The Role of the European Commission in the Control of Harmonised Standards Under the AI Act and the Challenges of "Opacity"

by **Mariolina Eliantonio** *

Abstract: This article examines the role of the European Commission in the European standardisation process, with a specific focus on the development of harmonised standards under the AI Act. Such standards, historically used in product safety regulation, are developed through a peculiar co-regulatory model (the New Legislative Framework). Thereby, private bodies, the European Standardisation Organisations (ESOs), draft technical standards that, once controlled by the Commission for compliance with the underlying legislation and subsequently referenced in the Official Journal, acquire binding public law relevance through the presumption of conformity. The latter allows products which respect the referenced harmonised standards to enter the internal market without the need for additional proof of compliance with the legislative requirements.

While this model has long raised rule of law concerns, the AI Act presents an unprecedented challenge by requiring ESOs to design standards that not only safeguard health and safety but also protect fundamental rights—an inherently vague, value-laden, and contested task. The article argues that the Commission's control over draft standards is the last crucial "public law check" in the European standardisation process. By retracing the evolution of this control before and after the CJEU's James Elliott ruling and interpreting the Standardisation Regulation historically, systematically, and teleologically, the contribution demonstrates that Commission oversight is a fundamental step in the process which the Commission ought to carry out with adequate depth, so as to prevent the transfer of indirect normative power to private actors.

Against the backdrop of delays in AI standardisation and pressure to operationalise the AI Act swiftly, the article warns against a "rubber stamping" approach and highlights the heightened importance of meaningful Commission scrutiny when standards affect not only market functioning but also the protection of fundamental rights and the very legitimacy of the EU legal order.

Keywords: AI Act, harmonised standards, European Commission, fundamental rights, New Legislative Approach

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A. Introduction

1 The New Legislative Framework (NLF) – a peculiar mode of co-regulation dating back from the 80s – is increasingly expanding its reach from product safety to digital regulation, as it is currently foreseen as a regulatory technique in, amongst others, the Cyber Resilience Act,[1] the Data Act,[2]

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1 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 29.10.2024.

2 Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules

the Chips Act[3] as well as the AI Act.[4] The co-regulatory core of this technique resides in a partnership between the EU co-legislators, which draft legislation foreseeing essential health and safety requirements for products and services, the European Standardisation Organisations (ESOs), in charge of drafting detailed technical specifications on how to meet those essential requirements, and the European Commission, which is mandated to draft standardisation requests to the ESOs and publish a reference to the produced standards in the Official Journal, rendering them "harmonised standards". As extensively argued in respect of the use of the NLF, there are many and clear benefits in relying on technical standards and co-regulation in the EU internal market and beyond. The use of the NLF technique has allowed overcoming the slowness of the removal of trade barriers by means of legislative action and, through the coordination with the global standard-setting bodies, the interconnection between the EU and the global markets.[5] In the words of the European Commission, "[S]tandardisation has played a leading role in creating the EU Single Market. Standards support market-based competition and help ensure the interoperability of complementary products and services. They reduce costs, improve safety, and enhance competition".[6] The same is true also for digital regulation: in the fast-paced world of technology, leaving technical details to experts while not overburdening law-makers ensures that the developed solutions remain up-to-date with scientific and technical developments as well as a high degree of interoperability, leading to undeniable trade benefits.[7]

2 At the same time, the public law relevance of the process of European standardisation and the tensions which it produces in respect of basic tenets linked to the rule of law have been at the core of much of the scholarly debate in the past years.[8] When the New Legislative Framework met the AI Act, the well-known "quandaries"[9] (is European standardisation in line with the *Meroni* doctrine of delegation of powers?[10] To which extent are harmonised standards judicially reviewable by the Court of Justice of the European Union (CJEU)?[11] Should the process of European standardisation respect general principles of administrative law, such as the duty to give reasons?[12]) have taken a whole new dimension.

3 Indeed, the AI Act - in its Article 40 - has entrusted the ESOs with the "mission impossible" to draft technical standards for high-risk AI systems which would ensure compliance with not only health and safety requirements, but also the fundamental rights of individuals.[13] The mission seems to be "impossible" because the AI Act remains overly

on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act) OJ L 22.12.2023.

3 Regulation (EU) 2023/1781 of the European Parliament and of the Council of 13 September 2023 establishing a framework of measures for strengthening Europe's semiconductor ecosystem and amending Regulation (EU) 2021/694 (Chips Act) OJ L229/1.

4 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) OJ L 12.7.2024.

5 H Schepel, *The Constitution of Private Governance – Product Standards in the Regulation of Integrating Markets*, (Hart, 2005); J Pelkmans, 'The New Approach to Technical Harmonization and Standardisation' (1987) 25 Journal of Common Market Studies 249.

6 European Commission, 'Standardisation policy' (*European Commission*) <https://single-market-economy.ec.europa.eu/single-market/goods/european-standards/standardisation-policy_en> accessed March 24th 2026.

7 PA Earls Davis and R Schmidt, 'Standardised Bias? The Role – and Limits – of European Standards Bodies in the EU's Artificial Intelligence Act' (*Internet Policy Review*, 24 July 2025) <https://policyreview.info/articles/news/bias-european-standards-bodies> accessed March 24th 2026.

8 E.g. H Schepel, 'The New Approach to the New Approach: The Juridification of Harmonised Standards in EU Law' (2013) 20 Maastricht Journal of European and Comparative Law 521; R van Gestel and HW Micklitz, 'European Integration through Standardisation: How Judicial Review Is Breaking Down the Club House of Private Standardisation Bodies' (2013) 50 Common Market Law Review 145; M Eliantonio, 'Private Actors, Public Authorities and the Relevance of Public Law in the Process of European Standardisation' (2018) 24 European Public Law 437; M Eliantonio and M Medzmariashvili, 'Hybridity Under Scrutiny: How European Standardization Shakes the Foundations of EU Constitutional and Internal Market Law' (2017) 44 Legal Issues of Economic Integration (special issue).

