From National to European - And Back Again: Fixing the Flaws of the New Approach

by **Olia Kanevskaia** *

Abstract: Harmonized standards are central to European policymaking. Traditionally intended to ensure technical harmonization and consumer safety, harmonized standards are increasingly becoming critical for regulating many societal aspects: to illustrate, the recently adopted AI Act outsources many legal and ethical decisions to the European standards bodies. In this setting, questions whether and how public interest is sufficiently safeguarded in the private setting of European standardizations are bound to arise.

Developed mainly by commercial actors, harmonized standards are under little – if any – control of civil society. Firstly, participation of societal stakeholders in technical standardization processes remains limited; secondly, despite the recent jurisprudence, access to harmonized standards remains challenging. Academic and policy discussions on these issues abound; however, the role of Member States, and more specifically National Standards Organizations in ensuring participation in and access to standards, tends to be sidestepped.

This paper examines two key transparency challenges posed by the New Approach: access to standardization processes and access to harmonized standards. It argues that although these issues are essentially European, their resolution depends on national institutions, which poses questions regarding the interplay between national and European accountability in standardization. Ultimately, it suggests possible solution to these challenges, placing them in the broader context of European standardization policy.

Keywords: New Approach – transparency – harmonized standards – copyright – AI Act

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A. Introduction

1 Regulatory responses to technological advancement are in high demand. In the European Union (EU), co-regulation is becoming an increasingly used tool to manage, and respond to, various challenges stemming from the development and use of emerging technologies.[2] A vivid example is the "New Approach" regulatory technique, that allows market actors to demonstrate compliance with EU legislation through private voluntary harmonized standards (HSs). Initially designed with product safety in mind, the New Approach is increasingly being used in regulating digital systems and spaces, i.e., in the Artificial Intelligence (AI) Act,[3] Data Act,[4]

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2 Michèle Finck, 'Digital Regulation: Designing a Supranational Legal Framework for the Platform Economy' (2018) LSE Law, Society and Economy Working Papers 15/2017; Nikita Divissenko, *Regulating Innovation in the Digital Age: A Demand-Centered Toolbox for the Data-Driven Economy* (Hart Publishing 2025) 89–90.

3 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 certain legislative acts [2024] OJ L 12.7.2024 ('AI Act').

4 Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU)

and Cyber Resilience Act.[5] Furthermore, HSs are deemed essential for the EU strategic and critical sectors, such as security, medical devices, and education,[6] while they also promote the EU global competitiveness and ensure stability of the Single Market.[7]

2 Despite its notable success, the New Approach has also created a quandary for the European legislator. As HSs gradually enter the realm of public law, a substantial part of the regulatory authority is wielded by private standards development institutions, arguably without proper delegation of the rulemaking power. The legitimacy and constitutional issues trigged by this regulatory metamorphosis have been discussed at length in the scholarly literature.[8] Some of these challenges were reflected in a complaint filed by an NGO in September 2025 with the European Ombudsman, contesting the European Commission's role in ensuring transparency, inclusiveness, and accountability in standardisation processes leading to the adopting of HSs for the purpose of the AI Act.[9] There seems to be a general consensus among scholars and societal stakeholders that the New Approach is due for an overhaul.

3 In brief, the main challenges that the New Approach presents to the rule of law swirl around the issue of transparency and *access,* and in particular: 1) access to standardization processes through open and meaningful participation and 2) access to HSs that are copyright protected and, until recently, have been under the paywall.[10] These challenges are particularly pertinent to the EU digital legislation. Take, for instance, the AI Act, where abstract requirements for high-risk level AI systems are effectuated by HSs[11] and where, for the first time, such technical standards are going to be used in assessing compliance with fundamental rights.[12] Access to these standards is essential for compliance, while access to standards development processes is crucial for ensuring that standards are indeed responsive to, and compliant with, fundamental rights and ethical frameworks. But despite the recent case law developments as well as continuous calls for opening standardization processes,[13] the issue of access still presents a challenge.

4 In this paper, I argue that while restricted access to HSs and to their development processes is essentially a *European* problem, the institutional and policy design of the New Approach requires their solutions to be *national.* Quite paradoxically, while the ultimate responsibility for European standardization seems to rest on the European Standards Organizations (ESOs) and the Commission, it is the National Standards Organizations (NSOs) of the Member States that are the gatekeepers of standards and processes. Such a division of labor is mutually convenient, not least

2017/2394 and Directive (EU) 2020/1828 (Data Act) [2023] OJ L 22.12.2023.

5 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 [2024] OJ L 20.11.2024.

