

# Trustworthy AI Through Standards?

## The Role and the Implications of Harmonised Standards for Fundamental Rights Protection in the AI Act.

by **Elvira M.R. Oliva** \*

**Abstract:** The promotion of trustworthy Artificial Intelligence (AI), ensuring a high level of protection of health, safety, and fundamental rights, is the declared objective of the AI Act. However, since the publication of the proposal by the EU Commission and throughout the entire legislative procedure, the indeterminacy of several key provisions has fuelled the scholarly debate. In this context, the presumption of conformity, enshrined in Article 40 of the AI Act, applicable to high-risk and general-purposes AI models complying with harmonised technical standards (HTS), assumes a pivotal function for providers. While the recourse to harmonised standards is not new in EU law, scholars have emphasized numerous controversial aspects of the process of entrusting the de-

termination of harmonised standards to private bodies, i.e. European Standards Organizations (ESOs). The contribution focuses on the role of harmonised standards for fundamental rights protection, scrutinising their relevance within the broader AI Act architecture specifically for high-risk AI systems. Firstly, it examines the relationship between the risk approach to fundamental rights and harmonised standards. Secondly, it explores the adequacy and the implications of the recourse to HTS in the fundamental rights realm, in light of the delegation doctrine. Ultimately, it argues that HTS are structurally ill-suited to ensure effective fundamental rights protection from AI risks.

**Keywords:** Artificial Intelligence, fundamental rights, AI Act, risk regulation, New Legislative Framework.

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### A. Introduction

1 The summer<sup>1</sup> of Artificial Intelligence (AI) has reignited the debate on the relationship between law and technology, and on whether the law merely reacts to or actively shapes socio-technical changes, with a consequent confrontation between proponents of tech-exceptionalism and defenders of the *Law of Horses*.<sup>2</sup> On this path, recently, various

jurisdictions have entered the race to regulate AI,

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moved to discussing the appropriateness of specific legal initiatives to regulate new technologies. These discussions are split between the literature supporting the risk of a new *Law of Horses* and that reaffirming the necessity to legally tackle the challenges of new technologies, even re-imagining of traditional law categories. See *inter alia*: Natalino Irti, Emanuele Severino *Dialogo su diritto e tecnica* (Laterza 2001); Frank H. Easterbrook, 'Cyberspace and the Law of the Horse' (1996) 1996 University of Chicago Legal Forum 207; Lawrence Lessig, 'The Law of the Horse: What Cyberlaw Might Teach' (1999) 113/2 Harvard Law Review 501; Roger Brownsword, 'Law, innovation and technology: fast forward to 2021' (2021) 13/1 Law, Innovation & Technology 1; Ryan Calo, 'Robotics and the Lessons of Cyberlaw' 103 California Law Review 513.

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1 Youjung Shin, 'The Spring of Artificial Intelligence in its global winter' (2019) 41 IEEE Annals of the History of Computing 71.  
2 The debate has emerged firstly regarding the intricacies of the relationship between law and technology and recently

proposing different legal approaches.<sup>3</sup> Within this context, the European Union (EU) has opted for an *ad hoc* legislative act aimed at fostering a human-centric ecosystem of trust aligned with EU values and principles, while promoting innovation.<sup>4</sup>

2 The EU Regulation (AI Act)<sup>5</sup> lays down harmonised rules for the development, placement on the market, and use of AI systems. From its first recital,<sup>6</sup> the Regulation sets out its dual objective: to ensure secure and trustworthy AI protecting fundamental rights, and to facilitate the effective functioning of the internal market for AI uptake. It thus attempts to combine two foundational pillars of EU law, namely product safety harmonisation and fundamental rights protection,<sup>7</sup> through a risk-based approach:<sup>8</sup> the intensity of the regulatory burden depends on the likelihood and significance of risks posed by the AI system to safety, health, and fundamental rights. Along these lines, the AI Act introduces a layered risk pyramid with corresponding legal regimes: a ban for systems posing unacceptable risks; *ex ante* requirements and *ex post* monitoring obligations for high-risk systems, which constitute the core of the Regulation, minimal duties for the remaining low-risk systems,<sup>9</sup> and a specific regime for most advanced general-purpose AI models.<sup>10</sup> The risk-based approach is not novel in EU law.<sup>11</sup> Even with

different nuances, the most relevant EU legislative initiatives in the digital domain have embraced it to foster innovation while ensuring the protection of fundamental rights. This is the case for the General Data Protection Regulation (GDPR)<sup>12</sup> and the Digital Services Act (DSA).<sup>13</sup>

3 The AI Act follows this route by relying on the most common risk-based regulatory instruments: precautionary tools, risk management and mitigation duties, and post-market measures.<sup>14</sup> Within this regulatory architecture, the concept of risk acquires both a foundational and functional value, serving as an anchor for the framework and guiding the allocation of legal obligations. Notably, the key notion of trustworthiness is defined in terms of the acceptability of risk and is tied to compliance obligations for high-risk AI systems.<sup>15</sup> The Regulation presumes that AI-related risks can be quantified and measured, implying a binary and static relationship between the AI system, as a source of harm, and its effects on three dimensions:

3 Nathalie A. Smuha, 'From a 'Race to AI' to a 'Race to AI Regulation' - Regulatory Competition for Artificial Intelligence' (2021) 13 *Law, Innovation & Technology* 57.

4 European Commission, *On Artificial Intelligence- A European approach to excellence and trust COM (2020) 65 final*.

5 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (AI Act), OJ L 12.07.2024.

6 Recital 1 states that the purpose of the Regulation is "to improve the functioning of the internal market, promoting the uptake of human centric and trustworthy artificial intelligence (AI) while ensuring a high level of protection of health, safety, fundamental rights as enshrined in the Charter of Fundamental Rights of the European Union, including democracy, the rule of law and environmental protection, to protect against the harmful effects of AI systems in the Union, and to support innovation (...)".

7 Marco Almada, Nicolas Petit, 'The EU AI Act: Between the Rock of Product Safety and the Hard Place of Fundamental Rights' (2025) 62 *Common Market Law Review* 85.

8 Recital 26 of the AI Act.

9 Art. 50 of the AI Act.

10 Chapter V of the AI act.

11 Examples come from various sectors: food safety, environmental and financial regulation. See inter alia: Springer, Marian Garcia Martinez, Paul Verbruggen,

Andrew Fearn, 'A. Risk-based approaches to food safety regulation: what role for co-regulation?' (2013) 16/9 *Journal of Risk Research*, 16(9) 1101; Katalin Mérő, 'The ascent and descent of banks' risk-based capital regulation' (2021) 22 *Journal of Bank Regulation* 308.

12 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons concerning the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, GDPR), OJ L119/1. On the notion of risk in GDPR see: Robert Gellert, 'Understanding the notion of risk in the General Data Protection Regulation' (2018) 34 *Computer Law & Security Review* 279.

13 Art. 34 of DSA defines the methodology and timing to perform risk assessment, specifically considering any actual or foreseeable negative effects for the exercise of fundamental rights, in particular to human dignity, to respect for private and family life, to the protection of personal data, to freedom of expression and information, including the freedom and pluralism of the media, to non-discrimination, to respect for the rights of the child and to a high-level of consumer protection, as enshrined in the Charter of fundamental rights. Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market for Digital Services and amending Directive 2000/31/EC (Digital Services Act, DSA), OJ L 277.

14 Margot Kaminski, 'Regulating the risks of AI' (2023) 103 *Boston University Law Review* 1347.

15 Recital 123: "In order to ensure a high level of trustworthiness of high-risk AI systems, those systems should be subject to a conformity assessment prior to their placing on the market or putting into service". See: Johann Laux, Sandra Wachter, Brent Mittelstadt, 'Trustworthy artificial intelligence and the European Union AI act: On the conflation of trustworthiness and acceptability of risk' (2024) 18/1 *Regulation & Governance* 3.

health, safety, and fundamental rights. Accordingly, the classification of an AI system in the diverse risk categories depends on its impact on health and safety, as in the typical product safety legislation<sup>16</sup> with, in addition, fundamental rights. In this context, fundamental rights protection is not only a legal parameter but also a rationale for pre-categorising the AI systems use cases<sup>17</sup> and, determining the applicable legal regime. Unlike other EU's digital regulation, such as the GDPR and the DSA, tailored to the protection of specific rights, respectively the right to data protection<sup>18</sup> and freedom of expression and of information,<sup>19</sup> the AI Act aims to safeguard all fundamental rights at stake, reflecting the diverse AI use cases it encompasses.