9 See Kanevskaia in this special issue who recalls the 'quandary' which the process of European standardisation has generated for the European legislator.

10 E.g. L Senden, 'The Constitutional Fit of European Standardization Put to the Test' (2017) 44 Legal Issues of Economic Integration 337; M Medzmariashvili, 'Delegation of Rulemaking Power to European Standards Organizations: Reconsidered' (2017) 44 Legal Issues of Economic Integration 353.

11 M Eliantonio, 'Judicial Control of the EU Harmonized Standards: Entering a Black Hole?' (2017) 44 Legal Issues of Economic Integration 395; C 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.

12 M Gnes 'Do Administrative Law Principles Apply to European Standardization: Agencification or Privatization?' 44 (2017) Legal Issues of Economic Integration 367.

13 See on this point Oliva in this special issue.

vague on which fundamental rights are at stake, how to control compliance, and how to balance possibly conflicting fundamental rights.[14] The vague, value-laden, requirements of the AI Act and the conundrum it generates for ESOs (needing to translate deeply contextual and politically sensitive concepts into universal procedures) has not gone unnoticed.[15]

4 What is more, technical standards themselves hide complex value judgements and require evidence which is often incomplete, uncertain, or context-dependent, generating a further "mission impossible" also for regulatees.[16]

5 The fact that the new EU Standardisation Strategy acknowledges that standards deal not only with technical components "but also incorporate EU core values and interests",[17] does not render the mission less "impossible", but rather brings to the fore the one actor which – by reason of its very existence – is supposed to pursue (in the process of European standardisation and beyond it) the public interest: the European Commission.

6 According to Article 17 TEU, the Commission is tasked with pursuing the general public interest in the EU. In the context of the process of European standardisation, the Standardisation Regulation specifically foresees that the Commission must check the compliance of the standards drafted by the ESOs with its initial request.[18] In light of the vagueness of the requirements set in the AI Act, of the crucial role assigned to the ESOs (ie private bodies) to assess technical standards against the equally opaque concept of fundamental rights, and of the relevant consequences which the law assigns to standards which – after approval of the Commission – become "harmonised", all eyes are on the European Commission.

7 The Commission is – in other words – the last "public law check" before a privately developed norm acquires public law relevance, namely through the presumption of conformity. In the context of the AI Act, for the reasons discussed above, this last check acquires, it can be argued, a heightened importance vis-à-vis, for example, "the making available on the market of electrical equipment designed for use within certain voltage limits".[19]

8 The aim of this contribution is to examine the specific juncture in which standards drafted by the ESOs upon a request by the European Commission under the Standardisation Regulation are at a crossroad of becoming (or not) harmonised standards through the publication of a reference to them in the Official Journal. The choice of which road to take is made by the European Commission which needs to assess whether the standards comply with its initial request and the underlying legislation.

14 On this see M Ho-Dac, 'Considering Fundamental Rights in the European Standardisation of Artificial Intelligence: Nonsense or Strategic Alliance?' in K Jakobs (ed), *Joint Proceedings EURAS & SIIT 2023* (Verlag Günter Mainz 2023); M Cantero Gamito and C T Marsden, 'Artificial intelligence co-regulation? The role of standards in the EU AI Act' 32 (2024) International Journal of Law and Information Technology, eaae011; A Mantelero, 'The AI Act: A Realpolitik Compromise and the Need to Look Forward' in I Spiecker Döhmann, L Schertel Mendes and R R Campos (eds), *Digital Constitutionalism* (Nomos 2025) 311; M Gornet, 'The European approach to regulating AI through technical standards' (2023) hal- 04254949v1<https://hal.science/hal-04254949v1>. From the side of civil society, see ANEC, EDRi and EDF, 'The Role of Standards and Standardisation Processes in the EU's Artificial Intelligence (AI) Act' (*EDRi*, May 2022) <https://edri.org/wp-content/uploads/2022/05/The-role-of-standards-and-standardisation-processes-in-the-EUs-Artificial-Intelligence-AI-Act.pdf> accessed 30 March 2026; Frederico Oliveira da Silva and Kasper Drazewski, 'Regulating AI to Protect the Consumer: Position Paper on the AI Act' (*BEUC*, 7 October 2021) <https://www.beuc.eu/sites/default/files/publications/beuc-x-2021-088_regulating_ai_to_protect_the_consumer.pdf> accessed 30 March 2026. See also the report by H-W Micklitz (commissioned by BEUC and ANEC), *The Role of Standards in Future EU Digital Policy Legislation - A Consumer* Perspective, especially 95 and ff.

15 A Tartaro, 'Value-laden challenges for technical standards supporting regulation in the field of AI' 26 (2024) Ethics and Information Technology 1. The author argues that "[I]t is impossible to technically specify what constitutes an *acceptable* level of risk, an *appropriate* level of accuracy, and a *commensurate* level of human oversight". Similarly, Peter Alexander Earls David and Rebecca Schmidt consider that "[B]ias and (fairness) in AI is a highly contested concept, even (or perhaps especially) in technical fields". P A Earls Davis and R Schmidt, 'Standardised bias?' (n 7).

16 See on this point Tartaro, Obnasca and Panai in this special issue.

17 European Commission, 'An EU Strategy on Standardisation: Setting Global Standards in Support of a Resilient, Green and Digital EU Single Market' (Communication) COM (2022) 31 final, 4.

18 Regulation (EU) No 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 [2012] OJ L 316/12, Article 10(5).

19 Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits [2014] OJ L 96/357.

9 The argument advanced here is that, if the Commission does not exercise a sufficient degree of control over the draft standards, it will contribute to the "opacity" of the regulatory architecture supporting the implementation of the AI Act, thereby ultimately undermining the legitimacy of this very architecture.[20] In order to build this argument, the notion of "opacity of the law", in the particular in the sense of "opacity of the legal provisions" will be employed.