6 European Commission, 'An EU Strategy on Standardisation: Setting global standards in support of a resilient, green and digital EU single market' COM(2022) 31 final (hereinafter: 2022 Standardization Strategy).

7 See also Enrico Letta, 'Much More Than a Market: Empowering the Single Market to Deliver a Sustainable Future and Prosperity for All EU Citizens' (European Council, April 2024).

8 See Annalisa Volpato, 'The publicity of EU law and the privatization of EU digital regulation' (2024) 31 Maastricht Journal of European and Comparative Law 319; Linda Senden, 'The Constitutional Fit of European Standardization Put to the Test' (2017) 44 Legal Issues of Economic Integration 337; Megi Medzmariashvili, 'Delegation of Rulemaking Power to European Standards Organizations: Reconsidered' (2017) 44 Legal Issues of Economic Integration 353; Megi Medzmariashvili, 'Delegation of Rulemaking Power to European Standards Organizations: Reconsidered' (2017) 44 Legal Issues of Economic Integration 353, 353–66; Christian Joerges et al, 'The Law's Problems with the Involvement of Non-Governmental Actors in Europe's Legislative Processes: The Case of Standardisation under the "New Approach"' (1999) EUI Working Paper LAW No 99/9.

9 European Ombudsman, 'Complaint against the European Commission Concerning Transparency, Inclusiveness and Accountability in the Adoption of Harmonised Standards Related to Artificial Intelligence', Case 1974/2025/MIK (opened 26 September 2025).

10 Zachariah Davies and Arnaud Van Waeyenberge, 'Better Regulation by Standards? Harmonized Technical Standards, Transparency and the Rule of Law' (2025) 62 Common Market Law Review 147, 169.

11 See AI Act, 40 and recital 121.

12 For further critique on using the New Approach in the AI Act as a tool to uphold fundamental rights, see Nathalie Smuha and Karen Yeung, 'The European Union's AI Act: Beyond Motherhood and Apple Pie?' in: Nathalie Smuha (ed) *The Cambridge Handbook of the Law, Ethics and Policy of Artificial Intelligence* (Cambridge University Press: 2025) 228; Mélanie Gornet and Winston Maxwell, 'The European approach to regulating AI through technical standards' (2024) 13 Internet Policy Review 3; Marta Cantero Gamito, 'Artificial Intelligence co-regulation? The role of standards in the EU AI Act' (2024) 32 International Journal of Law and Information Technology.

13 ANEC and BEUC, 'For a "Standardisation Governance Act": ANEC and BEUC Recommendations to Adapt Regulation (EU) 1025/2012' (BEUC, 23 January 2024) <https://www.beuc.eu/sites/default/files/publications/BEUC-X-2024-001_For_a_standardisation_governance_act.pdf> accessed 6 June 2025.

because it allows ping-ponging responsibilities for providing access, as well as to forum-shop for the sources of legitimacy; but it ultimately creates an accountability gap and causes corrosion of European standardization policy.

5 My argument proceeds as follows. Upon explaining the link between European and national standardization (Section B), I will tackle the two transparency issues – access to ESOs' processes (Section C) and to HSs (Section D). I focus on the European Committee for Standardization (CEN) and European Committee for Electrotechnical Standardization (CENELEC), the two ESOs that share governance and operational frameworks and which are mandated by the Commission to develop HSs in support of the AI Act,[14] and I illustrate the national regulatory and policy landscape using the example of the Netherlands. Next, I will discuss the growing accountability gap that emerges from the current institutional set-up (Section E), and propose legal and policy solutions for "fixing" the access problems (Section F), before concluding my argument with a broader outlook on European standardization policy (Section G).

B. The Interplay Between European and National Standardization

6 In the EU, HSs ensure market integration and eliminate trade barriers between the Member States, which makes them the ultimate instruments of European harmonization. But reliance on standards in rulemaking practices is not merely an EU-wide phenomenon: standardization has a strong international dimension through the Technical Barriers to Trade (TBT) Agreement of the World Trade Organization (WTO),[15] and an equally important national dimension that can be traced back to the XIXth century and the industrial revolution.[16] While the New Approach has inherited traditions and practices from the national standardization systems of its Member States, current policy and academic discourses focus on the European, rather than national standardization actors, institutions and processes. This is not surprising: after all, the growing Europeanisation, the necessary national uptake of international and European standards,[17] and the obligation for NSOs to withdraw any standards that may conflict with HSs (the so-called "stand-still" requirement)[18] leave one to wonder whether national standardization is still relevant. Yet, as will be demonstrated in this section, the national legislation, policy, and NSOs play a crucial role in enabling European standardization.