- 4 This comprehensive ambition is challenged by a continuously evolving material scope. During the legislative procedure, the release of ChatGPT<sup>20</sup> has prompted the introduction of an additional category to address the systemic risks<sup>21</sup> stemming from the most powerful and promising general-purpose AI systems. To bridge future potential gaps between the rapidity of technological development and the

slower pace of legislative update,<sup>22</sup> the Regulation has been designed to ensure both legal certainty and flexibility to face emerging AI models and use cases.<sup>23</sup> To this aim, the AI Act relies on soft law<sup>24</sup> and hybrid regulatory tools, such as Harmonised Technical Standards (HTS),<sup>25</sup> particularly relevant in high-risk AI systems where potential threats to fundamental rights have already emerged or are supposed to occur in the short term.<sup>26</sup> In these cases, the Regulation stipulates a continuous, lifecycle-wide risk management process aimed at preventing or minimising the relevant risks to health, safety and fundamental rights.<sup>27</sup> Specifically, it sets out requirements to be ensured by design, together with procedural obligations in terms of registration and documentation before the placement into market/use of the system. The technical translation of the *ex ante* requirements<sup>28</sup> is delegated to European Standardisation Organisations (ESOs) through HTS, adherence to which grants a presumption of conformity, as enshrined in Article 40. In particular, the HTS are expected to define detailed specifications for the management and mitigation of risks to health, safety, and fundamental rights.

- 5 While the recourse to HTS as a driver for internal market harmonisation is well-established and its legal challenges have been relevantly investigated,<sup>29</sup> its use in the realm of fundamental rights is a novelty, which revamps the traditional legal concerns raised by HTS with new nuances. In particular, the essence

16 In the Product Safety Regulation a safe product is defined as: “any product which, under normal or reasonably foreseeable conditions of use, including the actual duration of use, does not present any risk or only the minimum risks compatible with the product’s use, considered acceptable and consistent with a high level of protection of the health and safety of consumers” according to art. 3 (2), Regulation (EU) 2023/988 of the European Parliament and of the Council 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC, OJ L 135.

17 The categories of risk are defined in the Regulation, following a top-down approach. For a comparison with the bottom-up approach in GDPR and the mixed approach in DSA see: Giovanni De Gregorio, Pietro Dunn, ‘The European Risk-Based Approaches: Connecting Constitutional Dots in the Digital Age’ (2022) 59 *Common Market Law Review* 473.

18 Recital 1 of the GDPR.

19 Recital 3 of the DSA.

20 The release of ChatGPT on 30th November 2022 disrupted the discussion on the AI Act, which initially did not cover foundational models and general-purpose AI systems in its material scope. Consequently the co-legislators modified the text including general-purposes AI systems in Art. 3 (63): “AI systems based on a model trained with a large amount of data using self-supervision at scale, that displays significant generality and is capable of competently performing a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of downstream systems or applications”.

21 Art. 3 (65) of the AI Act.

22 Gary E. Marchant, Braden E. Allenby, Joseph R. Herkert (eds.), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight* (Springer 2011).

23 Stefan Larsson, Jockum Hildén, Kasia Söderlund, ‘Implications of Regulating a Moving Target: Between Fixity and Flexibility in the EU AI Act’ <<https://ssrn.com/abstract=5211101>> accessed 18.04.2025.

24 Art. 96 of the AI Act on the guidelines to be issued by EU Commission.

25 Art. 3 (27) of the AI Act.

26 The list of high-risk systems refers both to systems integrated as part of products already in the scope of harmonised legislation (ANNEX I) and to stand-alone systems (ANNEX III) of the AI Act.

27 Art. 9 mandates the establishment of a risk management system to be implemented, documented and maintained. It is based on processes and testing procedures. See Jonas Schuett, ‘Risk Management in the Artificial Intelligence Act’ (2024) 15 *European Journal of Risk Regulation* 367.

28 Chapter III, Section 2 of the AI Act.

29 Harm Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Hart 2005); Mariolina Eliantonio, Caroline Cauffman, ‘The Legitimacy of Standardisation as a Regulatory Technique in the EU – A Cross-disciplinary and Multi-level Analysis: An Introduction’ in Mariolina Eliantonio, Caroline Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique* (Edward Elgar Publishing 2020).

of fundamental rights<sup>30</sup> requires context-specific assessments to verify if its exercise is impaired by an interference without legitimate reasons;<sup>31</sup> thus, it escapes from the static and quantitative logic<sup>32</sup> of the traditional product standardisation procedure. High-risk AI systems may affect a plurality of fundamental rights, thereby giving rise to complex normative questions, which necessitate a balancing of rights and interests at stake.<sup>33</sup> In this line, the entrusting to ESOs of such delicate task may challenge the boundaries of the delegation doctrine.

- 6 Against the backdrop of these introductory remarks, the contribution asks whether Harmonised Standards (HTS), as envisioned in the EU AI Act, are suitable tools for managing risks to fundamental rights. To answer this question, it proceeds as follows: section B examines the role of HTS within the broader architecture of the AI Regulation, focusing on their intended function in managing high-risk

to fundamental rights; section C critically assesses the main legal challenges stemming from HTS when dealing with fundamental rights. The challenges will be examined through the delegation doctrine lens and will underscore the limits, and the prospects of the potential compensatory mechanisms envisaged in the AI Act, namely common specifications and the Fundamental Rights Impact Assessment (FRIA), drawing on Court of Justice of the European Union (CJEU) case law and legal doctrine. The conclusions summarize the key findings and propose a potential pathway.

## B. Embedding Fundamental Rights Dimension Into Technical Norms? The Role of Harmonised Standards in the AI Act

- 7 The AI Act reliance on HTS follows a well-established path of EU Legislation, started in the mid-80s, with the New Approach,<sup>34</sup> and refined through the New Legislative Framework (NLF)<sup>35</sup> aimed at harmonising the EU internal market products and enhancing legislative efficiency, establishing a common framework of general principles to approximate products' legislation. Normatively, the NLF complements the traditional top-down legislative approach with alternative regulatory and non-regulatory tools,<sup>36</sup> precisely self- and co-regulation,<sup>37</sup> to govern complex societal and

30 The concept of *essence* has been set out in the Article 52(1) of Fundamental Rights of the European Union, as a condition to be fulfilled to justify any limitation of a fundamental right. According to the CJEU case law, the essence of fundamental rights refers to its “very substance.” Broadly, it implies that any limitation to one of the fundamental rights enshrined in the Charter which does not respect its essence should be considered unlawful, without regard of the possible general interest pursued by the limitation. In this vein, it requires the consideration of the normative elements of each fundamental right at stake together with the characteristics of the case. On the issue see *inter alia*: Koen Lenaerts, ‘Limits on Limitations: The Essence of Fundamental Rights in the EU’ (2019) 20 German Law Journal 779; Maja Brkan, ‘The Concept of Essence of Fundamental Rights in the EU Legal Order: Peeling the Onion to its Core’ (2018) 14/2 European Constitutional Law 339; Tuomas Ojanen, ‘Making the Essence of Fundamental Rights Real: The Court of Justice of the European Union Clarifies the Structure of Fundamental Rights under the Charter: ECJ 6 October 2015, Case C-362/14, Maximilian Schrems v Data Protection Commissioner’ (2016) 12 European Constitutional Law Review 318.

31 The protection of the *essence* of a fundamental right requires an evaluation which differs from the proportionality test. More precisely “proportionality begins where essence stops”: see Takis Tridimas and Giulia Gentile, ‘The Essence of Rights: An Unreliable Boundary?’ (2019) 20 German Law Journal 794, 803.