10 A legal provision becomes opaque "when it contains technical terms or expressions, incorporated into the text on the advice of experts, which escape the understanding of the legislators".[21] In turn, this opacity affects the legitimacy of the legal provisions because legislators incorporate into legal provisions technical terms or expressions whose content lies beyond their own knowledge and understanding. The content of the "law" thus ends up being determined by technical bodies that operate outside the democratic-constitutional purview. In this way, "[T]he epistemic authority granted to experts [...] turns into an indirect normative power, removed from the institutional control mechanisms that are proper to a state governed by the rule of law".[22]

11 When applied to the process of European standardisation, these considerations would translate into the following: if the Commission accepts to publish in the Official Journal a reference to a technical standard without understanding and controlling its content and its consequences, it would end up affording an indirect normative power to the ESOs which would be in breach of the rule of law.[23] The question thus arises as to the scope and intensity of control which the Commission exercises and – from the point of view of avoiding "opacity" in the sense presented above – ought to exercise on the draft standards produced by the ESOs.

12 In order to elucidate both the positive and the normative question just enunciated, this article shall re-trace the evolution of this control before and after the CJEU's *James Elliott* ruling[24] and, through a historical, systematic, and teleological interpretation of the provisions of the Standardisation Regulation, discuss the scope and intensity of the Commission's control over harmonised standards, including the ones connected to the AI Act.

B. The Commission's Role in Controlling Draft Standards: A Long and Winding Road

I. Setting the Scene: Harmonised Standards, the AI Act and the Role of the Commission

13 On 22 May 2023, the European Commission issued a standardisation request to the ESOs to deliver standards in support of the AI Act.[25] CEN and CENELEC have been tasked to draft a first set of standards, which should reflect the generally acknowledged state of the art to prevent and minimise risks to health, safety, and fundamental rights of persons, as guaranteed in the Charter of Fundamental Rights as well as in relevant applicable EU law.[26]

14 Once drafted, according to Article 10(5), second sentence, and (6) of the Standardisation Regulation, the Commission is both obliged and entitled to check whether the mandated harmonised standards meet the requirements of the standardisation request, prior to publication of the reference in the Official Journal. Indeed, according to the former provision, the Commission together with the ESOs "shall assess the compliance of the documents drafted by the European standardisation organisations with its initial request". Pursuant to Article 10(6), "[W]here a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation, the Commission shall publish a reference of such harmonised standard without delay in the Official Journal of the European Union".

15 The scope and intensity of the Commission's control over the produced harmonised standards is not mandated or specified by the Standardisation

20 The legitimacy challenges in this context have been masterfully summarized by A Tartaro, 'Regulating by standards: current progress and main challenges in the standardisation of Artificial Intelligence in support of the AI Act' (2023) 1 European Journal of Privacy Law and Technology, 147.

21 D Canale, 'Quando gli esperti creano diritto: deferenza, opacità, legittimità", (2022) Analisi e Diritto, 157, 159. For similar considerations in English (but more focused on the role of courts in situations of "opacity"), see D Canale, 'The Opacity of Law: on the Hidden Impact of Experts' Opinion on Legal Decision-Making', 40 (2021) Law and Philosophy, 509.

22 D Canale, 'Quando gli esperti creano diritto' (n 21), 166.

23 See to this effect, the CJEU's *Meroni* ruling. Case 9-56, *Meroni & Co., Industrie Metallurgiche, SpA v High Authority of the European Coal and Steel Community* ECLI:EU:C:1958:7.

24 C-613/14, *James Elliott Construction Limited v Irish Asphalt Limited* ECLI:EU:C:2016:821.

25 European Commission, 'Commission Implementing Decision of 22 May 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.

26 Ibid., Annex II, 2.

Regulation and has been the subject matter of some debate in the aftermath of the *James Elliot* ruling in which the CJEU held that "harmonised standards form part of EU law".[27] The ruling established that the CJEU has jurisdiction to interpret harmonised standards and, in general, opened a debate on the side of both the European Commission and the ESOs[28] on the reach of public law guarantees over the process of European standardisation.

16 Both the silence on this matter in the Standardisation Regulation and the controversy sparked by the *James Elliott* ruling warrants an examination of the rules concerning the practice of the Commission in the control of harmonised standards, a matter, as will be shown in the next section, still of great contention.

II. How It Started and How It Is Going: The Evolution of the Role of the Commission Through the Standardisation Regulation

17 Traditionally, the publication of references to harmonised standards was not preceded by any substantive control by the Commission.[29] In a 1998 Report from the Commission it was actually explicitly stated that "no positive decision is required by which authorities approve the standards".[30] The same is reiterated in a 2002 guidance document where it was stated that "ex-ante control of the technical work by the legislation does not take place".[31] At the same time, rather contradictorily, that same guidance document provided that "the European legislator *maintains control* of the final results as he needs to publish the references of these standards in the OJ in order for the standards to have legal effect (presumption of conformity)".[32] (emphasis added)

18 The fact that the Commission was effectively not controlling the process is supported by the fact that, as noted by Schepel, in its most common form in early New Approach Directives, the Commission could initiate an *ex post* objection procedure if it thought that a harmonised standard did not (or no longer) respect the health and safety requirements foreseen by the underlying legislation.[33] Indeed, the relevant clauses read as follows: "Where a Member State or the Commission considers that the harmonized standards [...] do not entirely meet the essential requirements [...] the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Directive 83/189/EEC, giving the reasons therefor. The Committee shall deliver an opinion without delay. In the light of the Committee's opinion, the Commission shall inform the Member State whether or not it is necessary to withdraw those standards from publication".[34] From a formal perspective, the marginal role of the Commission is also shown by the fact that references to harmonised standards were contained in Commission Communications, non-binding measures published in the C Section of the Official Journal.

