JTC 1/SC 42 Artificial Intelligence' (ISO) <https://www.iso.org/committee/6794475/x/catalogue/p/0/u/1/w/0/d/0> accessed 4 November 2022.

[216] 'ISO/IEC DIS 25059: Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Quality model for AI systems' (ISO) <https://www.iso.org/standard/80655.html?browse=tc> accessed 4 November 2022.

[217] For a detailed account of ISO's and IEC's activity see Martin Ebers, 'Standardizing AI: The Case of the European Commission's Proposal for an Artificial Intelligence Act' in Larry DiMatteo, Michel Cannarsa and Cristina Poncibò (eds), *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics* (CUP 2022), 328-329.

[218] See the IEEE P7000™ standards project at <https://ethicsinaction.ieee.org/p7000/>; IEEE, *Ethically Aligned Design. A Vision for Prioritizing Human Well-being with Autonomous and Intelligent Systems* (1st edn) <https://ethicsinaction.ieee.org/wp-content/uploads/ead1e.pdf>; IEEE, *IEEE Finance Playbook Version 1.0. Trusted Data and Artificial Intelligence Systems (AIS) for Financial Services*; Raja Chatila and John C Avens, 'The IEEE Global Initiative on Ethics of Autonomous and Intelligent Systems' in Maria Isabel Aldinhas Ferreira and others, *Robotics and Well-Being* (Springer 2019).

[219] Cf Gian Luca Conti, 'La lex informatica' (2021) 14 Osservatorio sulle fonti 318 <https://www.osservatoriosullefonti.it/mobile-saggi/mobile-numeri-speciali/speciale-l-impatto-delle-dinamiche-transnazionali-sui-sistemi-normativi-1-2021/1607-la-lex-informatica/file>, 327; Olia Kanevskaia, 'ICT Standards Bodies and International Trade: What Role for the WTO?' (2022) 56 JWT 429, 432.

[220] Cf Olia Kanevskaia, 'ICT Standards Bodies and International Trade: What Role for the WTO?' (2022) 56 JWT 429, 432-433.

[221] Standardisation Regulation, Article 3(6).

pertaining to three fields of application of AI, namely industrial automation, mobility/logistics, and medicine.[222]

Finally, private norms on AI nowadays stem even from outside of professional and trade organisations. Indeed, technology companies like Microsoft[223] are increasingly publishing ethical guidelines or principles on AI as a mode of self-regulation.[224] Sometimes, companies provide professional guidelines and instructional material which delve into granular norms for engineers.[225] Furthermore, scholars have repeatedly shed light on the normative effects of the code itself and ultimately argued that it produces a similar effect to the law by regulating users' behaviour.[226] In fact, the design of software and digital infrastructures like platforms or social networks influences their use, and thus 'the coder acts as a regulator.'[227] Hence, decisions taken by companies, engineers, and technical experts have also an impact on the governance of AI.

In light of the foregoing, the regulation of AI is largely shaped by industrial actors. Against this background, it is of fundamental importance that ethical and legal concerns are duly considered by stakeholders.[228] Moreover, companies and professionals shall be held responsible for their decisions, such as decisions about datasets,[229] design choices, and model implementation.[230]

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[222] DIN and DKE, 'German Standardization Roadmap on AI' <https://www.din.de/resource/blob/772610/e96c34dd6b12900ea75b460538805349/normungsroadmap-en-data.pdf>.

[223] Microsoft, 'Microsoft Responsible AI Standard, v2. General Requirements' (2022) <https://query.prod.cms.rt.microsoft.com/cms/api/am/binary/RE4ZPmV> accessed 4 November 2022.

[224] Urs Gasser and Carolyn Schmitt, 'The Role of Professional Norms in the Governance of Artificial Intelligence' in Markus D Dubber, Frank Pasquale and Sunit Das (eds), *The Oxford Handbook of Ethics of AI* (OUP 2020), 145.

[225] *Ivi*, 152. The Authors make the example of Microsoft's Guidelines on Conversational AI: Microsoft, *Responsible Bots: 10 Guidelines for Developers of Conversational AI* (November 4, 2018) <https://www.microsoft.com/en-us/research/uploads/prod/2018/11/Bot_Guidelines_Nov_2018.pdf>.