32 On the attempt to quantitatively measure fundamental rights with a proportionality lens see: Giovanni Sartor, ‘The Logic of Proportionality: Reasoning with Non-Numerical Magnitudes’ (2013) 14/8 German Law Journal 1419.

33 In this context, the balancing exercise should be considered as the *ad hoc* activity to solve potential conflicts arising when at least one fundamental right enshrined in the Charter of Fundamental Rights is competing either with a public interest or with another fundamental right. See *inter alia*: Matthias Klatt and Moritz Meister, *The Constitutional Structure of Proportionality* (Oxford University Press 2012).

34 Council Resolution 85/C 136/01 of 7 May 1985 on a new approach to technical harmonisation and standards. OJ C 136, 4.6.1985, p. 1–9.

35 Regulation (EC) 765/2008 setting out the requirements for accreditation and the market surveillance of products; Decision 768/2008 on a common framework for the marketing of products, which includes reference provisions to incorporate in product legislation revisions; Regulation (EU) 2019/1020 on market surveillance and compliance of product, OJ L 169, 25.6.2019, p. 1–44.

36 Better Regulation Toolbox, July 2023 ed. <[https://commission.europa.eu/document/download/9c8d2189-8abd-4f29-84e9-abc843cc68e0\\_en?filename=BR%20toolbox%20-%20Jul%202023%20-%20FINAL.pdf](https://commission.europa.eu/document/download/9c8d2189-8abd-4f29-84e9-abc843cc68e0_en?filename=BR%20toolbox%20-%20Jul%202023%20-%20FINAL.pdf)> accessed 12.11.2024.

37 “Co-regulation means the mechanism whereby a community legislative act entrusts the attainment of the objectives defined by the legislative authority to parties which are recognised in the field (such as economic operators, the social partners, non-governmental organisations, or associations). Self-regulation is defined as the possibility for economic operators, the social partners, non-governmental organisations, or associations to adopt amongst themselves and for themselves common guidelines at the European level (particularly codes of practice or sectoral agreements).” Interinstitutional agreement on better law-making, OJ C 321, 31.12.2003.

technological changes, as framed within the Better Regulation agenda.<sup>38</sup> The consequent shift from the traditional “command and control” model<sup>39</sup> to more decentralised governance forms<sup>40</sup> has opened the regulatory space to private and non-institutional actors, such as European Standardisation Organisations (ESOs).<sup>41</sup>

- 8 Broadly, the NLF seeks to preserve the binding nature of legislation while allowing for flexible implementation, thereby accelerating market harmonisation and boosting innovation.<sup>42</sup> In this respect, it aligns with the same challenges prompting the recourse to risk regulation, relying on technocratic approaches to enhance regulatory efficiency, objectivity, and fairness for businesses.<sup>43</sup> Accordingly, in principle, the integration of a risk-based approach with the implementation toolkit provided by NLF seems particularly well-suited to regulate a highly technical and constantly evolving domain like AI, especially from an internal market perspective.<sup>44</sup>

- 9 The AI Act explicitly embraces the NLF<sup>45</sup> and refers to its catalogue of self and co-regulation tools for implementation,<sup>46</sup> considering HTS as a key compliance mechanism<sup>47</sup> for managing high risks to health, safety, and fundamental rights. Specifically, the adherence to HTS enables providers to conduct a conformity assessment based on internal controls, without involving external actors.<sup>48</sup> Alternatively, the providers may opt for third-party assessments, which are more costly and resource demanding. It is therefore reasonable to expect that providers of high-risk systems will prefer HTS to manage risks to fundamental rights, leveraging the simplified compliance mechanism. As confirmed by CJEU case law, HTS are *de jure* voluntary, but *de facto* mandatory.<sup>49</sup> This quasi-obligatory nature underscores their significance within the AI Act’s compliance architecture, especially considering their novel function in operationalising management of risks to fundamental rights.<sup>50</sup> However, despite this heightened importance, an analysis of Article 40 and the Commission’s Standardisation Request<sup>51</sup> reveals that AI HTS are expected to follow the traditional path of product technical standardisation, without specific adaptations to the fundamental rights’ domain.

38 Starting with Better Regulation for Growth and Jobs in the European Union, COM (2005) 97 final, Brussels, 16.3.2005.

39 Robert Baldwin, Martin Cave, Martin Lodge (eds) *Understanding Regulation - Theory, Strategy and Practice* (Oxford, 1999).

40 Julia Black, ‘Decentring Regulation: Understanding the Role of Regulation and Self-regulation in a ‘Post-regulatory’ World’ (2001) 54/1 *Current Legal Problems* 121.

41 CEN, CENELEC, ETSI, in Annex I Regulation (EU) 1025/2012 Regulation 1025/2012 of the European Parliament and of the Council 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 (Standardisation Regulation) OJ L 316.

42 Better Regulation Toolbox, July 2023 ed. <[https://commission.europa.eu/law/law-making-process/better-regulation/better-regulation-guidelines-and-toolbox/better-regulation-toolbox\\_en](https://commission.europa.eu/law/law-making-process/better-regulation/better-regulation-guidelines-and-toolbox/better-regulation-toolbox_en)> accessed 04.05.2025.

43 Bridget Hutter, ‘A risk regulation perspective on regulatory excellence’ in Cary Coglianese (ed.), *Achieving Regulatory Excellence* (Brookings Institution Press, 2017) 101.

44 The legal basis of the AI Act is the Article 114 TFEU used “to prevent the occurrence of these obstacles resulting from diverging national laws and approaches how to address the legal uncertainties and gaps in the existing legal frameworks applicable to AI (..) The new initiative will aim to address that problem by proposing harmonised technical standards for the implementation of common requirements applicable to the design and development of certain AI systems before they are placed on the market (...)in addition, considering that this Regulation contains certain specific rules, unrelated to the functioning of the internal market, restricting the use of AI systems for ‘real-time’

remote biometric identification by the law enforcement authorities of the Member States, which necessarily limits the processing of biometric data by those authorities, it is appropriate to base this Regulation, in as far as those specific rules are concerned, on Article 16 of the Treaty.” European Commission, Impact Assessment accompanying the Proposal for a Regulation laying down harmonised rules on Artificial Intelligence, SWD (2021) 84 final, p. 31.

45 The reference to New Legislative Framework appears both in reference to general structure of AI Act, see Recital 9, and related to specific provisions on high-risk AI systems, see Recitals 46, 64, 83, 84, 87, 124.

46 Art.56 introduces the Code of practices for providers of general-purpose AI models, drawn up by providers, national authorities with other stakeholders supporting the process. Art. 95 refers to codes of conduct to foster voluntary application of requirements established for high-risk cases for minimal risk systems.

47 Recital 121 of the AI Act.

48 Art. 43 of the AI Act.

49 Case C-171/11 *Fra.Bo SpA v DVGW* (2012) EU:C:2012:453, paras 27 to 32.

50 Josep Soler Garrido, Sarah De Nigris, Elias Bassani, Ignacio Sanchez, Tatjana Evas, André Antoine-Alexandre, Thierry Boulangé, ‘Harmonised Standards for the European AI Act’ (2024) JRC139430.

51 European Commission Implementing Decision C (2023) 3215 final. The decision has been repealed by the European Commission Implementing Decision C (2025) 3871 final which adjusts the timeline while maintain the content of the Request from Commission to CEN and CENELEC.

10 Although Article 40 underwent amendments during the legislative procedure, its core structure remains aligned with the traditional HTS framework, as in the original Commission proposal.<sup>52</sup> Firstly, the final version of the Article expands its material scope to the general-purpose AI models,<sup>53</sup> in addition to high-risk systems as initially foreseen, consistently with the inclusion of such systems in the scope of the Regulation. Secondly, as proposed both in Council and EU Parliament amendments,<sup>54</sup> a reference to appropriate stakeholders' participation has been added, without, however, introducing new binding requirements for the AI standardisation process beyond the provisions already established in Regulation (EU) 1025/2012.<sup>55</sup> While an *ad hoc* AI Task Group on inclusiveness has been launched to raise awareness and bring new stakeholders to the discussions within the ESOs, the effort remains within the spirit and the letter of the existing Regulation,<sup>56</sup> thus not formally enhance participation of the new actors.<sup>57</sup> Importantly, the final version of Article 40(3) emphasises that HTS must be consistent with

Union values, fundamental rights, and interests, also related to international cooperation. Crucially, HTS are not merely expected to consider EU values, but they must operationalise management and mitigation of risk to fundamental rights, alongside health and safety.

