Editorial

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Harmonised Standards in AI Regulation: An Introduction to the Special Issue

I. Introduction

1 The adoption of the Regulation on Artificial Intelligence ("AI Act") represents a major milestone in the European digital strategy. With its entry into force in August 2024, the EU is one of the first legal systems[1] to have adopted a comprehensive framework for regulating the development, the placing on the EU market, and the use of artificial intelligence ("AI") systems, while addressing the impact of AI on the fundamental rights of individuals, such as human dignity, the right to privacy, the protection of personal data and freedom of expression, and on societal values, including democracy, the rule of law, and the protection of the environment.

2 The actual implementation of this legislative framework, however, will require extensive technological expertise to further detail specific rules for producers and users of AI. For this reason, the EU institutions will heavily rely on the regulatory work of international and European standardisation organisations which have already been developing technical standards on artificial intelligence.[2] As stated by the European Commission, standardisation organisations are meant to lead the path for the digital transition of the EU economy by elaborating detailed specifications in support of EU legislation.[3] In particular, the AI Act expressly refers to harmonised standards for the operationalisation of the requirements for high-risk systems and, to a certain extent, for general-purpose AI models, establishing a presumption of conformity for systems and models compliant with them.[4]

3 While this regulatory technique makes the role of technical standards as complementary tools vis-à-vis EU regulation clearly visible,[5] it also shows that they do not only regulate technical and scientific aspects of AI and its value chains, but also have

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1 Compare the scope of the AI Act with the US AI Bill of Rights (2022); Executive Order on the Safe, Secure, and Trustworthy Development and Use of AI (2023); and with Chinese Law on Generative AI (2023).

2 See, inter alia, Andrew Leyden, 'Standards and the EU AI Act: Legitimacy, state of play, and future challenges' (2025) *Information & Communications Technology Law* 1.

3 See European Commission, *Communication: Shaping Europe's digital future*, Publications Office of the European Union, 2020, 7. See also Decision (EU) 2022/2481 of the European Parliament and of the Council of 14 December 2022 establishing the Digital Decade Policy Programme 2030, OJ 2022 L 323/4.

4 Art. 40 and 55 AI Act.

5 Irene Kamara, *Standardizing Personal Data Protection* (Oxford University Press 2025)

the potential to influence and express broader value policy choices.[6] As Majone has aptly put it, standards are "a microcosm in which conflicting epistemologies, regulatory philosophies, national traditions, social values, and professional attitudes are faithfully reflected".[7] At the same time, standard-setting at the international level is acquiring a stronger geopolitical meaning.[8] With some third states taking an unprecedentedly assertive stance to standardisation, the latter becomes a contentious terrain where the EU struggles to safeguard its values and interests in standard-setting against an increasingly competitive global context.[9]

4 Although the role of harmonised standards in the AI Act is gaining increasing attention in academic debate,[10] the interplay between the current dynamics in technical standardisation and the democratic guarantees that the implementation of the AI Act needs to abide by, has arguably not been sufficiently explored in the literature. The involvement of technical standardisation in the regulation of the AI Act raises a number of legal and non-legal questions pertaining to their role, their effects, and the control that public institutions and civil society can exercise on their activities. The unprecedented geopolitical, fundamental rights and ethical considerations enshrined in AI standardisation give new dimensions to these questions and thus deserve further scholarly attention. This is precisely the purpose of this special issue.

5 This introduction will provide an overview of the historical development of the New Approach and how, from a product regulation logic, standardisation found its way into digital regulation generally and the AI Act specifically. Moreover, it will outline the primary questions addressed and posit the central hypothesis of this special issue: that, as it acquires an unprecedented legal, ethical and geopolitical dimension, the use of technical standardisation in the field of AI represents a shift in the role of harmonised standards in EU law and this poses novel challenges to their legitimacy within the EU socio-legal order.