[226] See *ex multis* Lessig's seminal work: Lawrence Lessig, *Code and Other Laws of Cyberspace* (Basic Books 1999); see also *id.*, *Code version 2.0* (Basic Books 2006) and *id.*, 'Law Regulating Code Regulating Law' (2003) 35 Loy U Chi LJ. 1. Cf Joel R Reidenberg, '*Lex Informatica*: The Formulation of Information Policy Rules through Technology' (1998) 76 Tex L Rev 553; Leon E Trakman, 'From the Medieval Law Merchant to E-Merchant Law' (2003) 53 U Toronto LJ 265; Lena Ulbricht and Karen Yeung, 'Algorithmic Regulation: A Maturing Concept for Investigating Regulation of and through Algorithms' (2022) 16 Regulation & Governance 3. In the Italian scholarship cf Gian Luca Conti, 'La *lex informatica*' (2021) 14 Osservatorio sulle fonti 318 <https://www.osservatoriosullefonti.it/mobile-saggi/mobile-numeri-speciali/speciale-l-impatto-delle-dinamiche-transnazionali-sui-sistemi-normativi-1-2021/1607-la-lex-informatica/file>; Cristina Poncibò, '*Lex mercatoria ex machina*' [2021] MediaLaws 69 <https://www.medialaws.eu/wp-content/uploads/2022/01/3-21-Poncibo.pdf>.

[227] Thibault Schrepel, 'Law + Technology' (2022) Stanford CodeX Working Paper <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4115666> accessed 4 November 2022, 9.

[228] Cf Clothilde Goujard and Gian Volpicelli, 'Harmful AI Rules: Now Brought to You by Europe & Co., Inc.' Politico (31 October 2022) <https://www.politico.eu/article/harmful-ai-rules-european-union-corporate-influence/> accessed 4 November 2022.

[229] Mehtab Khan and Alex Hanna, 'The Subjects and Stages of AI Dataset Development: A Framework for Dataset Accountability' (2023) 19 Ohio St Tech. LJ (forthcoming) <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4217148>; David Lehr and Paul Ohm, 'Playing with the Data: What Legal Scholars Should Learn About Machine Learning' (2017) 51 UC Davis LRev 653.

[230] Virginia Dignum, *Responsible Artificial Intelligence: How to Develop and Use AI in a Responsible Way* (Springer 2019), 101-105 and 119; Joshua A Kroll and others, 'Accountable Algorithms' (2017) 165 UPaLRev 633.

6 The role of standards in liability litigation

Building on the previous sections, the role of standards and professional norms on AI for private law is now investigated. Specifically, the question is whether and how these private rules can help mitigate the uncertainty which characterises the assessment of liability for AI-related damage.

6.1 Challenges for liability from AI

AI technologies are pervasive. Therefore, damage caused by, or related to, the functioning of AI systems is likely to become very frequent. Nonetheless, the application of existing remedies of tort law and of contract law to such scenarios is not straightforward. Briefly, the judicial assessment of the elements of negligence and causation in tort law claims is challenged by distinctive features of many AI systems.[231] First, there is a certain lack of predictability as far as the reaction of the software to unseen instances is concerned.[232] Whereas it is common to other automated or dangerous activities, this issue is exacerbated by machine learning approaches[233] since they enable software to autonomously determine the class labels and decision trees for unseen inputs.[234] However, AI is not infallible. The erroneous output might be due to human decisions or errors at the developing stage, including modelling, pre-processing, training, validating, and testing. However, it might also depend on the way downstream deployers use the system and adapt it.[235] Finally, it is possible that a particular outcome was reasonably unforeseeable and unavoidable. In this latter case, then, humans are not at fault.[236]

Even in the case of a human error, it is challenging to identify the responsible person(s) for manifold reasons. First, not every AI-driven decision-making process is easily explainable, as some models are inherently obscure on how the data is processed and internal decisions are taken by the system (the so-called 'black box effect').[237]

[231] For a thorough analysis of said characteristics and of their impact on tort law institutes see Expert Group on Liability and New Technologies – New Technologies Formation (EG-NFT), 'Liability for Artificial Intelligence and Other Emerging Technologies' (European Commission 2019) <https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeetingDoc&docid=36608>. See also European Commission, 'Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics' COM (2020) 64 final.
[232] Christiane Wendehorst, 'Strict Liability for AI and Other Emerging Technologies' (2020) 11 JETL 150, 151-152.
[233] See Zhao Yan Lee, Mohammad Ershadul Karim and Kevin Ngui, 'Deep Learning Artificial Intelligence and the Law of Causation: Application, Challenges and Solutions' (2021) 30 Info & Comm Tech L 255.
[234] Christiane Wendehorst, 'Strict Liability for AI and Other Emerging Technologies' (2020) 11 JETL 150, 151-152.
[235] Lilian Edwards, 'Regulating AI in Europe: Four Problems and Four Solutions' (Ada Lovelace Institute 2022) <https://www.adalovelaceinstitute.org/report/regulatingai-in-europe/>, 6.
[236] Cf Andreas Matthias, 'The responsibility gap: ascribing responsibility for the actions of learning automata' (2004) 6 Ethics and Information Technology 175.
[237] See eg Frank Pasquale, *The Black Box Society: The Secret Algorithms That Control Money and Information* (Harvard University Press 2015); Davide Castelvecchi, 'Can We Open the Black Box?' (2016) 538 Nature 20.