I. Standardization at the EU Level

7 The history of the New Approach has been accounted for on multiple occasions.[19] As such, the New Approach, and later the New Legislative Framework,[20] was a response to the inefficient and labored process where harmonization requirements were highly detailed, top down, and binding, and developed through a legislative processes that required unanimity from the Council.[21] This mandatory reference was replaced in 1985 with the regulatory technique through which the European legislator established broadly defined health and safety requirements in its Directives, while technical standards concretizing these requirements were developed, upon the request of the Commission,

14 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' (Implementing Decision) C (2023) 3215 final.

15 Agreement on Technical Barriers to Trade (adopted 15 April 1994, entered into force 1 January 1995) 1868 UNTS 120, art 2.4. The link between international, European, and national standards falls outside the scope of this paper.

16 See Craig N Murphy and JoAnne Yates, *Engineering Rules: Global Standard Setting since 1880* (Johns Hopkins University Press: 2019) 19.

17 According to the recent data, an average of 86% of active HSs of CEN and CENELEC are transposed into national standards in all EU Member States. European Commission, Commission Staff Working Document, 'Evaluation of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation' SWD(2025) 171 final, 35.

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 L316/12, 3(6) and recital 14.

19 See, for instance, some fundamental works of Harm Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Hart Publishing 2005); Joerges et al, above n 8; Jacques Pelkmans, 'The New Approach to Technical Harmonization and Standardization' (1986) 25 Journal of Common Market Studies 249.

20 The New Legislative Framework was adopted in 2008, updating the New Approach with regulatory instruments for strengthening the Internal Market, clarifying the functions of the CE marking, conformity assessment processes and market surveillance.

21 Council Resolution of 7 May 1985 on a New Approach to Technical Harmonisation and Standards [1985] OJ C 136/1.

by three ESOs: CEN, CENELEC, and the European Telecommunication Standards Institute (ETSI). Compliance with these HSs granted presumption of conformity with the European legislation.[22] ESOs operated according to their own governance rules and processes and consisted of technical experts that were seconded by the industry through national channels, i.e. NSOs.[23]

8 Were HSs meant to have legal effects already at that point? Presumably not. The fact that standards are "voluntary" has been underlined in many Commission's documents and communications, supported by the reasoning that, at least on paper, alternative means of compliance with the regulatory requirements were available.[24] Furthermore, and importantly, the New Approach was not an intentional delegation of the regulatory power, but rather drew a clear distinction between binding legislation, on the one hand, and voluntary standards that would ease compliance with that legislation, on the other.[25] This separation between standardization and rulemaking likely explains why free access to HSs and broader stakeholder involvement were not initially seen as points of concern under the New Approach.

9 The voluntarism of HSs undoubtedly contributed to the wider success of the New Approach, legitimizing this regulatory technique through availability of alternatives for demonstrating compliance with legislation. That said, these alternatives were either too burdensome or simply non-existent,[26] leaving the industry no other choice than conforming to the HSs. One may even suggest that the "voluntary" nature of standards may have served as a disguise for an unconstitutional delegation of authority.[27] The Commission may have as well been aware of the potential issues that such "delegation in disguise" have created, having an established practice of using experts to verify whether standards created by ESOs are indeed compliant with the legislative requirements.[28]

10 As the distinction between standards and law continued to blur, the European Court of Justice (CJEU) gradually pulled HSs into the public domain, conforming the legal effects of such standards on multiple occasions[29] and re-opening the constitutional questions on delegation of the rulemaking power to private actors.[30] For instance, scholars questioned the constitutional fit of EU standardisation within the EU legal order particularly in light of the limited Treaty safeguards governing the Commission's own powers,[31] and raised concerns about potential *abus de pouvoir* and the risk of undermining both the inter-institutional balance and the principle of conferral.[32] Further issues relate to the constitutional validity of delegating regulatory powers to ESOs, including possible non-compliance with the *Meroni* doctrine[33] due to insufficient supervision of the standard-setting process, limited judicial review, and the absence of accountability mechanisms for ESOs comparable to those applicable to EU institutions and agencies.[34]

11 These debates should be seen within the broader development of EU law being increasingly shaped not only by administrative bodies but also by standardisation organisations that enjoy considerable discretion in concretising and supplementing vague legislative requirements.[35] From this perspective, such potentially unconstitutional delegation of regulatory power to ESOs is particularly problematic

22 Commission of the European Communities, 'Completing the Internal Market: White Paper from the Commission to the European Council (Milan, 28–29 June 1985)' (White Paper) COM(85) 310 final, para 68.