II. Harmonised Standards and EU Law: From Industrial Products to AI Regulation

6 The use of technical standardisation for the purpose of complementing and operationalising EU regulation is not a new regulatory technique in EU law. Since 1985, the EU legislator has relied on these – formally – non-binding, voluntary instruments in the regulation of the European market for industrial products through the so-called "New Approach". The New Approach (now refined in the New Legislative Framework) consists of regulating through legislative acts only the essential requirements of general interest of a product, while referring the detailed definition of technical aspects to private standardisation organisations.[11] The different steps are now set forth in the so-called Standardisation Regulation.[12] Accordingly, after the adoption of a legislative act, the European Commission issues a request to one or more European standardisation organisations to elaborate a document defining the technical requirements to be fulfilled by a product,

6 See Giandomenico Majone, 'Science and Trans-Science in Standard Setting' (1984) 9 *Science, Technology, & Human Values* 15; Sheila Jasanoff, 'Epistemic Subsidiarity – Coexistence, Cosmopolitanism, Constitutionalism' (2013) 4(2) *European Journal of Risk Regulation* 133.

7 Giandomenico Majone, *ibid*, 15.

8 See further Mélanie Gornet and Hélène Herman, 'A peek into European standards making for AI: between geopolitical and economic interests' (2024), hal-04784035. See also Cantero in this special issue.

9 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, *An EU Strategy on Standardisation Setting global standards in support of a resilient, green and digital EU single market*, Brussels, 2.2.2022, COM(2022) 31 final, 1 and 5. See also Marta Cantero Gamito, 'The influence of China in AI governance through standardisation' (2023) 47(10) *Telecommunications Policy*, 102673.

10 See, in particular, Sybe de Vries, Olia Kanevskaia and Rik de Jager, 'Internal Market 3.0: The Old 'New Approach' for Harmonising AI Regulation' (2023) 8(2) *European Papers*, 583; Andrew Leyden, above n 2, 1; Marta Cantero Gamito and Christopher Marsden, 'Artificial intelligence co-regulation? The role of standards in the EU AI Act' (2024) 32 *International Journal of Law and Information Technology*, eaae011; Marco Almada and Nicolas Petit, 'The EU AI Act: A medley of product safety and fundamental rights?' (2023) 59 EUI Working Papers.

11 See Commission of the European Communities, *Completing the Internal Market. White Paper from the Commission to the European Council,* Milan, 28-29 June 1985, COM(85)310 final; Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, OJ 1985, C 136/1; Council Resolution of 21 December 1989 on a global approach to conformity assessment, OJ 1990, C 10/1; Regulation (EU) No 1025/2012 on European Standardisation, OJ 2012, L 316/12.

12 Regulation 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, OJ 2012, L 316/12. See also Regulation (EU) 2022/2480 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 1025/2012 as regards decisions of European standardization organisations concerning European standards and European standardization deliverables, OJ 2022, L 323/1.

process, service or system. The standards are then elaborated by the European standardisation organisations and sent to the European Commission. These standards, adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation, are defined as "harmonised standards". If the Commission concludes that the standard is in compliance with the request and Union legislation, it publishs its reference in the Official Journal of the European Union. This publication provides a presumption of conformity with the legislative standards they are linked to.

7 The use of technical standards in EU legislation has rightfully attracted scholarly attention, initially from economists[13] and political scientists,[14] and more recently from legal scholars.[15] Technical standards elaborated by private European standardisation bodies are in theory voluntary and non-binding, in the sense that an economic operator can always prove the conformity of their products with EU legislation by providing evidence of their compliance with the essential requirements of safety in a different way. However, the presumption of conformity attached to the compliance with a harmonised standard has in practice relevant legal effects beyond the private sphere. Previous research has shown that, considering the legislative and regulatory context in which the standard-setting bodies operate, and the actual practice of the market, it is very difficult and expensive for the economic operators to prove the conformity of their products to the essential requirements of harmonisation legislation in a different way.[16] As confirmed by the Court of Justice of the European Union (CJEU), in certain cases voluntary standards issued in connection with legislation can be considered *de facto* binding.[17] Recent political[18], legal[19] and jurisprudential[20] developments in the EU have put the debate on the tight integration between the law and private technical standards in the spotlight.