Second, the AI pipeline can be particularly complex as it involves various professionals, such as computer scientists, engineers, software developers, policymakers, legal experts, business representatives (the so-called 'many hands problem'). Additionally, individuals outside of established professions and even high-tech amateurs might be involved in the development of AI-based technologies.[238] These characteristics of AI complicate further the judicial assessment of the elements of fault and causation.[239] Similarly, the assessment of product defects under the PLD is also hurdled.[240]

On top of that, most AI systems are open, ie subject to frequent or continuous change after they are placed on the market. Moreover, they are data-driven which means that software needs to be fed with data. Updates and inputs can be tossed by third parties like hackers though. Hence, AI systems are exposed to cybersecurity risks. Furthermore, said individuals might find ways to access stored data, particularly personal data. Moreover, sensors that captures data might malfunction, thus compromising the input and ultimately the functioning of the entire AI system.

In sum, AI systems are complex and vulnerable. Besides, even a minor flaw might have repercussions on a wide scale since many AI systems combine several interconnected AI units.[241] Hence, if a single unit is flawed, the entire hive will be so as well. In light of the foregoing, the application of traditional principles of tort law is not clear-cut. Moreover, the efficacy of legal remedies might be thwarted by evidentiary burdens.

Against this backdrop, the Commission was urged to intervene by the Parliament.[242] Eventually, the Commission put forward two proposals, respectively one for a revision of the PLD and the other one for an AI Liability Directive. Interestingly, in its proposed AI Liability Directive, the Commission departed significantly from the Parliament's suggestions. Indeed, the Commission addressed the problem of AI-related damage mainly by introducing duties of disclosure about AI systems and rebuttable presumptions of fault, causation, and defectiveness. Instead, the Parliament proposed a risk-based liability regime for operators of AI systems, including users and other frontend controllers as well as backend operators.[243] This means that the liability

[238] Urs Gasser and Carolyn Schmitt, 'The Role of Professional Norms in the Governance of Artificial Intelligence' in Markus D Dubber, Frank Pasquale and Sunit Das (eds), *The Oxford Handbook of Ethics of AI* (OUP 2020), 144 f.
[239] Moreover, the element of damage is also challenged as some type of loss related to AI, such as purely economic loss or data loss, might not meet the definition of damage under national tort law regimes. Notwithstanding the importance of this issue, it is not relevant to the present contribution.
[240] See fn 19.
[241] See Gunther Teubner, 'Digital Personhood? The Status of Autonomous Software Agents in Private Law' [2018] Ancilla Iuris 35, 75-77.
[242] Resolution of 20 October 2020 with recommendations to the Commission on a civil liability regime for artificial intelligence [hereinafter, 'Resolution']. For a critical analysis of the Resolution see Henrique Sousa Antunes, 'Civil Liability Applicable to Artificial Intelligence: A Preliminary Critique of the European Parliament Resolution of 2020' (December 2020) <http://dx.doi.org/10.2139/ssrn.3743242> and Gerhard Wagner, 'Liability for Artificial Intelligence: A Proposal of the European Parliament' in Horst Eidenmüller and Gerhard Wagner, *Law by Algorithm* (Mohr Siebeck 2021).
[243] Resolution, Annex, Article 3, lit. *e* and *f*.

regime depended on the gravity of the risk posed by the specific AI system. Accordingly, operators of high-risk AI systems were strictly liable for damage, ie regardless of any culpable behaviour on their behalf.[244] Differently, operators of AI systems that posed an 'average' level of risk were subject to a fault liability regime, coupled with a presumption of fault.[245]

Even though the Commission's proposals address some of the major problems related to the assessment of extracontractual liability for AI, the role of national courts remains crucial. In fact, judges are required to establish whether the specific circumstances of the case justify the issuance of an order of disclosure or the application of a presumption. Hence, they need to evaluate the difficulties faced by claimants in proving the elements of the cause of action in relation to the technical and scientific complexity of the issue on a case-by-case basis. More importantly, the proposals do not tackle the problem addressed in the present contribution. As they do not provide any guidance for defining the standard of care of the actors involved in the AI pipeline, this task is still entirely in the hands of domestic courts.

In addition to extracontractual liability, contractual liability is a thorny issue too. Where contract performance is partially or entirely automated with AI systems, the result does not only depend on the conduct of the parties but is also determined by the performance of the AI system. Therefore, courts must determine whether and under what conditions parties who use AI systems to perform their obligations are liable toward their contractual partners.[246]

6.2 The 'reasonable AI' and the 'reasonable AI operator'

Against this backdrop, standards and professional norms might help deal with uncertainty. The role of standards in the context of liability for AI-related damage has been largely overlooked hitherto though. Nevertheless, building on previous work by van Leeuwen,[247] Veale and Borgesius posit that AI standards might be considered in national tort cases.[248]

In Sections 3 and 4 I made the point that these private norms enter the courtrooms via various mechanisms. Transferring this line of reasoning to the AI context, standards