19 The 2012 Standardisation Regulation brought about a welcome clarification in this unclear *status quo* by introducing Article 10(5), pursuant to which the Commission must assess whether the standard produced complies with the request on which it is based. Furthermore, according to Article 10(6), the publication of a reference to a harmonised standard in the Official Journal is made condition upon whether the "harmonised standard satisfies the requirements which it aims to cover, and which are set out in the corresponding Union harmonisation legislation". The Regulation therefore highlighted and strengthened the role of the Commission in the standardisation process.

20 The necessity of a form of control is also made clear in the 2015 Vademecum, according to which "specifications delivered by the ESOs in support of Union legislation can never be automatically regarded as complying with the initial request, as this is a political responsibility. As the requesting authority, the Commission will always have to assess compliance with its initial request, in cooperation with the ESOs [...], before deciding to publish the references of a delivered standard in the Official Journal".[35]

27 C-613/14, *James Elliott* (n 24), para 40.

28 CEN and CENELEC, 'CEN and CENELEC Position on the Consequences of the Judgment of the European Court of Justice on *James Elliott Construction Limited v Irish Asphalt Limited*' (*CEN-CENELEC*, 17 May 2017) <https://opil.ouplaw.com/view/10.1093/law-oxio/e246.013.1/law-oxio-e246-document-1.pdf > accessed March 24th 2026.

29 This was noted also by doctrine. H Schepel, *The Constitution of Private Governance* (n 5), 235.

30 See e.g. European Commission, 'Report of 13 May 1998 on efficiency and accountability in European standardisation under the New Approach' COM(1998)291 final, 9.

31 European Commission, 'Methods of Referencing Standards in Legislation with an Emphasis on European Legislation' (Enterprise Guide, European Communities 2002) 9.

32 Ibid.

33 H Schepel, 'The New Approach to the New Approach' (n 8) 529.

34 See e.g. Article 6 of the Simple Pressure Vessels Directive 87/404/EEC [1987] OJ L 220/48. Noted by H Schepel, 'The New Approach to the New Approach' (n 8).

35 European Commission, 'Vademecum on European Standardisation in Support of Union Legislation and Policies: Part I' (Staff Working Document) SWD (2015) 205 final, 9.

21 There is therefore no doubt that – post 2012 – *some* degree of control on the side of the Commission is in line with (and actually required by) the applicable regulatory framework. What remained, however, unclear, is the extent of this control.

III. The Post-James Elliott Scenario and Its Discontents

22 As a consequence of the groundbreaking 2016 *James Elliott* ruling, the Commission felt compelled to take its role in the standardisation process more seriously.

23 In particular, in November 2018, the Commission published a Communication on harmonised standards,[36] where it stated to have "the *obligation* to follow the development process of harmonised standards thoroughly and to assess whether they comply with the requirements set out in harmonised Union legislation and/or standardisation requests in order to ensure that harmonised standards fully comply with the applicable legislation. This does not only include the technical aspects of standards but also other elements of the European Standardisation Regulation, such as whether their development process has been inclusive". It further confirmed that "[I]t is the Commission's intention to fulfil these obligations in a manner which is as swift and efficient as possible".[37]

24 The Commission did not specify (in this document or elsewhere) what precisely its control will entail post-2018. However, several signs show that the Commission wished to be more actively involved in the process of European Standardisation than in the past. In particular, certain concrete changes were brought about. First of all, the Commission ceased to publish references of harmonised standards in the form of a communication in the C series of the Official Journal, but instead in the form of an implementing decision in the L series, reflecting the change in the view of the legal effects of harmonised standards in EU law.[38]

25 Importantly for the purposes of this contribution, the European Commission introduced the Harmonised Standards (HAS) consultants system. HAS consultants are a group of experts provided by a Contractor, currently Ernst & Young, with the purpose of implementing the assessment mechanisms stipulated by the Standardisation Regulation.[39] They have replaced the previous system of so-called NA Consultants (New Approach Consultants), which were managed by the CEN-CENELEC Management Centre but financed via a grant given by the Commission. Although more could (and arguably should) be done in providing more transparency on the role of HAS consultants,[40] these developments do strengthen the impression that the Commission is willing to take more ownership of the process of European Standardisation.[41]

26 This impression is corroborated when looking at the on-going evaluation of the Standardisation Regulation, where reference is made to both of these aspects as a sign of the Commission's efforts to comply with the essence of the *James Elliott* ruling.[42] In particular, the Staff Working Document on the evaluation of the Standardisation Regulation shows that the number of rejections of draft standards rose from 54% to 69%. While this result does not *per se* show a heightened control on the part of the Commission it may give some evidence of a renewed role of the Commission in the process.[43] The same document also states, for example, that there have been "specific cases where the Commission's compliance assessments, supported by HAS consultants, uncover[ed] quality issues that prevent[ed] standards from meeting publication requirements, leading to rejections or the need for further revisions".[44]

27 The depth of the Commission's assessment remains, however, both contested and unclear. The shift towards a supposedly more intensive control has indeed been criticised notably in the Redecker Opinion, commissioned by the German Federal Ministry for Economic Affairs and Energy in view of the Commission's reaction to the *James Elliott* ruling.[45]

36 European Commission, 'Harmonised Standards: Enhancing Transparency and Legal Certainty for a Fully Functioning Single Market' (Communication) COM (2018) 764 final.

37 Ibid., 3.

38 On this A Volpato and M Eliantonio, 'The Butterfly Effect of Publishing References to Harmonised Standards in the L series' (*European Law Blog*, 7 March 2019) DOI: 10.21428/9885764c.3503fd81.

39 Further information on the role envisaged by the Commission for the HAS Consultants can be found in the Tender Specifications published by the Commission itself, Available at https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/tender-details/docs/etender/9845/9845_122895_EN-Tender%20Specifications%20GROW-2021-OP-0016_ENG_V1.pdf .

40 H-W Micklitz, *The Role of Standards in Future EU Digital Policy Legislation* (n 14), 50.

41 For the earlier system CEN/CENELEC see *Guide 15 - Tasks and responsibilities of the New Approach Consultants*, April 2009.