8 In the light of this progressive "juridification" of harmonised standards,[21] seminal EU public law literature has questioned the legality of the delegation of regulatory powers to private bodies in the light of the strict limits established by the case law of the CJEU.[22] Others have focused on the more specific violations of EU rules on fair competition and intellectual property which technical standardisation may cause.[23] Finally, stark criticism

13 See inter alia, Franklin Edward Powell, *Some Aspects of Standardization and Economic Theory* (Catholic University of America 1947); H Landis Gabel, *Product Standardization and Competitive Strategy* (Elsevier Science 1987); H Landis Gabel, *Competitive Strategies for Product Standards: The Strategic Use of Compatibility Standards for Competitive Advantage* (McGraw-Hill 1991); Peter Grindley, *Standards, Strategy, and Policy: Cases and Stories* (Oxford University Press 1995); Carmen Matutes and Pierre Regibeau, 'A Selective Review of the Economics of Standardization. Entry Deterrence, Technological Progress and International Competition' (1996) 12(2) *European Journal of Political Economy* 183. More recently, see Knut Blind, *The Economics of Standards: Theory, Evidence, Policy* (Edward Elgar 2004).

14 Susanne K Schmidt and Raymund Werle, *Coordinating Technology: Studies in the International Standardization of Telecommunications* (MIT Press 1998); Kenneth W Abbott and Duncan Snidal, 'International Standards and International Governance' (2001) 8(3) *Journal of European Public Policy* 345; Tim Büthe and Walter Mattli, 'Setting International Standards: Technological Rationality or Primacy of Power?' (2003) 56(1) *World Politics* 1; Tim Büthe and Walter Mattli, 'International Standards and Standard-Setting Bodies' in David Coen, Wyn Grant, and Graham Wilson (eds), *The Oxford Handbook of Business and Government* (Oxford University Press 2010) 440; Tim Büthe and Walter Mattli, *The New Global Rulers: The Privatization of Regulation in the World Economy* (Princeton University Press 2011).

15 Harm Schepel, *The Constitution of Private Governance. Product Standards in the Regulation of Integrating Markets* (Hart 2005); Günther Teubner, *Constitutional Fragments: Societal Constitutionalism under Globalisation* (Cambridge University Press 2012).

16 See, inter alia, Mariolina Eliantonio and Caroline Cauffman (eds), *The Legitimacy of Standardization as a Regulatory Technique A Cross-disciplinary and Multi-level Analysis* (Edward Elgar 2020); H Schepel, above n 15; Jacques Pelkmans, 'The New Approach to Technical Harmonisation and Standardization' (1987) 25(3) *Journal of Common Market Studies* 249.

17 See Case T-474/15, *Global Garden*, EU:T:2017:36, para 67; Case C-171/11, *Fra.bo. v DVGW*, EU:C:2012:453. See also Case C-367/10 P, *EMC*, EU:C:2011:203.

18 European Commission, *An EU Strategy on Standardization*, above n 9.

19 Regulation (EU) 2022/2480 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 1025/2012 as regards decisions of European standardization organisations concerning European standards and European standardization deliverables, OJ 2022, L 323/1.

20 *Inter alia*, Case C-588/21 P, *Public.Resource.Org*, EU:C:2024:201; Case C-160/20, *Stichting Rookpreventie Jeugd*, EU:C:2022:101.

21 Hans-W. Micklitz and Rob van Gestel, 'European integration through standardization: How judicial review is breaking down the club house of private standardisation bodies', (2013) 50(1) *Common Market Law Review* 145.

22 Christian Joerges, Harm Schepel and Ellen Vos, *The Law's Problems with the Involvement of Non-Governmental Actors in Europe's Legislative Processes: The Case of Standardization under the New Approach* (European University Institute 1999).

23 Pierre Arhel, 'Comportements anticoncurrentiels dans le cadre de la normalisation' (2010) 147 *Petites affiches*, 4; François Lévêque, 'La normalisation et le droit de la concurrence face au hold-up' (2007) *Revue Lamy de la concurrence*, 170-175; Björn Lundqvist, 'European

was raised with regard to the lack of transparency and participation of the standard-setting process, as well as in relation to the lack of access to the text of standards for the public, and of procedural guarantees to counter-balance the regulatory capture by big companies.[24]