[244] Resolution, Annex, Articles 4-7.
[245] Resolution, Annex, Articles 8-9.
[246] André Janssen, 'AI and Contract Performance' in Larry A DiMatteo, Cristina Poncibò and Michel Cannarsa (eds), *The Cambridge Handbook of Artificial Intelligence* (CUP 2022); Tycho J de Graaf and Iris S Wuisman, 'Contractual Liability for the Use of AI under Dutch Law and EU Legislative Proposals' in Bart Custers and Eduard Fosch-Villaronga (eds), *Law and Artificial Intelligence: Regulating AI and Applying AI in Legal Practice* (Springer 2022).
[247] Barend van Leeuwen, *European Standardisation of Services and Its Impact on Private Law: Paradoxes of Convergence* (Hart Publishing 2017), 20-21.
[248] Michael Veale and Frederik Zuiderveen Borgesius, 'Demystifying the Draft EU Artificial Intelligence Act. Analysing the Good, the Bad, and the Unclear Elements of the Proposed Approach' (2021) 22 Computer L Rev Int'l 97, 111.

might inform the duty of care of professionals in the AI field and of operators of AI systems for liability purposes. Standards and professional norms will have an evidential role in product liability cases, fault liability cases, and contractual cases.[249] Furthermore, they will likely guide judicial interpretation of negligence and conformity.[250]

At the developing stage, harmonised standards and other professional norms will *de facto* set the rules of the game in spite of their non-binding nature. For instance, best practices are already emerging in the field of automated driving.[251] The responsibility of AI providers is likely to extend beyond the mere supply of products and services. It has been observed that some professional norms tentatively address the problem of the potential behaviour of autonomous systems and recommend a 'frequent reassessment' of the technology when the risk is uncertain.[252]

Suggestively, Barfield theorises the emergence of a 'reasonably prudent algorithm' standard of care in relation to liability for damage caused by robots.[253] Accordingly, he encourages courts to focus on the machine learning software and algorithms controlling a robot in determining liability, 'especially if no human was aware of the robot's activities or was knowledgeable of the workings of the algorithms controlling the robot's behaviour.'[254] For this, Barfield proposes to use performance measures to evaluate the algorithm in court. Performance measures are measurements usually conducted by developers of AI systems to test a trained model. The choice between

[249] Cf Barend van Leeuwen, *European Standardisation of Services and Its Impact on Private Law : Paradoxes of Convergence* (Bloomsbury Publishing 2017), 154-155, 169.

[250] This thesis is supported in the literature with regard to the related field of cybersecurity. See Shackelford and others, 'Toward a Global Cybersecurity Standard of Care? Exploring the Implications of the 2014 NIST Cybersecurity Framework on Shaping Reasonable National and International Cybersecurity Practices' (2015) 50 Tex Int'l LJ 305, 341-46; Tari Schreider, *Cybersecurity Law, Standards and Regulations* (2nd edn, Rothstein Publishing 2020), 49: 'Courts will look at nationally or internationally accepted cybersecurity standards to define your duty of care.'

[251] For international harmonisation efforts on automated driving regulations see United Nations Economic Commission for Europe, 'Framework Document on Automated/Autonomous Vehicles (Updated)' <https://unece.org/sites/default/files/2022-02/FDAV_Brochure%20-%20Update%20Clean%20Version.pdf>, accessed 16 July 2022. For an overview of relevant standards see Martin Ebers, 'Civil Liability for Autonomous Vehicles in Germany' (2022) <https://ssrn.com/abstract=4027594>, 18. For a thorough assessment of the safety components of autonomous vehicles see Hannah YeeFen Lim, *Autonomous Vehicles and the Law. Technology, Algorithms and Ethics* (Edward Elgar 2018), 20-81. More specifically, the Author identifies as vital components on-board multiple redundant overlapping detection systems, namely, global positioning systems, high-definition maps, lidars, radars, cameras, and infrared systems. There must of course be sufficient numbers of these devices and they must be appropriately positioned on the autonomous vehicle. Finally, the Author recommends installing appropriate warning alerts and effective hands-on-steering-wheel mechanisms to ensure drivers are in fact in control of the vehicle.

[252] Urs Gasser and Carolyn Schmitt, 'The Role of Professional Norms in the Governance of Artificial Intelligence' in Markus D Dubber, Frank Pasquale and Sunit Das (eds), *The Oxford Handbook of Ethics of AI* (OUP 2020), 151. The Authors make the examples of Microsoft's 'Future Computed' and of the Code of Ethics of the Association for Computing Machinery-ACM: Microsoft, *The Future Computed* (Microsoft Corporation 2018) <https://1gew6o3qn6vx9kp3s42ge0y1-wpengine.netdna-ssl.com/wp-content/uploads/ 2018/02/The-Future-Computed_2.8.18.pdf>, 56; Association for Computing Machinery 'ACM Code of Ethics and Professional Conduct' (July 2019) <https://www.acm.org/code-of-ethics>.