11 This expectation is clearer in the Request<sup>58</sup> to CEN and CENELEC,<sup>59</sup> issued by Commission in May 2023, during the AI Act legislative procedure. The two ESOs have been tasked with drafting the first set of HTS, which should reflect the generally acknowledged state of the art to prevent and minimise risks to health, safety, and fundamental rights, as guaranteed in the Charter of Fundamental Rights and in relevant EU law, to cover the requirements established in the Regulation. Nevertheless, in the case of fundamental rights, the operationalisation of requirements not only deals with technical specifications, but it also implies guidance on complex rights-related normative issues.<sup>60</sup> A non-exhaustive but immediate sample is offered by the data set requirements: the AI Act mandates the detection, prevention, and mitigation of potential biases of data that could have an adverse impact on fundamental rights.<sup>61</sup> In particular, the quality and the representativeness of datasets used for AI systems training and validation could affect rights to privacy as well as non-discrimination, and, depending on the context of use, further fundamental rights and interests.<sup>62</sup> In this line, ESOs are tasked with providing orientation to navigate the complex balancing of fundamental rights required when two or more rights and interests are at stake. It could be contended that HTS merely perform a procedural operationalization of rights, standardizing risk management methodologies. However, when an HTS establishes the acceptable threshold for risk to fundamental rights, it is not

52 In the Commission proposal, Article 40: "High-risk AI systems which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements set out in Chapter 2 of this Title, to the extent those standards cover those requirements." 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.

53 See n 19.

54 In the Council's proposal: enhance multistakeholder governance, representative of all relevant European stakeholders (e.g. industry, SMEs, civil society, researchers) Council, General Approach 14336/22 25.11.2022; in the Parliament's amendment: a balanced representation of interests and effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of the Standardisation Regulation. European Parliament, Negotiation Position, P9\_TA (2023)0236 14.06.2023.

55 See n 40.

56 Art. 3 of the Standardisation Regulation.

57 Art. 5 of the Standardisation Regulation, which has been amended in 2023 introducing limited changes in the standardisation process, specifically to reinforce national organizations' role and to require the publication of the deliverables plans from the ESOs. Despite the numerous concerns highlighted by doctrine and related to CJEU's case law, the legislative changes have not yet solved either transparency or accountability shortcomings, with no mandatory participation for enhancing civil society representativeness. See: Annalisa Volpato, Mariolina Eliantonio, 'The participation of civil society in ETSI from the perspective of throughput legitimacy' (2024) 37/5 Innovation: The European Journal of Social Science Research 1375.

58 See Annex II, point 2 of the Implementing decision (n 51)

59 On ETSI's exclusion see: Marta Cantero Gamito, 'The Role of ETSI in the EU's Regulation and Governance of Artificial Intelligence' (2024) Innovation: The European Journal of Social Science Research, available at SSRN <<http://dx.doi.org/10.2139/ssrn.4770324>> accessed 22.04.2025.

60 Johann Laux, Sandra Wachter and Brent Mittelstadt, 'Three Pathways for Standardisation and Ethical Disclosure by Default under the European Union Artificial Intelligence Act' (2024) 53 Computer Law & Security Review.

61 Art. 10 of the AI Act.

62 See *inter alia*: Raphaelae Xenidis, 'When Computers Say No: Towards a Legal Response to Algorithmic Discrimination in Europe' in Bartosk Brożek, Przemyslaw Palka, Olga Kanevskaia (eds), *Research Handbook on Law and Technology* (Edward Elgar Publishing 2024), 222; Keith Sonderling, Aram Gavoor, 'A New Approach to Measuring AI Bias in Human Resources Functions: Model Risk Management' (2023) 54/4 Seton Hall Law Review 965; Uwe Peters, 'Algorithmic Political Bias in Artificial Intelligence Systems' (2022) 35/2 Philosophy & Technology.

merely performing procedural task, it is engaging in a substantive balancing of rights, which goes beyond a pure technical translation of legislative requirements

- 12 Finally, it should be noted that during the AI Act legislative process, the Commission has released a new EU Standardisation Strategy,<sup>63</sup> which recognises the essential role of standards for the internal market and EU competitiveness, particularly at the international level, while highlighting its participation and transparency shortcomings. Interestingly, the new Strategy acknowledges that standards deal not only with technical components but also incorporate and promote EU core values and interests. As a matter of fact, with the new Strategy, the Commission confirms that technicalities cannot be separated from normative values,<sup>64</sup> which is particularly evident in legislative acts like the AI Act, where HTS are expected to define methods to ensure a proper fundamental rights protection from current and potential harms posed by high-risk AI systems, in addition to their traditional function for the internal market harmonisation.
- 13 This section has highlighted the pivotal role assigned by the AI Act to HTS in managing and mitigating risks to fundamental rights to ensure conformity of high-risk systems, recently confirmed by the Commission proposal for a postponement of high-risk implementation timeline linked to the availability of HTS.<sup>65</sup> While embedding the rights-based dimension into the standardisation process constitutes a novelty, it remains situated within the traditional product standardisation framework. The analysis of Article 40, read in conjunction with the Standardisation Request, suggests that AI HTS for fundamental rights would not depart from the existing regimes established for traditional product-related HTS.

63 An EU Strategy on Standardisation Setting global standards in support of a resilient, green, and digital EU single market, COM (2022) 31 final, specifically on the promotion of EU values see p.4.

64 On the difficulties and implications to separate 'technical' from 'value-laden' considerations in HTS see Schepel (n 27), 255.

65 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.

## C. Legal Challenges of Harmonised Standards in the Management of Risks to Fundamental Rights

- 14 The reliance on HTS as a tool to operationalise fundamental rights protection in the management of risks posed by high-risk AI systems raises acute legal concerns, stemming from value-laden and normative judgments required, which ought to be assessed through the lens of the EU's delegation doctrine.
- 15 Since the landmark *Meroni* ruling,<sup>66</sup> the CJEU has recognised that executive powers may be delegated by the entitled institutions to private third parties only under specific and strict conditions, within the limits settled in the Treaties.<sup>67</sup> Particularly, it has been established the requirements for both a clear executive mandate, according to objective and precise criteria, and a strict oversight by the delegating institution, to prevent the exercise of a discretionary power<sup>68</sup> and the consequent shift of responsibilities towards delegated subjects, which would undermine the principle of institutional balance.<sup>69</sup> The CJEU has reaffirmed this reasoning, with a non-formalistic approach, in the *ESMA* case,<sup>70</sup> allowing a broader delegation to public Union bodies, offices or agencies, provided that judicial review mechanisms are in place,<sup>71</sup> the delegated entities possess the necessary technical expertise,<sup>72</sup> and a detailed delineation of the powers is well established.<sup>73</sup> The possibility of entrusting<sup>74</sup> power

66 Case C-10/56 *Meroni v High Authority of the European Coal and Steel Community* (1958), EU:C:1958:7.

67 *ibid*, para 173.

68 For an analysis of the relevance and the implications of the definition of discretionary power in the case law see Joana Mendes, 'Law, Public Interest and Interpretation: Prolegomena of a Normative Framework on Administrative Discretion in the EU' (2014) 519 *Yale Law & Economics Research Paper*.

69 Maria Patrin 'Meroni behind the scenes: uncovering the actors and context of a landmark judgement' (2021) 6/1 *European Papers* 539.

70 Case C- 270/12 *UK v European Parliament and Council of the European Union* (2014) EU:C:2014:18.

71 *ibid*, para 80.

72 *ibid*, paras 82 and 105.

73 *ibid*, para 51.