42 European Commission, 'Evaluation of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation' (Staff Working Document) SWD (2025) 171 final, 179.

43 Ibid., 19.

44 Ibid.

45 K Dingemann and M Kottmann, *Legal Opinion on the European System of Harmonised Standards,* Commissioned by the

Considering the trend towards what seemed a tighter form of control, the Opinion argued that this would be incompatible with the Standardisation Regulation and the New Approach paradigm, uncalled for in light of the *James Elliott* ruling, and ultimately as undermining the efficiency and smooth functioning of the standardisation process.[46]

28 Similarly, in a 2023 Report, it has been argued that the post-*James Elliott* approach by the Commission would run against its own established practice, "whereby the technical content of harmonised standards was expressly left to ESOs to decide upon", a practice considered a "core element" of the European standardisation process.[47] Also the move to the use of HAS consultants has been the subject matter of some debate, especially for the alleged limited benefits the new system would deliver and the delays it would generate instead.[48]

29 The next section will unveil why these viewpoints cannot find a basis in the applicable legal framework. Conscious of the hybridity of the model on which European standardisation is founded and of the fact that the delicate public–private balance underlying European standardisation remain normatively important, the argument brought forward is that a substantive control of the Commission over the draft standards is both legally permitted and normatively opportune.

IV. Who Is Afraid of a Tighter Control Over Harmonised Standards?

30 Despite the above-mentioned criticism, a more intense – substantive – control of standards by the Commission before publishing a reference in the Official Journal is fully in line with the legal architecture of European standardisation and, from the perspective of the rule of law, in fact, required to avoid its "opacity". This conclusion can be reached through the systematic, historic and teleological interpretation of the applicable provisions.

31 One argument that has been brought in this context is that Articles 10 and 11 of the Standardisation Regulation would seem to suggest that the Commission should restrict itself to a mere formal control of harmonised standards.[49] A systematic interpretation of the Standardisation Regulation, and in particular the relationship between its Articles 10 and 11, seems, however, to lead to a different conclusion.

32 Article 11 deals with the procedure of formal objection to harmonised standards and it entails the adoption by the Commission of an implementing decision (with the participation of the relevant Comitology committee).[50] In particular, pursuant to this provision, if a Member State or the European Parliament considers that a harmonised standard does not (entirely) satisfy the requirements which it aims to cover, it must inform the Commission. The latter must, after consulting the relevant Comitology committee, decide, to publish, not to publish or to publish with restriction the references to the harmonised standard concerned or, in case the objection is raised after publication, to maintain, to maintain with restriction or to withdraw the references. By contrast, Article 10(6) does not foresee the assistance of a committee and does not make reference to a specific procedure. The difference is procedures would seem to suggest a more limited role for the Commission under Article 10(6) compared to that it would appear to play under Article 11.

33 From these differences, however, and specifically from the circumstance of the presence of the Member States representatives in a consultative role (as foreseen in Article 11), one cannot directly descend any consequence concerning the intensity of the control of the Commission. In both procedures, the decision is ultimately the Commission's, and it is the latter which is entitled to choose how intensively the delivered standards ought to be controlled (regardless of the consultative presence of the Member States authorities).

34 Another criticism brought against a tighter control of draft standards on the part of the Commission is that it would "betray" the aim and spirit of European standardisation. A teleological interpretation of the Regulation would not, however, seem to lead to this result. In particular, and unlike what mentioned in the Redecker Opinion, the main aim of the New Approach is not "to give legislative requirements a concrete form by what of voluntarily applicable, non-binding technical specifications",[51] but to set up, in the words of the Commission, a "public-private-partnership between the Commission and the

German Federal Ministry for Economic Affairs and Energy, 2020.

46 Ibid., 25 to 42.

47 J Baron and P Larouche, *The European Standardisation System at a Crossroads* (Centre on Regulation in Europe Report 2023) 58.

48 Ibid.

49 K Dingemann and M Kottmann, Legal Opinion on the European System of Harmonised Standards (n 45), 28-31.

50 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [2011] OJ L 55/13.

51 K Dingemann and M Kottmann, Legal Opinion on the European System of Harmonised Standards (n 45), 32.

standardisation community",[52] the basis of which is enshrined in the peculiar legal consequences arising from the presumption of conformity granted to products which conform to harmonised standards. In light of the relevance of standardisation as a tool to support Union legislation and policies, the Standardisation Regulation stresses the importance that public authorities participate in standardisation at all stages of the development of those standards.[53] Exactly because of the existence of such close partnership, and of the public law consequences arising from the decision of the Commission to publish a reference to a harmonised standard in the Official Journal, a teleological interpretation cannot lead to the conclusion that the control of the Commission over the delivered standards must be limited to a mere formal check.

35 On the contrary, a historical interpretation of the Standardisation Regulation and an examination of the evolution of the regulatory context set up by the New Approach would lead to the opposite conclusion that a more pervasive (and substantive) control of the Commission over harmonised standards before publication is fully compatible with the legislative framework currently in place.

36 As observed in much of the literature discussing technical standards in the EU, the process of European Standardisation has been subject to a progressive "juridification"[54] which has progressively removed it further from the sphere of purely private regulation towards a system of hybrid governance where public authorities play a fundamental role. One of the turning points in this respect can be identified in the Standardisation Regulation. Before its entry into force, the point of departure was that harmonised standards were published in the Official Journal "for information purposes" only.[55] In line with this point of departure, which de-responsabilized the Commission of any form of control, harmonised standards were published as Commission Communications in the C section of the Official Journal.

37 Even before the *James Elliott* ruling, the tide had started to turn with the enactment of the Standardisation Regulation, which instead provides that it is for the Commission to "assess the compliance" of the standards delivered with its initial request prior to the publication of the reference in the Official Journal. Another clear step in the same juridification process is the above mentioned practice, since 2019, to no longer public reference to harmonised standards as non-binding Communications in the C section of the Official Journal, but as implementing decisions in the L section. The legislative and regulatory changes clearly point towards a larger role of the Commission in the process of control of harmonised standards.