[253] Woodrow Barfield, 'Liability for Autonomous and Artificially Intelligent Robots' (2018) 9 Paladyn, Journal of Behavioral Robotics 193, 198, 201.

[254] *Ivi* at 194.

different kinds of performance measures depends on the specific class of tasks the robot is assigned. In fact, some measures score the average of correct predictions (accuracy), whereas others score the average of true positives (precision) or their ratio (recall). In fact, depending on the specific application, false positives might be less dangerous than false negatives and vice versa. Hence, with the help of experts, courts will have to shift through such measures.

Piercing the veil of the 'reasonable algorithm' formula, low scores on relevant performance measures can provide evidence of negligence in designing and developing the AI. It might also constitute evidence of defects in product liability, or of lack of conformity under contract law. After all, many errors by the machine are the perpetuation of human errors.[255] Therefore, performance measures are best practices that might help mitigate uncertainty.

Perhaps the main limitation of this approach is that not every algorithmic decision-making process is explainable. This notwithstanding, there are always some value choices that are made by humans, including the choice of whether to use an opaque model rather than an explainable one and even the decision to resort to an AI system to perform a given task in the first place. Arguably, these decisions should be challengeable by aggrieved parties. Furthermore, producers and sellers should be liable for their misleading statements if they encouraged overconfidence in the machine's capability which resulted in an accident.[256]

As for the liability of those who deploy AI systems, it must first be considered that AI systems can be operated by different users of various knowledge and expertise. AI systems can be operated by professionals whose main business purpose is the operation of digital systems. However, they can also be operated by non-professionals, including both consumers and professionals in fields other than AI who employ AI-

[255] For instance, this is true for algorithmic bias or discrimination: Maarten Buyl and others, 'Tackling Algorithmic Disability Discrimination in the Hiring Process: An Ethical, Legal and Technical Analysis', *2022 ACM Conference on Fairness, Accountability, and Transparency* (Association for Computing Machinery 2022) <https://dl.acm.org/doi/pdf/10.1145/3531146.3533169>, 1071.

[256] For instance, Tesla has been facing several lawsuits for false advertising for misrepresenting their vehicles' features and capabilities since 2016. In China, the driver of a Tesla Model S died in a crash that occurred while the vehicle was in Autopilot mode. The driver's family filed a lawsuit for false advertising accusing Tesla of exaggerating Autopilot's capabilities: Rose Yu, 'Family of Driver Killed in Tesla Crash in China Seeks Court Investigation' *The Wall Street Journal* (20 September 2016) <https://www.wsj.com/articles/family-of-driver-killed-in-tesla-crash-in-china-seeks-court-investigation-1474351855> accessed 16 July 2022. In the same vein, in July 2020 the Regional Court Munich I (file no. 33 O 14041/19) prohibited Tesla from using the term 'autopilot' and other misleading statements on its German website advertising the driver assistance features of its electric cars pursuant to German competition law: Dirk Seiler, Nina Ballwanz and Nathalie Thorhauer, 'Munich Regional Court Prohibits Tesla's Advertising Claims for Its Electric Cars' (Herbert Smith Freehills, 12 August 2020) <https://hsfnotes.com/cav/2020/08/12/munich-regional-court-prohibits-teslas-advertising-claims-for-its-electric-cars/> accessed 16 July 2022. Similarly, in Santa Barbara, California, the purchasers of a Tesla Model S sued the company for fraud as the car was misleadingly advertised as fully self-driving: see Tyler Hayden, 'Santa Barbara Brothers Accuse Tesla of False Advertising' *The Santa Barbara Independent* (22 July 2021) <https://www.independent.com/2021/07/22/santa-barbara-brothers-accuse-tesla-of-false-advertising/> accessed 16 July 2022.

driven solutions to automate the execution of their tasks. Paradigmatic examples are those of algorithmic credit scoring,[257] robo-advising,[258] AI-driven detecting tools for disease diagnosis, and robotic surgery.[259]

With regard to devices of a type for which users are already subject to a strict liability regime under the majority of legal systems like motor vehicles, it is arguably preferable to apply strict liability regardless of whether a device contains AI or not in the light of the principles of technology neutrality and legal certainty.[260]

In other cases, instead, ordinary fault liability may be appropriate. Hence, it must be determined whether the operator fulfiled the standard of care of a reasonable person of comparable education and expertise. The Commission did not provide any criteria for the assessment of fault in its proposal for an AI Liability Directive. In its Resolution of 2020, the Parliament suggested that fault should arise from failure to maintain the system or to oversee its functioning. These norms are quite vague though and thus it is unclear how courts and experts are going to interpret them in practice.