23 See also Rob van Gestel and Hans-W Micklitz, 'European Integration Through Standardization: How Judicial Review Is Breaking Down the Club House of Private Standardization Bodies' (2013) 50 Common Market Law Review 145, 149.

24 See the Commission's White Paper, above n 22.

25 See, for a similar argument, Joerges et al, above n 8, 5, arguing that the "world of thought lying behind 'delegation' both represents a distorted perception of constitutional problems along neat public/private and Community/Member State dichotomies and prescribes a misconceived solution to these problems."

26 Case C-588/21 P *Public.Resource.Org, Inc and Right to Know CLG v European Commission*EU:C:2023:509, Opinion of AG Medina, point 48.

27 See Joerges et al, above n 8.

28 Initially performed by the "New Approach Consultants" (NAC), and at present, by the Harmonized Assessment System (HAS) consultants.

29 See the landmark cases as Case C-613/14 *James Elliott Construction Ltd v Irish Asphalt Ltd* EU:C:2016:821; Case T-474/15 *Global Garden Products Italy SpA v European Commission* EU:T:2017:36; Case C-630/16 *Anstar Oy* EU:C:2017:971; Case C-588/21 P *Public.Resource.Org Inc v European Commission* EU:C:2024:201.

30 See the analyses of constitutional issues by Senden and by Medzmariashvili, above n 8.

31 Senden, above n 8, 338

32 Ibid, 343.

33 Case C-9/56 *Meroni & Co., Industrie Metallurgiche, SpA v High Authority of the European Coal and Steel Community* [1958] ECLI:EU:C:1958:7. Later in ESMA, Case C-270/12 *United Kingdom v European Parliament and Council of the European Union* [2014] ECLI:EU:C:2014:18, the Court justified the delegation of power to adopt the rules of general application to an EU agency based on technical expertise.

34 See also Vallejo on this point, Rodrigo Vallejo, 'The Private Administrative Law of Technical Standardization' (2022) 40 Yearbook of European Law 172, 175.

35 See in this regard Annalisa Volpato, *Delegation of Powers in the EU Legal System* (Routledge, 2022).

in the context of AI standards, given the significant fundamental rights implications and broader policy objectives at stake.[36] With the myth of voluntarism of HSs debanked by the CJEU, concerns surrounding delegation, although not the central focus of this paper, remain salient.

12 Another issue trigged by the increasing juridification of HSs was the financing of European standardization activities and, subsequently, the free access to the HSs that have become a "part of law".[37] This debate is not new: ESOs are dependent both on public (through the Commission) and private (through their members and, arguably, the sales of standards)[38] sources of financing. In this regard, the Commission suggested already in its 1990 Green paper that ESOs should make long-term financial commitments and change both the retribution of revenue from sales of standards and the membership fees for the industry; and even attempted to gradually cut back on lump-sum subsidies by switching to project-based financing.[39] This reiterates that the financing of European standardization activities is a policy baggage, entangled in a broader context of legitimacy and constitutionality.

II. Standardization at the National Level

13 Before globalisation instigated the need for cross-border harmonization and the creation of global and regional institutions, standards were largely produced by a homogeneous group of national industry actors, cooperating in loosely administrated processes shielded from political or market influence.[40] With the New Approach, these technical processes suddenly became central to the European integration; accordingly, standardization ceased being immune to institutionalization and Europeanization, as more structured standards bodies were required to operate at the EU level. This ricocheted to NSOs whose preliminary responsibilities as ESOs members became achieving the national level of consensus through consulting relevant stakeholders (public enquiry) and voting on acceptance of HSs.[41]

14 That said, standardization systems in Member States have significant differences, often embedded in national administrative laws and agreements made by NSOs with the relevant governmental bodies. The Netherlands provides an illustrative example: the Dutch NSO is the Royal Netherlands Standardization Institute (NEN). NEN develops national standards, including those that are based on, or implement, international and European standards. It is independent from the government but receives a task-oriented financing for its activities, including participation in ESOs, as per agreement with the Dutch Ministry of Economic Affairs.[42] Despite being an NSO and respecting the applicable CEN/CENELEC guides, NEN establishes its own procedures, participation rules and membership fees. While the current Dutch standardization system was largely inspired by the New Approach and presumption of conformity, it is still very much rooted in private sector traditions, where the industry initiated standards development[43] (unlike in the EU, where the initiative to develop HSs is the prerogative of the Commission). Similar to ESOs, NEN holds copyright over its standards, which – with the exception of standards that are made mandatory in national Dutch law, – are under the paywall.[44]