9 Despite the academic criticism towards the mechanism of referencing to harmonised standards in EU legislation, the supranational legislator has decided to follow this well-established regulatory technique of the New Approach - which has proven undoubtedly successful in the regulation of the internal market for industrial products – in the regulation of a vast, value-loaded and cutting-edge field such as that of digital technologies. References to harmonised standards are included in many recent legislative acts in the field, including the Data Act,[25] the Cyber Resilience Act,[26] and - most importantly for the purpose of this special issue - the AI Act. In fact, Articles 32, 42 and 53 of the AI Act establish a presumption of conformity for AI systems and general-purpose AI models which comply with harmonised standards. This entails that, in particularly sensitive sectors, such as education, critical infrastructures, justice and employment,[27] the precise rules to ensure compliance with the requirements set in the AI Act - concerning, for instance, risk management, the quality and relevance of data sets used, and human oversight[28] - will be *de facto* spelled out by European standardisation organisations. CEN and CENELEC have received the request to issue the relevant harmonised standards from the European Commission on 22nd May 2023[29] and are currently developing them in five working groups within the Joint Technical Committee 21 (JTC21).[30]

III. Harmonised Standards and the AI Act: A Paradigm Shift and New Challenges

10 The decision of the EU co-legislators to rely on harmonised standards in the AI Act not only transplants the same legal issues that the academic community had highlighted in relation to the regulation of industrial products according to the New Approach to the digital regulation field, but also represents a fundamental shift in the role of technical standards in EU law, as has been acknowledged by the EU institutions[31] and by the standardisation community itself.[32] The object of this form of private regulation will be inevitably imbued with value judgments and sensitive implications, in particular as standards will explicitly have to address fundamental rights.[33]

11 This special issue gives an interdisciplinary account of this highly topical development, bringing together scholars with legal, socio-political and philosophical backgrounds. Thus, while most contributions are based on a legal doctrinal approach[34] and draw from

Harmonised Standards as 'Part of EU Law': The Implications of the James Elliott Case for Copyright Protection and, Possibly, for EU Competition Law' (2017) 44(4) *Legal Issues of Economic Integration* 421.

24 Mariolina Eliantonio, 'Judicial Control of the EU Harmonized Standards: Entering a Black Hole?' (2017) 44(4) *Legal Issues of Economic Integration*, 399-404; Carlo Tovo, 'Judicial Review of Harmonised Standards: Changing the Paradigms of Legality and Legitimacy of Private Rulemaking under EU Law' (2018) 55(4) *Common Market Law Review*, 1187-1216; Carlo Colombo and Mariolina Eliantonio, 'Harmonized Technical Standards as Part of EU Law: Juridification with a Number of Unresolved Legitimacy Concerns?' (2017) 24(2) *Maastricht Journal of European and Comparative Law*, 323-340; Mariolina Eliantonio and Megi Medzmariashvili, 'Hybridity Under Scrutiny: How European Standardization Shakes the Foundations of EU Constitutional and Internal Market Law' (2017) 44(4) *Special issue of the Legal Issues of Economic Integration*.

25 Art. 33 of Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act), OJ L 2023, 2854.

26 Art. 27 of Regulation of the European Parliament and of the Council on horizontal cybersecurity requirements for products with digital elements, OJ L 2024, 2847.

27 The full list of sectors can be found in Annex III. See also Art. 6 AI Act.

28 As well as technical documentation and record-keeping, transparency and the provision of information to deployers, human oversight, and robustness, accuracy and cybersecurity, see Art. 8-27 AI Act.

29 Thus, before the adoption of the AI Act, see European Commission, Implementing Decision on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence, C(2023) 3215 final.

30 See https://www.cencenelec.eu/areas-of-work/cen-cenelec-topics/artificial-intelligence/.

31 European Commission, above n 9.

32 Dermott Jewell, Speech at the first meeting of the High-Level Forum on European standardization, 20 January 2023.

33 See, inter alia, Marion Ho-Dac, 'The EU AI Act and the challenge of protecting fundamental rights' (2025) 62(5) *Common Market Law Review*, 1299 – 1336.

34 Jan M Smits, 'What Is Legal Doctrine? On the Aims and Methods of Legal-Dogmatic Research' in Rob van Gestel, Hans-Wolfgang Micklitz and Edward L Rubin (eds), *Rethinking Legal Scholarship: A Transatlantic Dialogue* (Cambridge University Press 2017), 210.

political, ethical, societal considerations[35] in order to place AI standardisation in its social, economic, political and cultural context,[36] others employ empirical or theoretical methodologies. From this interaction between different perspectives on the topic, the multifaceted and transversal meaning and value of the role of technical standardisation in AI regulation, as well as the risks arising from it, clearly emerge.