74 It should be noted that the Court relates to an entrusting process, avoiding the word «delegation», see Case C-613/14 *James Elliott Construction Limited v. Irish Asphalt Limited* (2016) EU:C:2016:821, para 43. Differently, the Advocate General expressly refers to a legislative «controlled delegation» to private organisations, see Case C-613/14 *James Elliott Construction Limited v. Irish Asphalt Limited* (2016) EU:C:2016:63, Opinion of A.G. Bordona, para. 55.

to private third parties has been expanded with the seminal *James Elliott* case,<sup>75</sup> a preliminary ruling where the Court has established its interpretive jurisdiction on HTS, stating that, once referenced in the Official Journal by the Commission, HTS form part of EU law with legal effects, since compliance with such standards grants a presumption of conformity with essential requirements of the legislative act originating the delegation.<sup>76</sup> Within this framework, it could be inferred that ESOs must operate under a clear mandate and the standardisation process must be subject to a strict control by the Commission to avoid an unlawful transfer of power, as prohibited by the *Meroni* doctrine, in addition to a judicial reviewability and the professional expertise, as established in *ESMA* case, here recalled by analogy. Against this backdrop, the next paragraphs will examine whether the use of HTS for management of AI risks to fundamental rights comply with these requirements.

- 16 In the context of the AI Act, the EU Commission Standardisation Request issued pursuant Article 40 can be interpreted as the act of entrustment. Nonetheless, the compliance with the delegation doctrine's requirement for a clear and precise mandate is highly contestable, particularly with respect to fundamental rights, given the vague wording employed in both the Standardisation Request and the Regulation. Indeed, the AI Act broadly and generically refers to fundamental rights,<sup>77</sup> but fails to clarify criteria and procedures to assess and mitigate risk to fundamental rights, thus a clear guidance to be operationalised by HTS is lacking.<sup>78</sup> The only identifiable criteria emerge in relation to the future possibility to amend the Annex on high-risk AI systems list,<sup>79</sup> recalling the approach followed by Commission in its proposal.<sup>80</sup>

75 *ibid.*

76 *ibid.*, para 40.

77 The reference to "fundamental rights" occurs 103 times: 56 in the Recitals, 47 in the Articles.

78 Alessandro Mantelero 'The AI Act: a realpolitik compromise and the need to look forward in Digital Constitutionalism' (2025) *Nomos* 311.

79 Art. 7 (2) of the AI Act.

80 "These criteria include: a) the extent to which an AI system has been used or is about to be used; b) the extent to which an AI system has caused any of the harms referred to above or has given rise to significant concerns around their materialization; c) the extent of the adverse impact of the harm; d) the potential of the AI system to scale and adversely impact a plurality of persons or entire groups of persons; e) the possibility that an AI system may generate more than one of the harms referred to above; f) the extent to which potentially adversely impacted persons are dependent on the outcome produced by an AI system, for instance their ability to opt-out of the use of such an AI system; g) the extent to which potentially adversely

Moreover, apart from the recitals,<sup>81</sup> the Regulation does not define which specific rights are at risk and how they should be protected in the diverse high-risk scenarios.

- 17 Article 40(3) calls for consistency of HTS with Union values and fundamental rights, as a legal parameter, without detailing the requirements to technically translate fundamental rights protection. Similarly, the Standardisation Request reiterates the importance of compliance with fundamental rights and EU Charter values, again, with no further details, leaving the mandate unclear.<sup>82</sup> This vagueness is critical not only from a delegation perspective, but even under NLF, whose legislative framework prescribes that legislative provisions must be worded with sufficient clarity and precision to establish legally binding obligations,<sup>83</sup> to ensure that the technical specifications developed by standardisation bodies remain within the boundaries of the legislative mandate and do not result in the exercise of normative and political discretion by private actors.<sup>84</sup> Importantly, the determination of methods for establishing thresholds of acceptable risk to fundamental rights<sup>85</sup> is not merely a technical or procedural exercise but a normative task that inherently involves value-based judgment, which requires a clearer mandate to comply with *Meroni* doctrine.
- 18 It may be argued that the Standardisation Request and the Regulation's vagueness could be mitigated by a rigorous control mechanism implemented by the Commission during the standardization process

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impacted persons are in a vulnerable position vis-à-vis the user of an AI system; h) the extent to which the outcome produced by an AI system is reversible; i) the availability and effectiveness of legal remedies; j) the extent to which existing Union legislation is able to prevent or substantially minimize the risks potentially produced by an AI system". Impact Assessment (n 43), p.50.

81 See Recital 48-62 of the AI Act. On the limits of recitals: Maarten Den Heijer, Teun Van Os Van Den Abeelen and Antanina Maslyka, 'On the Use and Misuse of Recitals in European Union Law' (2019) 31 *Amsterdam Law School Research Paper*.

82 While the standardisation process is still in progress, from the public documentation it can be derived that the operationalisation of fundamental rights dimension could be absorbed in the main HTS related to AI Risk Management and Trustworthiness Framework, instead of treated in a specific item, as originally foreseen.

83 Recital 11 Decision 768/2008 (n 34).

84 European Commission, *Vademecum on European Standardisation – Part I*, SWD (2015) 205, 8-9.

85 See: AI Risk Management, prEN 18228, [https://standards.cencenelec.eu/dyn/www/f?p=205:110:0:::FSP\\_PROJECT,FSP\\_LANG\\_ID:79438,25&cs=1CB88DD3F349909A6F65743B3FBFF0992](https://standards.cencenelec.eu/dyn/www/f?p=205:110:0:::FSP_PROJECT,FSP_LANG_ID:79438,25&cs=1CB88DD3F349909A6F65743B3FBFF0992) accessed 19.07.2025.

and before the publication of the references in the Official Journal, which would involve conducting the compliance assessment.<sup>86</sup> It is worth noting that the Request allows the Commission to monitor project plans and assess the deliverables for consistency with fundamental rights and data protection laws, accounting for both common horizontal risks and potentially vertically specific standards related to intended purposes and/or context uses of AI high-risk systems.<sup>87</sup> However, while formally this complies with the requirement of the delegation doctrine, the substantial effectiveness of the oversight could be limited by the lack of the technical capacity to navigate complex AI standards.<sup>88</sup>

19 Under these circumstances, the concerns of tasking ESOs with guidance on fundamental rights are further amplified given that high-risk AI systems engage diverse fundamental rights and interests, intersecting or even conflicting,<sup>89</sup> both at individual and societal levels.<sup>90</sup> When diverse fundamental rights are at stake, the establishment of compliance pathways implies indications on a delicate balancing exercise governed by the principle of proportionality. As enshrined in the EU Charter of Fundamental Rights<sup>91</sup> and constantly emphasised in the CJEU case law,<sup>92</sup> any potential limitations on fundamental rights require a well-defined scope of the measures providing for an interference and the conditions of their applicability. Specifically, in the case of the AI systems, the balancing would need to account not only for individual fundamental rights but also for broader public interests<sup>93</sup> and economic freedom of providers to conduct business and their legitimate expectations to market access when adhering to HTS.<sup>94</sup>

20 Drawing a parallel with data protection law, where such balancing is established, may serve to

underscore the flaw in the AI Act. Under GDPR, where a data processing is likely to result in a high risk to the rights and freedoms of natural persons, the controller shall perform a data protection impact assessment (DPIA):<sup>95</sup> an *ex ante* evaluation containing, *inter alia*, an analysis of the necessity and proportionality of the operations, including the legitimate interest pursued and the risks to rights for data subjects, considering the scope, the context and the purpose of the activity, together with mitigation measures. Significantly, the DPIA is grounded in the principle of accountability,<sup>96</sup> establishing the discretion of the regulated subjects within a clear legal framework. In this context, an operational guidance on balancing methodologies is offered by *ad hoc* Guidelines adopted by Data Protection Authorities, which provide interpretative direction within a clearly define mandate.<sup>97</sup> Conversely, under the AI Act, the task of defining balancing methodology<sup>98</sup> is instead entrusted to the ESOs, private third parties, through HTS, which, once referenced in the Official Journal, grant the presumption of conformity for management of risks to fundamental rights. This divergence is relevant when assessing the procedural rather than the substantive nature of HTS. Far from serving as guidance, HTS are expected to serve as a compliance tool through which high-risk AI systems demonstrate conformity with the AI Act, thus entering into the EU market.<sup>99</sup>

86 Vademecum (n 84), p. 26-27.

87 Annex II, point 1 of the Implementing Decision. It should be noted that, in its latest Request, the Commission requests a report from ESOs every three months, instead of six months established in the previous one. (n 51).