38 The same can be concluded when looking at the evolution of the objection procedure. Before the entry into force of the Standardisation Regulation, the objection procedure could be initiated by the Commission or the Member States.[56] The Standardisation Regulation, in its Article 11, gives *Member States* and the *European Parliament* the right to object, but not the Commission itself.

39 This exclusion can only be explained in light of the changed role of the Commission in the process. As observed, indeed, "[A]ccording to the old conception of the act of publication as an act of providing information, the anomaly of the Commission objecting to an act of the Commission could be explained away. Now, however, it seems accepted that the Commission has to take a decision to publish the references, based on a prior assessment: in that case, it is only right and proper that the Commission should not be allowed to object to itself".[57]

40 All of the above suggests that a control of the Commission which extends beyond a mere formal control of the standards but touches also the "substance" (hence the content) of a standard is fully in line with the evolution of the process of European standardisation and the role of the Commission therein.

52 Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, *Harmonised standards: Enhancing transparency and legal certainty* (n 36), 1.

53 Recital 25 of Regulation No 1025/2012.

54 H Schepel, 'The New Approach to the New Approach' (n 8); R van Gestel and HW Micklitz, 'European Integration through Standardisation' (n 8); M Eliantonio and C Colombo, 'Harmonized Technical Standards as Part of EU Law: Juridification with a Number of Unresolved Legitimacy Concerns?' (2017) 24 Maastricht Journal of European and Comparative Law 323.

55 See eg Article 5 of the Low Voltage Directive 73/23/EEC [1973] OJ 1973 L77/29.

56 As noted by Schepel, in its most common form in early New Approach Directives, the relevant clause read as follows: "Where a Member State or the Commission considers that the harmonized standards [...] do not entirely meet the essential requirements [...] the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Directive 83/189/EEC, giving the reasons therefor. The Committee shall deliver an opinion without delay. In the light of the Committee's opinion, the Commission shall inform the Member State whether or not it is necessary to withdraw those standards from publication". See e.g. Article 6 of the Simple Pressure Vessels Directive 87/404/EEC, OJ 187, L 220/48. H Schepel, 'The New Approach to the New Approach' (n 8), 529.

57 *Ibid*., 530.

41 A final point in support of a substantive control of harmonised standards by the European Commission can be made with respect specifically to the AI Act, through a systematic interpretation of Article 40 in combination with Article 41. While Article 40 mandates indeed ESOs to draft standards which would fulfil the requirements of the AI Act, Article 41 foresees the possibility for the Commission to adopt common specifications through implementing acts, "as fallback solution, so as to ensure that the public interest is served where harmonised standards are absent and insufficient".[58] In particular, the Commission can do so when, amongst other reasons, the relevant harmonised standards insufficiently address fundamental rights concerns or does not comply with the request. When looking at these two provisions together, it can be deduced that their joint reading necessarily implies a control by the Commission on the content of the draft standards, as this control is the condition to trigger eventually the applicability of Article 41 itself.

42 When it comes specifically to the role of the newly introduced HES consultants, it has been considered that their presence is, first of all, unwarranted, "as there is no reason to believe that the opinion of the HAS consultant on the adequacy of the standard is necessarily to be preferred to the collective view of the experts gathered in the ESO technical working group and its decision-making bodies".[59] This view, however, does not take the different roles of the HAS consultants and the experts in the ESOs into account. The ESOs are and remain private organisations, executing admittedly a request coming from a public institution, but at their core still private actors (with clear financial interests in the sale of the standards). The HAS consultants work instead exclusively under the supervision of the Commission: their very *raison d'être* is to support the Commission in the control of harmonised standards. Their role, therefore, while based on expertise as much as that of the ESOs, is fundamentally different and, if the Commission's role in the process is to be taken seriously, their presence constitutes a fundamental step in the public control of the life of a standard towards its mutation into a "harmonised standard".

43 Similarly, while it is true that at the time when the mandate is issued, the technical content of a potential harmonised standard is unknown or at least undetermined, this very circumstance does not logically exclude an external (ie outside the ESOs) control of the draft standards. This would not amount to "second-guessing as to the meaning and interpretation of the mandate in the light of information that was simply not available a priori",[60] but an independent control as to the compliance of the draft standard with the mandate.

C. The Commission's Control of Harmonised Standards Under the AI Act: How to Avoid "Opacity"

44 Having concluded that a substantive control of harmonised standards by the Commission does not violate either the Standardisation Regulation or the New Legislative Framework regulatory paradigm in general, this section analyses the possible intensity of this substantive control. In this context, one could imagine at least two types of substantive control: (i) a more limited one, on the basis of which the Commission would control whether the delivered standard complies with requirements of the underlying legislation, and (ii) more invasive one, on the basis of which the Commission would not only control compliance of the harmonised standard with the mandatory health and safety requirements (as well as fundamental rights under the AI Act), but also whether the specific standard was the most appropriate way to comply with those requirements. The latter – more intense – substantive control would in essence entail that the Commission would end up duplicating the work of the ESOs and eventually substituting its own assessment to that of the ESOs.

45 Despite what has been argued,[61] this latter type of control does not seem what the Commission pledges to carry out in its 2018 Communication, where it "merely" states to intend to control whether harmonised standards "comply with the requirements set out in harmonised Union legislation".[62] An enhanced control of the Commission on the requirements of the harmonisation legislation does not necessarily entail a substantive intrusion in the role of the ESOs. Also from this perspective, therefore, it does not seem that the Commission is intending to perform a stricter control than one which is both allowed *and* required under the current legislative framework. Literature focussing on the AI Act has also specifically called for this type of substantive control, in combination with an increased effort on the part of the Commission to

58 An EU Strategy on Standardisation Setting global standards in support of a resilient, green and digital EU single market (n 17), 8.