12 As highlighted in the contribution of **Elvira Maria Rosaria Oliva**, the role of harmonised standards is particularly crucial in complementing the architecture foreseen for the protection of fundamental rights in the AI Act. In particular, she notes that in the AI Act fundamental rights function not only as legal parameters for harmonised standards, but also as a criterion to categorise AI systems and, consequently, the applicable legal regime. However, the assessment of a possible violation of fundamental rights is necessarily context-specific, which sets the AI Act apart from "the static and quantitative logic"[37] of the traditional product regulation where harmonised standards have traditionally been employed. Furthermore, AI systems may affect a plurality of fundamental rights, requiring a complex balancing exercise. Oliva thus raises doubts as to whether entrusting ESOs with fundamental right compliance respects the limits of the *Meroni* delegation doctrine,[38] especially in light of the limited judicial control over harmonised standards by the CJEU.

13 The vague requirements of the AI Act are difficult to operationalise and thereby pose fundamental "decision problems" not only for ESOs but also for regulatees because they require implementation through value judgments and evidence assessment under conditions of uncertainty, as argued by **Alessio Tartaro, Arvin Obnasca** and **Enrico Panai**. They link this issue specifically to the contestability of several essential requirements of the AI Act and the epistemic dependence this entails. The potential misalignment between the logic of the New Legislative Framework which was conceived for product regulation - where such "decision problems" are of a different nature and of lesser complexity - and the realities of AI governance brings, in their view, the risk of undermining the regulatory effectiveness of the AI Act. They, therefore, propose procedural steps aimed to introduce a body of evidence and argumentation, as part of the relevant technical documentation, "that explicitly demonstrates how the regulatee has identified, analysed, deliberated upon, and resolved the key decision problems pertinent to their specific high-risk AI system in order to meet the Act's essential requirements" [39]

14 The increasing ethical dimension of technical standardisation is also discussed by **Simone Casiraghi** and **Niels van Dijk** who examine the 'ethification' of technical standards and the institutionalisation of ethics through international standardisation on AI, exploring the challenges raised by this development in particular in relation to the Institute of Electrical and Electronics Engineers (IEEE). This examination of the politics of ethical standards in the governance of AI focuses on two elements: first, how ethics change through standardisation and, second, the mutual roles for risk producers, assessors and bearers in the use of ethical standards for governing AI risks. They argue that ethics standards, while they promise to offer a more responsible way to govern AI, transform ethics into an engineering requirement modelled on the procedures, language and logic of operationalisation of standardisation, exacerbating the traditional challenges related to representation, accountability, enforcement and transparency.

15 Finally, as underlined also in the 2022 EU Standardization Strategy,[40] international standardisation of digital technologies - and AI in particular - is currently characterised by complex geopolitical tensions, with competing "digital empires"[41] and other standardisation organizations active in the field. The outcome of these geopolitical frictions in international organisations, such as the International Organisation for Standardisation (ISO) and the Institute of Electrical and Electronics Engineers (IEEE), traditionally more vulnerable to regulatory capture by multinational corporations, will almost inevitably influence - in different ways and to different extents - the implementation of the AI Act in the EU. This dimension is explored in particular in the contribution by **Marta Cantero**, highlighting the role of standards for governing critical infrastructure and the influence of external regulatory dynamics in shaping legal structures. Her analysis of the impact of global (geo-) political dynamics on AI standardisation showcases that reliance on standardisation offers the EU an opportunity for global influence and resilience against changing dynamics, but it also generates a situation of vulnerability as procedural consensus

35 Bruno De Witte, 'Legal Methods for the Study of EU Institutional Practice' (2022) 18(4) *European Constitutional Law Review*, 639-640.

36 Francis Snyder, 'Establishing Law in Context: An Insider's Perspective' (Verfassungsblog, 20 April 2024). See also Agustín J Menéndez, 'The Triumph of EU Law in Context?' (Verfassungsblog, 22 April 2024).

37 Oliva in this special issue.

38 Case C-10/56 *Meroni v High Authority of the European Coal and Steel Community [1958] EU:C:1958:7.*

39 Tartaro et al. in this special issue.

40 European Commission (n 9).

41 Anu Bradford, *Digital Empires* (Oxford University Press 2023).

frequently conceals deep normative and strategic fractures, as well as the existence of a regulatory pacing problem and asymmetric participation in standardisation. Ultimately, this situation raises the question of which kind of legal order can sustain effective regulation in an environment where competing governance models seek to project their norms globally.