88 Megi Medzmariashvili, 'Delegation of Rulemaking Power to European Standards Organizations: Reconsidered' (2017) 44 *Legal Issues of Economic Integration* 353, 361.

89 See Impact Assessment accompanying the proposal of Regulation, SWD (2021) 84 final, point 5.5.

90 Confirmed in the scope of AI Risk Management HTS (n 85).

91 Art. 52 (1) of the Charter of Fundamental Rights.

92 C-817/19 *Ligue de droits* (2022) EU:C:2022:65, Opinion of A.G Pitruzzella, paras 85-88 and cited case-law.

93 Article 5 of the Convention 108+ ; Case C-470/21 *La Quadrature du Net* (2024) EU:C:2024:370, para 130.

94 The European Court of Human Rights has repeatedly intervened on the issue, see *inter alia*: *Roman Zakharov, v Russia* App no. 47143/06 (ECHR, 4 December 2015); *Malone v UK* Application App no. 8691/79 (ECHR, 2 August 1984).

95 Art. 35 of GDPR.

96 Art. 5(2) of GDPR. See *inter alia*: Tuulia, Karjalainen, 'All talk, no action? The effect of GDPR Accountability Principle on the EU Data Protection paradigm' (2022) 8(1) *European Data Protection Law Review*, 19.

97 See Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is "likely to result in a high risk" for the purposes of Regulation 2016/679, WP 248 rev.01, adopted 4 April 2017 by Article 29 Working Party Data Protection.

98 See the description of the HTS on AI Risk Management stating that 'Risks covered include both risks to health and safety and risks to fundamental rights which can arise from AI systems, with impact for individuals, organisations, market and society. This document also defines methods that can be used to determine if a package of risk management measures associated with an AI system will be able to ensure that certain risks arising from that product or system are identified, monitored, and managed, leading to an acceptable level of risk.' Available at: [https://standards.cencenelec.eu/ords/f?p=205:110:::::FSP\\_PROJECT,FSP\\_LANG\\_ID:79438,25&cs=126AEABA70EBCF2433A6A5472A8FD6F84](https://standards.cencenelec.eu/ords/f?p=205:110:::::FSP_PROJECT,FSP_LANG_ID:79438,25&cs=126AEABA70EBCF2433A6A5472A8FD6F84) accessed 14.01.2026.

99 Marion Ho-Dac, 'Considering fundamental rights in the European Standardisation of artificial intelligence: nonsense or strategic alliance?' in Kai Jacobs (ed) *Joint Proceedings EURAS & SIIT 2023* (Verlag Gunter Mainz 2023)

21 Finally, in line with the need for expertise recalled in *ESMA*, the limited competences of ESOs in the fundamental rights domain should be highlighted, as acknowledged by the Commission itself,<sup>100</sup> in combination with the time and resources required to provide the contextual and proportionality-based guidance that fundamental rights protection requires. In this regard, the recent Memorandum of Understanding between ESOs and the European Union Agency for Fundamental Rights (FRA)<sup>101</sup> represents a significant step aimed at introducing fundamental rights expertise into HTS drafting process. While such initiative should be welcomed, both as a partial corrective to the overrepresentation of AI industry actors<sup>102</sup> and as a means of fostering a more balanced consideration of rights-related issues, it does not overcome the inherent legal limitation characterising stakeholder involvement in the standardisation process. As consistently emphasized by legal scholars,<sup>103</sup> under current framework, stakeholders have only limited tools to shape the process. Consequently, even when their participation is formally provided for, their possibilities to influence the substance of HTS remains structurally constrained. Accordingly, although an increased engagement of fundamental rights actors is normatively desirable and may partially enhance transparency,<sup>104</sup> it does not address the structural

elements that call into question the appropriateness of relying on HTS for the compliance of AI systems with high implications for fundamental rights.

## I. Limits and Prospects of the Compensatory Mechanisms.

22 The evaluation of the impossibility of delivering HTS properly protecting fundamental rights has led to the provision on common specifications to be adopted by the EU Commission,<sup>105</sup> via implementing acts, as a fall-back mechanism when fundamental rights concerns are insufficiently addressed. Considering the current state-of-art, this mechanism also suffers from ambiguity, for two main reasons: (i) the threshold of sufficiency in safeguards for fundamental rights that would trigger the adoption of common specifications is not clarified in the Regulation; (ii) the procedural adoption of common specifications relying on the new Excellence Hub on Standardisation, which could raise criticisms similar to the ones related to HTS dealing with fundamental rights.<sup>106</sup>

23 Firstly, like HTS, the common specifications have been introduced as technical tools primarily for products and services.<sup>107</sup> At this stage, the Commission is expected to set up a horizontal approach and to establish the criteria and the processes to define the conditions under which common specifications are required, instead of HTS.<sup>108</sup> Notably, common specifications are not a specific mechanism of the AI Act, they appear in other legislative acts which have a prominent technical or sectoral nature. In

100 See Annex II, point 1 of Implementing Decision (n 51).

101 CEN-CENELEC, 'CEN and CENELEC Sign a Memorandum of Understanding with FRA' (*CEN-CENELEC*, 20 January 2026) <https://www.cencenelec.eu/news-events/news/2026/press-releases/2026-01-19-mou-with-fra/> accessed 23.01.2026.

102 See *inter alia*: Mélanie Gornet, Winston Maxwell, 'The European approach to regulating AI through technical standards' (2024) 13/3 *Internet Policy Review*.

103 The Standardisation Regulation stipulates that ESOs must encourage and facilitate the appropriate representation and effective participation of all relevant stakeholders in their technical work, specifically Annex III identifies the categories of Organisations that are entitled to engage in the standardisation process. Yet, the comments and the opinions issued by these stakeholders throughout the drafting phases are purely consultative, with no binding effect on the ESOs, this limitation is coupled with the absence of formal voting rights. See n.58 and *inter alia* Morten Kallestrup, 'Stakeholder Participation in European Standardization: A Mapping and an Assessment of Three Categories of Regulation' (2017) 44 (4) *Legal Issues of Economic Integration* 381; Mariolina Eliantonio, 'Private Actors, Public Authorities and the Relevance of Public Law in the Process of European Standardization' (2018) 24 (3) *European Public Law* 473; Mariolina Eliantonio, Annalisa Volpato, 'The European System of Harmonised Standards. Legal Opinion for ECOS (2022), <: <https://ssrn.com/abstract=4055292>. or <http://dx.doi.org/10.2139/ssrn.4055292>> accessed 24.01.2026.

104 Stakeholders participating in the standardization process

can have access to working documents of technical bodies, under specific circumstances. See CEN-CENELEC Guide 25- The concept of Cooperation with European Organizations and other stakeholders. Edition 3, updated version January 2026 <<https://www.cencenelec.eu/media/Guides/CEN-CLC/cenclcguid25.pdf>> accessed 25.01.2026.

105 Art. 41 of the AI Act.

106 Marta Cantero Gamito, Christopher Marsden, 'Artificial intelligence co-regulation? The role of standards in the EU AI Act' (2024) 34 *International Journal of Law and Information Technology*.

107 See, for example, common specifications on diagnostic medical devices Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council OJ L 178 pp. 3-56; or see Art. 27 (2) of Cyber Resilience Act, Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act) OJ L 2847.

108 New Standardisation Strategy (n 63), p.5.

the AI Act, their adoption is foreseen when HTS fail to sufficiently address fundamental rights concerns. In this regard, the Regulation does not specify what constitutes a sufficient level of protection of fundamental rights, nor does it clarify whether common specifications will be adopted before or after HTS are referenced in the Official Journal.