Where the AI system is operated by a consumer for his or her private activities, the user should follow the instructions and take the required precautions. This is without prejudice to the fact that the provider should minimise the risks of the system, taking into account the knowledge and expertise of the intended user.[261] For instance, where the producer or the seller instilled too much confidence in the system with their statements,[262] the consumer could be excused for not taking the adequate precautions.

Where the operator is also a professional in the AI field, it can be reasonably expected that judges will follow standards delivered by standardisation organisations and other professional norms. Hence, these private norms will represent the benchmark for the 'reasonable operator' who is also a professional in the AI field.[263]

For operators who are not professionals in the AI field, but who use AI systems to perform their professional activities, safety standards and best practices are likely to

[257] Julie Goetghebuer, 'AI and Creditworthiness Assessments: The Tale of Credit Scoring and Consumer Protection. A Story with a Happy Ending?' in Jan De Bruyne and Cedric Vanleenhove (eds), *Artificial Intelligence and the Law* (1st edn, Intersentia 2021); Noah Vardi, *Creditworthiness and 'Responsible Credit': A Comparative Study of EU and US Law* (Brill 2022), 97-104.

[258] Marika Salo-Lahti, 'Good or Bad Robots? Responsible Robo-Advising' (2022) 33 European Business LRev 671.

[259] See PwC, 'Study on eHealth, Interoperability of Health Data and Artificial Intelligence for Health and Care in the European Union' (European Commission 2021) <https://digital-strategy.ec.europa.eu/en/library/artificial-intelligence-healthcare-report>, 39-42.

[260] This is the position of Wendehorst: Christiane Wendehorst, 'Strict Liability for AI and Other Emerging Technologies' (2020) 11 JETL 150.

[261] AI Liability Directive, Recital 29.

[262] Cf Miriam Buiten, Alexandre de Streel and Martin Peitz, 'EU Liability Rules for the Age of Artificial Intelligence' (Centre on Regulation in Europe - CERRE 2021) <https://cerre.eu/publications/eu-liability-rules-age-of-artificial-intelligence-ai/>, 35.

[263] As pointed out by Herbosch, 'if the system user adheres to AI soft law standards, this may serve as another abstract indicator of diligence' (Maarten Herbosch, 'The Diligent Use of AI Systems: A Risk Worth Taking?' (2022) 11 EuCML 14, 21).

emerge in the relevant communities.[264] It is also possible that they will be asked to undergo some training prior to using AI technology. Arguably, professionals need to carefully validate the output of these recommendation systems, perform risk assessments, and control the operation of the system as much as possible. Whilst these precautions could undermine objectives of time and resource saving, they are essential to a human-centred approach to AI.[265] This is notwithstanding the fact that human oversight suffers from practical limitations.[266] For instance, humans might misjudge a certain output as flawed because of their inability to grasp the underlying correlations.

Whilst I suggest that standards might help courts define the required standard of care, judges need also to consider whether the specific circumstances of the case justify a departure from established standards and good practices. Moreover, as pointed out in Section 1, standardisation is in a complicated relationship with innovation.[267] The possible tension between AI standardisation and innovation should be taken into account by domestic courts.[268] When the defendant can demonstrate the adequacy and validity of a technique or practice other than those laid down in the relevant standards, his/her fault should not depend on deviation from said standards. Otherwise, innovation would be significantly hampered.

Notably, AI systems are characterised by different levels of automation, from manual teleoperation to fully autonomous systems. This might complicate further the assessment of the degree of control retained by operators in each case. Interestingly, some criteria in this regard are already available. The Society of Automotive Engineers (SAE International), a professional association, defined six levels of automation from 0 to 5 in its standard on Levels of Driving Automation.[269] Whereas they pertain to automotive, they might provide guidance also for other sectors. For instance, they inspired the recent classification of surgery automation by Fosch-Villaronga and

[264] See for instance the recent study by Fosch-Villaronga and others on a liability attribution framework for robotic surgery: Eduard Fosch-Villaronga and others, 'The Role of Humans in Surgery Automation Exploring the Influence of Automation on Human–Robot Interaction and Responsibility in Surgery Innovation' [2022] International Journal of Social Robotics <https://doi.org/10.1007/s12369-022-00875-0>.

[265] Ursula von der Leyen, 'Shaping Europe's digital future: op-ed by Ursula von der Leyen, President of the European Commission' (19 February 2020); Commission, 'White Paper on Artificial Intelligence' COM (2020) 65 final; High-Level Expert Group on Artificial Intelligence (AI HLEG), 'Assessment List for Trustworthy Artificial Intelligence' (Commission 2020) <https://digital-strategy.ec.europa.eu/en/library/assessment-list-trustworthy-artificial-intelligence-altai-self-assessment>, 7-8; Committee of Ministers, 'Recommendation CM/Rec(2020)1 of the Committee of Ministers to member States on the human rights impacts of algorithmic systems'.

[266] Ben Green and Amba Kak, 'The False Comfort of Human Oversight as an Antidote to A.I. Harm' [2021] Slate <https://slate.com/technology/2021/06/human-oversight-artificial-intelligence-laws.html> accessed 20 July 2022.