59 J Baron and P Larouche, *The European Standardisation System at a Crossroads* (n 47), 58.

60 Ibid., 59.

61 K Dingemann and M Kottmann, Legal Opinion on the European System of Harmonised Standards (n 45), 39-40.

62 Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, *Harmonised standards: Enhancing transparency and legal certainty* (n 36), 3.

set clear boundaries to ESOs in the standardisation requests.[63]

46 What still remains to be concretised, however, is what that control would entail, not least in the context of the fundamental rights aspects foreseen by the AI Act. The assessment framework used by HAS consultants has been developed by the Commission and can be found in a 2016 document issued by DG GROW.[64] Mindful of its own role, the Commission states that the control under Article 10 of the Standardisation Regulation "contributes to the proper functioning of the single market" and ensures "that the Commission has final control over any assessment work done during the drafting of a harmonised standard".[65]

47 This control process, understood as an "endorsement based on sufficient (but not absolute) certainty that the standard satisfies the relevant legal requirements and other requirements referred to in the relevant standardisation request(s)"[66] comprises three steps. The first step relates to a number of "procedural formalities" relating to the relationship of a standard with the work programme, its availability in all EU languages, the transparency and inclusiveness in the course of development of the standard and the correct presence of normative references. The second step is labelled as a "quantitative verification". It requires checking that the essential requirements of EU legislation that are meant to be operationalised in a given standard are clearly and transparently identified, and that the standard does not include normative elements outside the scope of the essential requirements as identified in the Commission mandate. The third step is the one which is most relevant for the present analysis. It is called "qualitative assessment". Here the Commission (with the support of HAS consultants) has to assess whether the draft standard "sufficiently satisfies the relevant legal requirements aimed to be covered".[67] This requires, amongst others, answering whether the standard complies with the state-of-the art knowledge, whether the standard would either privilege one economic operator over others, or give choices to economic operators in such a way that the essential requirements listed in the mandate can be circumvented.

48 All in all, this checklist allows a control which is both thorough and not overly invasive. If taken seriously, it would seem to lead to a check of the content of the draft standards of such a depth and breadth that it would allow the Commission to retain sufficient knowledge and understanding of the standards (admittedly through the use of the HAS consultants) so as to avoid "opacity", while not duplicating or indeed second-guessing the work of the ESOs. The control thus carried out would not "grant unchecked epistemic authority to experts",[68] as the Commission would still remain both formally and in substance in charge of deciding whether a reference to a standard is to be published in the Official Journal.[69]

49 In the context of the AI Act, because of peculiar fundamental rights implications, the process sketched above might need to be sharpened towards the specificities of this piece of legislation. In this respect, what has been proposed in literature is a clear list of key parameters for fundamental rights risk assessment for the European Commission.[70] Research carried out on how to operationalise Article 27 of the AI Act could also prove useful in this respect.[71] Indeed, while this provision is addressed to deployers, it concerns deployers of high-risk AI systems as well as deployers "that are bodies governed by public law, or are private entities providing public services". The suggestion to use, for example, a risk index for each potentially impacted right based on a matrix combining two dimensions (likelihood of the infringement of a right and severity of that infringement)[72] could possibly also be of use for the Commission and the HES consultants when assessing the respect of draft standards with fundamental rights.

50 Finally, in light of the sensitivity of the task, more transparency in the role of the HES consultants, their mandate, their identities and their responsibility

63 See eg Oliva in this special issue.

64 European Commission, 'Verification of Conditions for the Publication of References of Harmonised Standards in the Official Journal' Ref Ares(2016)6548298 (22 November 2016).

65 Ibid, 2.

66 Ibid.

67 European Commission, Verification of conditions for the publication of references of harmonised standards in the Official Journal, (n 64) Annex I.

68 See *supra* in the Introduction on the concept of 'opacity'.

69 It has been noted that the risk exists that HES consultants could overstep their role if they interfere in the standard development process. While this opinion is entirely defensible, further empirical research would be needed in order to assess whether this risk concretely materialized. See further J Baron and P Larouche, *The European Standardisation System at a Crossroads* (n 46), 59.

70 A Mantelero 'The AI Act: a realpolitik compromise and the need to look forward' (n 14).

71 A Mantelero, 'The Fundamental Rights Impact Assessment (FRIA) in the AI Act: Roots, legal obligations and key elements for a model template' 54 (2024) Computer Law & Security Review 106020; G Malgieri and C Santos, 'Assessing the (severity of) impacts on fundamental rights' 56 (2025) Computer Law & Security Review 106113.

72 A Mantelero, 'The Fundamental Rights Impact Assessment (FRIA) in the AI Act' (n 71), 16.

would need to be ensured.[73] In order to avoid "capture" of HES consultants (resulting in a sort of "second-degree opacity" caused by those who were tasked to avoid it in the first place), certain independence guarantees would specifically have to be in place to ensure that they remain guarantors of the public interest in the process. Equally, the Commission would have to closely monitor the process in order to minimize the chances of "rent-seeking" behaviours, whereby HES consultants would have an incentive to "overcontrol" the draft standards in order to justify their role in the process.

D. Conclusions

51 The AI Act has entered into force in August 2024 and ESOs were tasked to develop standards for high-risk AI systems by 30 April 2025, a deadline which was not respected and extended to August 2025 and subsequently into 2026.[74] The recent Digital Omnibus on AI Proposal has further determined that certain rules governing high-risk AI systems (Chapter III, Sections 1-3) will not enter into force until the Commission has adopted a corresponding decision confirming the existence of adequate support measures for the AI Act. This decision confirms the paramount role which standards are to play in the implementation of the AI Act.[75]

52 When standards are delivered, the Commission will have the task to decide whether the draft standards will become "harmonised standards" through the publication in the Official Journal. The consequence of this publication is paramount: companies demonstrating compliance with these harmonised standards can benefit from a "presumption of conformity", which means these companies will be presumed to comply with certain elements of the AI Act unless there is evidence of non-conformity. Far from being neutral technical tools, "standards have politics",[76] they reflect "a preference for a specific logic and set of priorities",[77] they carry immense normativity. When privately developed standards acquire this peculiar public law role, it is imperative that the political choices underlying them be appropriately controlled. In specific case of the AI Act, adopted amid unprecedented political controversy,[78] and following sustained criticism on the side of both societal stakeholders[79] and academics[80] on the suitability of the use of the New Legislative Framework technique to regulate AI, the Commission's control remains a crucial juncture in the regulatory architecture.