- 24 Secondly, according to the latest Standardisation Strategy,<sup>109</sup> in the development of common specifications, the Commission would leverage the Excellence Hub, aimed at enhancing cooperation in the existing standardisation expertise within the Commission, EU agencies and Joint Undertakings. It could thus be expected that the fundamental rights protection will be not the core of its activities, unless a proper and specific expertise is included.
- 25 Another potential compensatory mechanism could be the Fundamental Rights Impact Assessment (FRIA),<sup>110</sup> which requires deployers of certain high risk-high system to assess potential impacts on fundamental rights, prior to deployment. Undoubtedly, the FRIA provision enhances fundamental rights protection; however, its subjective and material scope was significantly narrowed during the trialogue,<sup>111</sup> compared to the initial proposal by the EU Parliament.<sup>112</sup> As a result, it applies only to a limited subset of deployers, differently from HTS established for all high-risk providers.
- 26 In sum, although the Commission could formally exercise procedural controls over AI-HTS, the lack of a clear and precise mandate to ESOs raises serious reservations about its lawfulness under the delegation doctrine, as well as on the adequacy of HTS as tools for managing risks to fundamental rights. Furthermore, neither the fallback mechanism of common specifications nor the FRIA obligations for

deployers can fully compensate for these structural shortcomings. This criticism is further compounded by the limited judicial reviewability of HTS.

## II. HTS Limited Judicial Reviewability

- 27 The hybrid legal nature of HTS presents significant challenges for its judicial review, as extensively pointed out by legal scholars.<sup>113</sup> These are particularly relevant in the realm of fundamental rights protection. Indeed, the Court has expressly recognised that HTS, once referenced in the Official Journal, form part of the EU law and produce legal effects, thus sustaining its interpretative jurisdiction on HTS under Article 267 TFEU.<sup>114</sup>
- 28 However, the CJEU has consistently held that HTS are acts of ESOs and are not of EU institution, thus restraining the possibility of direct actions for annulment,<sup>115</sup> under Article 263 TFEU, which is one of the main judicial means to ensure fundamental rights protection.<sup>116</sup> The legal status of HTS as non-institutional acts precludes them from being categorized as reviewable acts *per se*. Nonetheless, a procedural pathway for judicial review exists via an action for annulment contesting the Commission's decision to refer to HTS in the Official Journal. However, even in this case, the *locus standi* of private parties would be problematic.<sup>117</sup> As non-privileged

<sup>109</sup> *ibid.*

<sup>110</sup> Art. 27 of the AI Act, see: Gianclaudio Malgieri, Cristiana Santos, 'Assessing the (Severity of) Impacts on Fundamental Rights' (2024) *Computer Law & Security Review*, 56.

<sup>111</sup> Art. 27 firstly establishes an obligation on the deployer, rather than on provider, secondly it provides an exception of high-risk AI systems intended to be used in the critical infrastructure and used for public services, which could be derived by Recital 96. In addition, only AI systems in the public sector, for credit worthiness assessment and insurance risk assessments are captured in the scope. For an overview on the differences between risk management in high-risk conformity procedure and FRIA see: Pier Giorgio Chiara, Federico Galli, 'Normative Considerations on Impact Assessments in EU Digital Policy' (2024), 1 *Rivista di diritto dei media*, 85.

<sup>112</sup> In the amendment tabled by Parliament the provision would be applicable to deployers of all high-risk systems listed in Annex III, Amendment 413, P9\_TA (2023)0236, adopted 14.06.2023.

<sup>113</sup> See: Analisa Volpato, Mariolina Eliantonio, 'The Contradictory Approach of the CJEU to the Judicial Review of Standards: A Love-Hate Relationship?', in Annalisa Volpato and Mariolina Eliantonio, *The Legitimacy of Standardisation as a Regulatory Technique* (Edward Elgar Publishing 2020); Carlo Tovo, 'Judicial Review of Harmonized Standards: Changing the Paradigms of Legality and Legitimacy of Private Rulemaking under EU Law' (2018) 55 *Common Market Law Review* 1187. Mariolina Eliantonio, 'Alternative Forms of Regulation: Are They Really "Better" Regulation?: A Case Study of the European Standardization Process' (2017) 19 *European Journal of Law Reform* 141, 151; Robert van Gestel, Hans Wolfgang Micklitz, 'European Integration Through Standardization: How Judicial Review is Breaking Down the Club House of Private Standardization Bodies' (2013) 50 *Common Market Law Review* 145.

<sup>114</sup> Case C-613/14 *Elliott* para 47.

<sup>115</sup> Annalisa Volpato, 'The harmonized standards before the ECJ: James Elliott Construction' (2017) 54 *Common Market Law Review* 591.

<sup>116</sup> Interestingly, from quantitative assessment, 1/3 of action for annulments lodged before Grand Chamber and related to fundamental rights regards rightly the effective judicial protection, see Giulia Gentile, 'The Power of Procedure: Fundamental Rights in the Action for Annulment before EU Courts' in Melanie Fink (ed), *Redressing Fundamental Rights Violations by the EU* (Cambridge University Press 2024).

<sup>117</sup> Mariolina Eliantonio, 'Judicial Control of the EU Harmonized Standards: Entering a Black Hole?' (2017) 44 *Legal Issues of*

actors, if private parties were to lodge an action for annulment, they would be required to prove an individual and a direct concern, which is hampered by the restrictive *Plaumann* formula,<sup>118</sup> constantly recalled by the CJEU also in cases concerning potential fundamental rights infringements.<sup>119</sup> It stands to reason that mandatory participation in the procedure leading to the controversial act would allow for the possibility of challenging it, following the *Cofaz* ruling.<sup>120</sup> However, even for private parties participating in the standardisation procedure to HTS, the difficulties in proving the individual and direct concern persist. In the *Schmoldt* case,<sup>121</sup> the Court has clarified that the applicants' participation in the process leading to the adoption of the HTS does not make them individually concerned *per se*, unless the legislation establishes a specific individual procedural guarantee. In the same vein, the Court has stated that an association representing the collective interests of a category cannot be considered individually concerned under Article 263(4) by a measure affecting the general interests of the represented category, and it is not entitled to bring an action for annulment on behalf of its members,<sup>122</sup> where they may not do so individually, unless procedural rights are granted or its interests are affected.<sup>123</sup> It may be expected that the Court would adopt a similar approach in future direct challenges by private parties to AI-related harmonised standards or Commission implementing decisions, even on fundamental rights protection.

29 An alternative possibility for an action for annulment would be the recourse to the “regulatory act” exception within the meaning of Article 263(4) TFEU, which would require the sole demonstration of a direct concern when no further implementing

measures are needed.<sup>124</sup> In this regard, in the *Global Garden* case,<sup>125</sup> the Court has affirmed that the Commission decisions to publish HTS are acts of general application against which an action for annulment may be brought. Following the *Global Garden* isolated opening, private parties could file a case for Commission procedural infringements of Regulation on 1025/2012 on standardisation or for non-compliance with the essential requirements established in the AI Act. On these hypotheses, the abovementioned lack of precise criteria and procedural guidance in both the AI Act and the Standardisation Request significantly hinders the possibility of establishing a breach of the essential requirements established in the legislative act, which refer to fundamental rights only in vague and general terms. More relevantly, even if the Commission implementing decisions on HTS reference could be labelled as a “regulatory act,” the need for transposition in national standardisation systems could be considered an implementing measure, thus excluding the possibility of relying on the relaxed *locus standi* requirements recognized in such scenarios.<sup>126</sup>

30 It could be inferred that the likelihood of private parties clearing the admissibility threshold in action for annulment is diminished, even without accounting for the limited substantial judicial review<sup>127</sup> that will be conducted in an admissible action.

31 The less intricate possibility to challenge HTS through an indirect preliminary ruling on the validity could be considered. In this regard, substantial and procedural reflections should be made. Firstly, a possible preliminary question to the CJEU would be sent by a national court. This implies that the question(s) would be drafted by national court(s), which would decide its contents, with limited influence for the applicants in the national procedure as well as in the EU proceedings. Indeed, in principle, this judicial procedure aims to ensure uniformity of EU law rather than offer an alternative judicial remedy.<sup>128</sup>

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Economic Integration 395.