[267] Zongjie Xie and others, 'Standardization efforts: The relationship between knowledge dimensions, search processes and innovation outcomes' (2016) 48-49 Technovation 69, 75-77.

[268] I am indebted to one anonymous reviewer for pointing out this issue.

[269] SAE International J3016_202104 'Taxonomy and Definitions for Terms Related to Driving Automation Systems for On-Road Motor Vehicles' <https://www.sae.org/standards/content/j3016_202104/> accessed 4 November 2022, last revised 30 April 2021.

others, based on autonomy levels and the role of humans.[270] Most importantly, they have already made their way from soft to hard law. In fact, the German Road Traffic Act[271] contemplates specific provisions for accidents caused by autonomous vehicles. More specifically, it distinguishes between vehicles of SAE levels 3 and 4. The reference to the SAE standards bears direct consequences on the liability of operators. For vehicles of SAE level 3, drivers are still in control of the car and are presumed liable in case of accidents. For vehicles of SAE level 4 instead, the German law introduces the 'technical supervisor' who is entrusted with deactivating the system and approving an alternative driving manoeuvre. The supervisor, who can be the driver or another natural person, is liable for fault under the general conditions of § 823(1) BGB[272] and must fulfil specific duties and requirements that will be specified by the Federal Ministry of Transport and Digital Infrastructure.[273]

Finally, the decision to use an AI system for performing a given task in the first place should also be subject to scrutiny. Vice versa failure to use technology might become a violation of a legal standard. For instance, in some cases, it may be considered more diligent to use AI rather than not. Interestingly, in *Cass v. 1410088 Ontario Inc.*, the Superior Court of Ontario capped the costs award by reasoning that counsel's preparation time would have been significantly reduced if AI technology had been employed.[274] Arguably, a potential legal obligation to adopt a certain technology might depend on the state of the art and on available resources.

Mutatis mutandis these arguments bear relevance to contractual liability too. Conformity of digital products and services under the SGD and the DCSD, satisfactory performance, unforeseeability, and unpredictability of impediments: all these elements might be interpreted in the light of existing and upcoming standards. For instance, the forthcoming ISO standard on 'Systems and software Quality Requirements and Evaluation (SQuaRE)' might be a good candidate for evaluating the conformity of software to contractual and legal requirements.

[270] Eduard Fosch-Villaronga and others, 'The Role of Humans in Surgery Automation Exploring the Influence of Automation on Human–Robot Interaction and Responsibility in Surgery Innovation' [2022] International Journal of Social Robotics <https://doi.org/10.1007/s12369-022-00875-0>, 3-6.

[271] *Straßenverkehrsgesetz*. For an English version see <https://www.gesetze-im-internet.de/englisch_stvg/index.html> accessed 20 July 2022.

[272] *Bürgerliches Gesetzbuch*, ie the German Civil Code. § 823(1) BGB is the cornerstone of German tort law, and it states that any person who, intentionally or negligently, unlawfully injures the life, body, health, freedom, property, or another right of another person, is liable for compensation to the aggrieved person.

[273] For an extensive overview see Martin Ebers, 'Civil Liability for Autonomous Vehicles in Germany' (2022) <https://ssrn.com/abstract=4027594>.

[274] *Cass v. 1410088 Ontario Inc.*, 2018 ONSC 6959 (CanLII) [34], available at <https://www.canlii.org/en/on/onsc/>.

7 Conclusions

The present research has investigated the link between standards on AI and liability. For this purpose, the normative force of standards and professional norms and their relevance to liability disputes have been first demonstrated. The extensive reach of standards and professional norms onto private relationships reinforces constitutional concerns about standardisation.[275] Standards are ubiquitous in everyday life and also in numerous areas of public policy.[276] European standards are essential to the development of the internal market[277] and eventually means for the global reach of EU law.[278] Indeed, they not only shape global markets but also function as mechanisms of regulatory and policy diffusion.[279] Hence, the ample leeway that is usually given to ESOs due to their expertise must be reconciled with the essential administrative and constitutional safeguards of law-making to make sure that societal needs are taken into account by standards makers.[280] Furthermore, the legitimacy of standards is contested due to a lack of transparency and involvement of consumers and SMEs. Similar concerns emerge with respect to international and national standardisation, particularly in the field of ICT standardisation, which is essential to AI.[281]

Next, the framework of AI standardisation has been pinpointed. Accordingly, the European approach to AI standardisation in the AI Act has been thoroughly analysed and an overview of international and national standardisation initiatives has been provided. A complex patchwork of rules, standards, and other professional norms laid down by professional associations and companies has emerged. This overview unveiled the pivotal role played by industry actors in regulating AI. In this regard, scholars