IV. The Legitimacy Implications of the Paradigm Shift

16 As a result of the dynamics explored in the above-mentioned contributions to the special issue, it is clear that the role of technical standardisation in AI regulation goes beyond the regulatory setup which was established through the New Approach mechanism, acquiring more complex, multifaceted dimensions which have significant (geo-)political and ethical implications. This, in turn, entails unprecedented challenges for the existing mechanisms of accountability, eventually requiring a re-thinking of the way in which the European Commission and civil society interact with standardisation organisations.

17 In particular, **Mariolina Eliantonio** discusses the mechanisms and intensity of the control of the European Commission over harmonised standards, also in the light of the evolution of the case law and the practice of the European Commission. She argues that the Commission's control over draft standards represents the last crucial "public law check" in the European standardisation process, which the Commission ought to carry out with adequate depth. Going beyond mere rubber-stamping of draft standards prepared by ESOs is, in her view, both allowed and required by the Standardisation Regulation and the legislative setup foreseen by the New Legislative Framework. This control would prevent the transfer of indirect normative power to private actors - a risk all the more relevant in the framework of the AI Act where harmonised standards need to be controlled also for compliance with fundamental rights.

18 In the same perspective of improving the legitimacy of European standardisation activities, **Olia Kanevskaia** instead reflects on the existing instruments for securing that public interest is upheld in European standardisation, addressing the role of civil society and the issue of accessibility of technical standards for the public in this perspective. By discussing two key transparency challenges posed by the New Approach - i.e. access to standardisation processes and access to harmonised standards - the author argues that, although these issues are problematic at the European level, their resolution depends also on national institutions. In this sense, these issues pose compelling questions regarding the interplay between national and European accountability in the broader context of European standardisation policy, as well as the intentions and limits of the regulatory model adopted by the EU for pursuing a strong internal market that is based on the rule of law.

19 These reflections have become even more relevant today in the face of recent developments in the working method of JTC21. In order to accelerate the delivery of harmonised standards to support the AI Act, CEN and CENELEC have decided to allow, in the case of a positive "enquiry vote", direct publication of the drafts without a separate formal vote and to establish a small drafting group, composed of few experts, to finalise some standards.[42] This marks a "non-participatory turn", a stark reduction in transparency and stakeholder involvement compared to earlier standardisation efforts in adjacent regulatory domains, which calls for increased attention to the public and national avenues of control over standardisation processes.

V. Conclusions

20 The adoption of the AI Act represented a watershed moment in the EU governance of emerging technologies. At the heart of this regulatory architecture lies a reliance on technical standardisation that, while promising efficiency and agility, raises profound questions about the role of private actors in shaping public regulatory outcomes. The contributions to this special issue situate these technical instruments within broader ethical, legal, and geopolitical contexts. Whereas this practice is familiar in EU product safety regulation, it takes on new dimensions when applied to technologies with far-reaching implications for fundamental rights, democratic governance, and societal transformation. In particular, the presumption of conformity that the AI Act grants to harmonised standards, whereby compliance with such standards creates a rebuttable presumption of conformity with the Act's legal requirements, effectively delegates norm-setting authority to institutions whose decision-making procedures, composition, and accountability mechanisms differ markedly from those of public legislative and administrative bodies. As such, the standardisation of "risks" to fundamental rights forms an unprecedented delegation the task of protecting constitutional imperatives to private actors,[43] which exacerbates the long-standing issues of European standardisation and creates additional tensions with the EU legal system.