53 The aim of this contribution has been to discuss the role of the Commission in the European standardisation process and, in particular, the scope of its control before the publication of the reference to a standard. In the aftermath of the CJEU's *James Elliott* ruling, the Commission seems to have intensified its control, a step of the process enshrined in the Standardisation Regulation. This move has attracted a substantial amount of criticism, including a possible "loss of synergies, which have historically allowed the Commission to tap into the subject matter expertise of private industry stakeholders for the development of the standards required for EU regulatory activities".[81]

54 Using a historical, teleological and systematic interpretation of the Standardisation Regulation, this contribution has demonstrated that, instead, a control of the Commission over the process and the content of draft standards is entirely allowed and in fact required by the applicable legal framework. The delays incurred in the delivery of the standards

73 See Micklitz, who argues that HAS consultants have an almost impossible task under the AI Act, requiring both expertise in law and in technology. H-W Micklitz, *The Role of Standards in Future EU Digital Policy Legislation* (n 14), 164.

74 Cynthia Kroet, 'EU standards bodies flag delays to work on AI Act' (*EuroNews*, 16 April 2025) <https://www.euronews.com/next/2025/04/16/eu-standards-bodies-flag-delays-to-work-on-ai-act> [date accessed]. This is also noted in the Commission Staff Working Document Accompanying the Digital Omnibus and Digital Omnibus on AI) COM(2025) 837 final, COM(2025) 836 final, 68.

75 Article 1(31) of the Proposal for a Regulation the European Parliament and of the Council amending Regulation (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI) SWD(2025) 836 final.

76 A Solow-Niederman, 'Can AI standards have politics?' (2024) UCLA Law Review, 231.

77 S Timmermans and S Epstein, 'A world of standards but not a standard world: Toward a sociology of standards and standardization' 36 (2010) Annual Review of Sociology, 69.

78 F Palmiotto, 'The AI Act Roller Coaster: The Evolution of Fundamental Rights Protection in the Legislative Process and the Future of the Regulation' 16 (2025) European Journal of Risk Regulation, 770.

79 C Galvagna 'Inclusive AI governance. Civil society participation in standards development' (*Ada Lovelace Institute,* 30 March 2023) <https://www.adalovelaceinstitute.org/report/inclusive-ai-governance/?utm_source=chatgpt.com> accessed March 24th 2026.

80 M Veale and F Zuiderveen Borgesius, 'Demystifying the Draft EU Artificial Intelligence Act. Analysing the good, the bad, and the unclear elements of the proposed approach 4 (2021) Computer Law Review International 97; M Ebers 'Standardizing AI: The Case of the European Commission's Proposal for an 'Artificial Intelligence Act' LA DiMatteo, C Poncibò and M Cannarsa (eds) *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics* (Cambridge University Press, 2022), 321.

81 J Baron and P Larouche, *The European Standardisation System at a Crossroads* (n 47), 8.

and the voices raised in favour of a "pause" to the implementation of the AI Act,[82] might evoke fears that, as soon as standards are available, the Commission might be tempted to "fast-track" them to get the AI Act operational as soon as possible. These fears are further supported by the decision taken by the ESOs to skip certain stages of the standard-setting process to accelerate the delivery of harmonised standards to support the AI Act.[83] What is worse, the stages which will be compressed as a consequence of this decision are the deliberative ones, leading standard-setting power entirely in the hands of a small group of experts.[84]

55 Under these circumstances, should the Commission choose for a "rubber stamping" approach, it would contribute to the "opacity" of the legal architecture of European standardisation and, in turn, undermine its legitimacy because it would be granting indirect normative power to private standard-setting bodies. This would be all the more concerning when standards touch upon not only health and safety aspects of individuals' lives but also their fundamental rights (as is the case with the AI Act) and are linked – it can be argued – to the very upholding of the rule of law in the EU. The rushed nature of this process exacerbates these legitimacy concerns.

56 The process currently in place at the Commission, and the step it entails - if correctly carried out (through the support of the HES consultants) - would ensure a sufficient degree of control over draft standards, without the risk of "overcontrolling" on the part of the Commission. At the same time, the novelty of the fundamental right aspects of AI standards, and the delicate task of balancing fundamental rights with no specific variables or objective criteria, would seem to call for a renewed attention and possibly the need for adaptations in the process.

82 E Gkritsi, 'Europe's top CEOs ask EU to pause AI Act' (*Politico*, 4 July 2025) <https://www.politico.eu/article/top-european-ceos-plead-for-pause-in-ai-act/> last accessed April 17.

83 CEN and CENELEC, 'Update on CEN and CENELEC's Decision to Accelerate the Development of Standards for Artificial Intelligence' (*CEN-CENELEC*, 23 October 2025) <https://www.cencenelec.eu/news-events/news/2025/brief-news/2025-10-23-ai-standardization/> last accessed April 17.

84 See further on this point, M C Gamito, 'From Consensus To Exceptionality – What The EU's AI Standards Crisis Reveals About Delegated Technical Governance, (*REALaw.blog*, 28 November 2025) <https://realaw.blog/2025/11/28/from-consensus-to-exceptionality-what-the-eus-ai-standards-crisis-reveals-about-delegated-technical-governance-by-marta-cantero-gamito/> accessed March 24th 2026