118 Case C- 25/62 *Plaumann v Commission* (1963) C:1963:17 on the admissibility the Court stated that persons other than those to whom a decision is addressed may only claim to be *individually* concerned if that decision affects them because of certain attributes which are peculiar to them, or by reason of circumstances in which they are differentiated from all other persons and by virtue of these factors distinguishes them individually.

119 Case C-565/19 *Armando Carvalho et al. v Parliament and Council* (2021) P EU:C:2021:252, para.48.

120 Case C- 169/84 *Cofaz v Commission* (1986) EU:C:1986:42, para. 30.

121 Case T- 264/03 *Schmoldt et al. v Commission* (2003) EU:T:2004:157.

122 *Ibid*, para 127.

123 See n 117, p. 402-403.

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124 Roberto Mastroianni, Andrea Pezza ‘Striking the right balance: limits on the right to bring an action under Article 263(4) of the Treaty on the functioning of the European Union’ (2016) 31/4 *American University International Law Review* 743.

125 Case T-474/15, *Global Garden v Commission*, T:2017:36, para 60.

126 See n 117.

127 Case T- 201/04 *Microsoft v Commission* (2007) EU:T:2007:289, para 85 and cited case-law.

128 Lucia Lopez Zurita, ‘Fundamental Rights Complaints in the Preliminary Reference Procedure’ in *Melanie Finck (eds). Redressing Fundamental Rights Violations by the EU* (Cambridge University Press 2024).

32 It follows that the long-standing limited judicial reviewability of HTS significantly affects the effective judicial protection of fundamental rights, thus eroding the rule of law, evoked by CJEU in one of its latest ruling on HTS<sup>129</sup> and recalled in the first recital of the AI Act itself.

## D. Conclusions

33 The AI Act's reliance on HTS to manage risks to fundamental rights in high-risk scenarios lies at the heart of the broader debate on the appropriate legal tools for addressing the multifaceted challenges posed by AI. In this light, it reflects the underlying tension between the two goals of the Regulation: increasing the well-functioning of the internal market and safeguarding fundamental rights.

34 The risk-based approach seeks to reconcile these objectives by introducing a layered regulatory framework that incorporates soft and hybrid instruments, with HTS playing a key compliance role. While HTS have long been foundational in facilitating market harmonisation, their adequacy for ensuring fundamental rights protection is highly debatable.

35 This contribution has examined the legal and structural limitations of AI HTS in this domain, focusing on high-risk cases. It has emerged that the delegation of delicate normative tasks to private standardisation bodies, without a clear and detailed mandate risks exceeding the boundaries of the EU's delegation doctrine. The vague references in the AI Act and the Standardisation Request fail to provide the necessary legal clarity, potentially opening the door to a discretionary power exercised by private third parties in the delicate domain of fundamental rights. Moreover, the procedural safeguards currently in place, such as Commission oversight and emergency fallback mechanisms like common specifications, appear insufficient to compensate for these shortcomings. Similarly, the Fundamental Rights Impact Assessment (FRIA), while valuable, is limited in scope and cannot substitute for a robust and rights-oriented assessment to be ensured by design and by providers. The limited judicial reviewability of HTS, highlighted by legal scholars, remains a critical structural weakness, raising serious concerns about effective fundamental rights protection, linked to the rule of law within the AI regulatory framework.

36 It should be noted that a revision of the Standardisation Regulation is expected by the second quarter of 2026. However, in line with the

Standardisation Strategy, it is not expected to mark a revolution of HTS, which will remain strongly a market-oriented instrument.<sup>130</sup> The recourse to common specifications by EU Commission could be a potential alternative, but their effectiveness will depend on their implementation and the inclusion of rights-based expertise in its adoption procedure.

37 Considering that the fundamental rights protection is both an AI-risk dimension and a prominent objective of the Regulation, it emerges that alternatives to HTS are required.

38 Looking ahead, the issuance of specific Guidelines by the Commission, as already envisaged within its mandate,<sup>131</sup> constitutes a prospective pathway to be further investigated. Notably, the adoption of Guidelines concerning the identification and the management of risks to fundamental rights in high-risk scenarios could provide an interpretive framework, thereby streamlining the *ex ante* risk assessment mandated for providers. The recourse to Guidelines has been consistently used in mature EU legal domain, though their function varies, triggering a presumption of legality, as in the competition law,<sup>132</sup> or function as a guidance, such

130 See Call for Evidence for an Impact Assessment, European Commission, Ares (2025) 4981369 - 23/06/2025

131 See Art. 96 (1), let. a) of AI Act which establishes that the Commission is expected to develop guidelines on the practical implementation of the Regulation, in particular on the application of the requirements and obligations referred to in Articles 8 to 15, thus including articles to be covered by HTS.

132 The EU Commission issues Guidelines on diverse topics in the competition law domain, including on the applicability of the Articles 101 and 102 of TFEU which represents its pillars. The Guidelines provide guidance and analytical framework to undertakings and reflect the EU courts' caselaw evolution, as emerged from the latest adopted Guidelines on horizontal cooperation agreements. See European Commission, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal cooperation agreements, C(2023)4752 final. It should be noted the role played by the Commission in the enforcement competition architecture, which grants a relevant value to related soft law instruments, specifically through the so called 'safe harbour' which preclude a finding of a competition infringement and/or make it unnecessary to assess market circumstances in order to find a conduct lawful if certain pre-determined conditions established in the Guidelines are met. See *inter alia*: Lorenzo Federico Pace *European competition law: the impact of the Commission's Guidance on article 102* (Edward Elgar 2011); Zlatina Georgieva, 'Soft Law in EU Competition Law and its Judicial Reception in Member States: A Theoretical Perspective' (2015), 16/2 German Law Journal 223; Martine de Koning, Jelle Blom, 'The New European Block Exemption Regulation on Vertical Agreements: Renewal of the Safe Harbor for Vertical

129 Case C-588/21 P *Public Resources Org v Commission* (2024) EU:C:2024:201, para 81.

as in the aforementioned data protection field.<sup>133</sup> This latter case seems to offer a particularly salient model for the AI Act. In this vein, the precedent set by Commission Guidelines on prohibited AI practices<sup>134</sup> demonstrates the possibility to support the interpretation and the implementation of AI Act key provisions, underscoring its relationship with EU law *acquis*, including fundamental rights protection, while orienting AI operators. Relevantly, the Guidelines on prohibited AI practices suggest criteria and analytical framework to assess the potential significant harms to fundamental rights for certain AI systems. Ultimately, the Guidelines adoption process would facilitate the integration of diverse stakeholders' inputs, as established under the Better Regulation,<sup>135</sup> while leveraging the expertise of the Advisory Forum members<sup>136</sup>, including ESOs, to ensure coherence and synergy with HTS, which would play a supplementary role in fundamental rights domain.<sup>137</sup>

- 39 As the AI Act enters in its critical implementation phase, the EU must ensure that it remains both technologically resilient and properly protective for fundamental rights, to serve its objectives and build up a human-centric and trustworthy AI ecosystem.

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Agreements Such as Franchise Agreements and a New Era on What Is (and Is Not) Permitted on Digital Commerce Within the European Union' (2023) 23/3 Franchise Law Journal, 295.

- 133 See n 96. In data protection, the Guidelines have been issued by European Data Protection Board (EDPB), according to its mandate, as established by Art.70 (1) let.d) of Regulation (EU) 2016/679. Differently, the European Artificial Intelligence Board (EAIB) can issue recommendations, while assisting the Commission for guidance documentation, as derived from art. 64 of the AI Act.
- 134 European Commission, Guidelines on prohibited artificial intelligence practices established by Regulation (EU) 2024/1689 (AI Act), C(2025) 5052 final.
- 135 See Better Regulation Guidelines, SWD (2021) 305 final.
- 136 Art. 67 of the AI Act. Particularly, art. 67 (3) establishes that ESOs together with the Fundamental Rights Agency and ENISA shall be permanent members of the Advisory forum.
- 137 See n 134 and Marion Ho-Dac, 'The EU AI Act and the challenge of protecting fundamental rights' (2025) 62 Common Market Law Review 1299.