[275] See eg Eric J Iversen, Thierry Vedel and Raymund Werle, 'Standardization and the Democratic Design of Information and Communication Technology' (2004) 17 Knowledge, Technology & Policy 104; Olia Kanevskaia, 'ICT Standards Bodies and International Trade: What Role for the WTO?' (2022) 56 JWT 429. For proposals of alternative regulatory models see Rob van Gestel and Hans-W Micklitz, 'European Integration through Standardization: How Judicial Review Is Breaking down the Club House of Private Standardization Bodies' (2013) 50 CML Rev 145.
[276] Cf *Stichting Rookpreventie*, Opinion of AG Saugmandsgaard Øe, para 79.
[277] ibid and Standardisation Regulation, Recital 5.
[278] Standardisation Regulation, Recital 6; cf Marta Cantero Gamito and Hans-W Micklitz (eds), *The Role of the EU in Transnational Legal Ordering: Standards, Contracts and Codes* (Edward Elgar 2020); Hans-W Micklitz, 'The Internal vs. the External Dimension of European Private Law – A Conceptual Design and a Research Agenda' EUI WP 2015/35, 10-11; Rodrigo Vallejo, 'The Private Administrative Law of Technical Standardization' (2021) 40 YEL 172.
[279] Marta Cantero Gamito, 'Europeanization through Standardization: ICT and Telecommunications' (2018) 37 YEL 395, 421.
[280] See Case C-9/56 *Meroni & Co., Industrie Metallurgiche, SpA v High Authority of the European Coal and Steel Community* [1958] ECR 133. According to the *Meroni* formula, in the EU system delegation of rule-making powers is allowed only if they are of a purely executive nature, if appropriate procedural guarantees are in place, and if judicial review of delegates' decisions is ensured. For a critique of the New Approach framework in light of the *Meroni* doctrine see Takis Tridimas, 'Community Agencies, Competition Law, and ECSB Initiatives on Securities Clearing and Settlement' (2009) 28 YEL 216.
[281] Marta Cantero Gamito, 'Europeanization through Standardization: ICT and Telecommunications' (2018) 37 YEL 395, 431.

highlight the need for cooperation between scientists, developers, policymakers, and ethicists in light of a 'Responsible AI' approach to innovation.[282]

Finally, the article dealt with the problem of liability for AI from the angle of negligence and conformity. Courts deal with these general clauses by interpreting them in the light of the specific circumstances of the case. In highly technical cases, courts count on their own experience and on the advice of experts. Their determinations are based on empirically observable data.[283] Now, the problem with AI-related damage is that there is not much data on which courts and experts can rely. Uncertainty is unavoidable.[284] Moreover, the features of AI significantly complicate the assessment of human responsibility for negative outputs. The limitations of established tort law and contract law *vis-à-vis* AI are the objects of lively scholarly and political debate.

In this respect, this article has explored the possibility of using standards and professional norms to mitigate this uncertainty. Standards are no panacea for sure. The tentative conclusion though is that standards provide a valuable yardstick against which the behaviour of developers and deployers can be evaluated. Furthermore, for operators of AI systems, I have distinguished between professionals in the field of AI, professionals in fields other than AI, and consumers. Arguably, their respective duty of care should mirror their different expertise. Therefore, the Parliament's proposal is not satisfactory insofar as it establishes a cross-cutting strict liability regime for all operators of high-risk AI systems, including consumers. The decision of the Commission to reject said suggestion in its proposal for an AI Liability Directive must thus be welcomed. Finally, it may be possible that courts will find professionals liable for failure to use AI systems in performing their tasks.

Like standards, AI is ubiquitous. Many AI systems are also autonomous, which means that once activated, they provide outputs without further input from humans. At first glance, the autonomy of AI might exclude the relevance of human behaviour. Instead, we make the point that AI is shaped by those who develop and deploy them, at least to a certain extent. Indeed, standards are flourishing precisely to guide humans in the creation and use of AI systems. Arguably, before providing answers, AI standards help pose the right questions. Therefore, the quest for liability for AI involves a set of questions about whether, how, and with what safeguards human activity and decision-making authority are transferred to a machine.[285]

[282] Virginia Dignum, *Responsible Artificial Intelligence: How to Develop and Use AI in a Responsible Way* (Springer 2019).
[283] Alan D Miller and Ronen Perry, 'The Reasonable Person' (2012) 87 NYULR 323, 371.
[284] Cf F Patrick Hubbard, '"Sophisticated Robots": Balancing Liability, Regulation, and Innovation' (2014) 66 Fla L Rev, 1803, 1861: "Where the tort system continues to use traditional fault approaches to address the control, use, and service of robots, the application of concepts like reasonable care will change where increasingly sophisticated robots are involved because the legal system measures the level of skill reasonably required by the nature of the activity undertaken."
[285] Simon Chesterman, 'Artificial Intelligence and the Problem of Autonomy' (2020) 210 Notre Dame Journal on Emerging Technologies 210, 249.