42 See https://www.cencenelec.eu/news-events/news/2025/brief-news/2025-10-23-ai-standardization/

43 See further Ho-Dac (n 33).

21 Still, the reliance on harmonised standards as a core compliance mechanism continues as a well-established trajectory in EU digital regulation, which was most recently reaffirmed in the Union's Data Strategy.[44] The promises of efficiency and agility of standardisation, however, are being concretely tested against the complex reality of AI regulation as a fast-paced and globally contended technology. Having entered into force in August 2024, the AI Act based the implementation of its rules concerning high-risk AI systems on the adoption of the relevant standards by 30 April 2025.[45] Following sensitive delays in the development of these standards by the ESOs, the deadline was first postponed to August 2025[46] and will probably extend into 2026.[47] Even more remarkably, the proposed Digital Omnibus on AI Regulation now puts forward that certain rules governing high-risk AI systems (Chapter III, Sections 1-3) would not enter into force until the Commission has adopted a corresponding decision confirming the existence of adequate support measures for the AI Act.[48] While these recent developments in the implementation of the AI Act confirm the crucial importance of harmonised standards for the functioning of this regulatory architecture, they also show actual limits in the speed and responsiveness to innovation of the current European standardisation ecosystem on which, *inter alia*, the European Commission intends to intervene.[49]

22 Moreover, the urgency in the adoption of these harmonised standards paved the way for worrisome recent changes in the process of standard-setting, in particular the decision to skip or compress certain stages of the standard-setting process,[50] specifically the deliberative ones, *de facto* leaving standard-setting power entirely in the hands of a small group of experts.[51] Shortly afterwards, the international standardisation organisations ISO and IEC decided to turn down the parallel development of two AI-related standards.[52] This development occurs against a backdrop of mounting tensions between European standardisation initiatives and international standard-setting processes, raising questions about regulatory fragmentation, technical interoperability, and the EU's broader aspirations for regulatory influence beyond its borders. Arguably, these issues cannot be divorced from broader geopolitical tensions, which have questions of digital regulation at their core.[53]

23 In the light of this, the aim of this special issue has been to reflect on the multifaceted implications of relying on technical standardisation in the context of the implementation of the AI Act, locating them in a broader context of ethical, legal and geopolitical issues, and examining the avenues for public control over these private activities. By exploring these dynamics, its ambition was to contribute to a broader emerging debate concerning the design and implementation of harmonised standards for AI systems and their intersection with fundamental rights protection, the legitimacy of EU decision-making processes, the trajectories of AI innovation and its limitations, and the contested terrain of European digital sovereignty. When private standardisation bodies develop technical specifications that effectively determine whether AI systems may lawfully process personal data, make

44 Communication from the Commission to the European Parliament and the Council data Union strategy unlocking data for AI, COM/2025/835 final, esp at 12.

45 Commission Implementing Decision of 22.5.2023 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence, C(2023) 3215 final.

46 Commission Implementing Decision of 23.06.2025 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation as regards high-risk AI-systems in support of Regulation (EU) 2024/1689 of the European Parliament and of the Council and repealing Implementing Decision C(2023)3215.

47 As reported in the press: Cynthia Kroet, 'EU standards bodies flag delays to work on AI Act' Euronews Next (16 April 2025) https://www.euronews.com/next/2025/04/16/eu-standards-bodies-flag-delays-to-work-on-ai-act accessed 2 March 2026.

48 Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI), COM/2025/836 final.

49 European Commission, Call for evidence for an evaluation/fitness check, res(2023)5955298.

50 See https://www.cencenelec.eu/news-events/news/2025/brief-news/2025-10-23-ai-standardization/

51 See further on this point, Marta Cantero Gamito, 'From Consensus To Exceptionality – What The EU's AI Standards Crisis Reveals About Delegated Technical Governance', *(REALaw Blog, 28 November 2025).*

52 See https://www.mlex.com/mlex/articles/2403848/eu-ai-standard-setters-pause-of-consensus-process-has-international-fallout.

53 See further European Commission, *'Special Address by President Ursula von der Leyen: World Economic Forum Annual Meeting, Davos'* (Press Corner, European Commission, 19 January 2026) https://ec.europa.eu/commission/presscorner/detail/en/speech_26_150 accessed 2 March 2026 ("This reality also reflects the fact that Europe has all the assets it needs to attract investment – the savings, the skills, and the innovation – with our AI Factories and Gigafactories and the applications that are necessary, the 'AI first› principle. What we need is to mobilise collectively these assets to their full potential. And to focus on the essential. Focal point number one is to create a conducive and predictable regulatory environment".)

decisions affecting access to employment or social services, or shape the information environments within which citizens form opinions and exercise democratic rights, they are not regulating just a technical issue – it becomes a matter of how we want substantive rules to be adopted and the (digital) future of the EU to be shaped.