15 Standardization systems in EU Member States may also be contrasting. For instance, Germany, akin to the Netherlands, has a strong tradition of private standardization, whereas in France standards are part of the body of administrative law, and in Portugal, Spain and Greece, standardization used to be a public sector activity that then got privatized.[45] NSOs business models also vary in terms of funding mechanisms. In Finland, the NSO, SFS Finnish Standards, controls and coordinates almost all national standardization activities (with an exception

36 See Andrew Leyden, 'Standards and the EU AI Act: Legitimacy, State of Play, and Future Challenges' [2025] Information & Communications Technology Law 1, 16-17.

37 See also Olia Kanevskaia, 'Is it really all about the money? The future of European standardization after *PublicResourceOrg*' (2024) 16 European Journal of Risk Regulation 344.

38 But see Alexandru and Mateus Frazao Correia Magalhaes De Carvalho, 'Lawtify Premium: Public.Resource.Org (T-185/19), a Judicial Take on Standardisation and Public Access to Law' (2022) 15 Review of European Administrative Law (2022) 57, challenging the statement that sales of harmonized standards constitute a significant income for ESOs.

39 Commission of the European Communities, 'Commission Green Paper on the Development of European Standardization: Action for Faster Technological Integration in Europe' (Green Paper) COM (90) (1990) 456 final 66 – 73; see also Joerges and others (n 8) 18-19.

40 See van Gestel and Micklitz (n 23), 149.

41 CEN-CENELEC, Guide 4: General Guidelines for the Cooperation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association (2003) 4.

42 See Ministerie van Economische Zaken en Klimaat, DG Economie en Digitalisering, 'Evaluatie van de taakgerichte financiering van NEN,' letter to the Parliment (19 March 2024) < https://open.overheid.nl/documenten/29b7f397-f6ed-4065-a98b-204452878deb/file> accessed 6 June 2025.

43 See also the opinion of AG in the Dutch Supreme Court case *Knooble*, Hoge Raad 11/01017 (30 March 2012) LJN: BW0393.

44 See Section D for further treatment of the issue.

45 See Joerges and others (n 8), 30, and the related references.

of electrotechnical and telecommunications sectors) including the selling of standards; however, national standards are developed in one of the 9 national standards writing bodies.[46] According to the SFS website, as of 2024, 97% of Finnish national standards were based on European or international standards, while sales of standards constituted about 80% of SFS's funding, and governmental financing amounted to 10% of SFS's funding.[47]

16 While these differences may fade for the European landscape, they remain important for national implementation of the HSs as well as for their access since, as we will see in Section D, HSs are sold exclusively through NSOs, often as "nationalized" standards translated into the national language. It is this interprlay between the European and national that sustains the EU standardisation but that ultimately gives rise to numerous challenges.

C. Access to Processes: Stakeholder Participation

17 Regardless of whether HSs arise from delegated powers,[48] participation in ESOs' is seen as one of the ex ante mechanism within the checks and balances of standardization processes,[49] which furthermore serves as a cornerstone of legitimacy and a complementary source of democratic input.[50] It is partly for this reason that broad stakeholder participation is one of the key priorities on the EU standardization agenda.[51]

18 The goal of broad and inclusive participation is typically directed at two types of actors. The first type can be generally categorized under an umbrella term "civil society": parties that are affected by HSs and have a keen interest in contributing to their development, but have been traditionally isolated from standardization processes, such as consumers, environmental organizations and non-for-profits. The extent to which these stakeholders are included in technical deliberations serves as a useful barometer for legitimacy of ESOs as institutions creating normative material,[52] addressing in part their democratic deficit and enabling consensus among the relevant stakeholders. At the same time, a truly meaningful inclusion of these stakeholders is often challenging due to the lack of funding and a steep learning curve of both the technical substance matters and institutional processes. Furthermore, consensus-building, which is an essential condition for standardization, often takes longer in a heterogenous group of actors,[53] while speed is crucial for the rapidly evolving technology markets.

19 The second type of under-represented stakeholders are Small and Medium Enterprises (SMEs) that amount to a large share of the European industry.[54] While SMEs participation in standardization processes is often essential to be able to access, and survive on, markets, their involvement is often not proportional to large companies, not least due to the lack of operational capacity, funding and technical expertise to tap into.[55] Increasing SME participation further prevents a capture by big market players, especially large non-European companies that dominate the global arena. Broadening the scope of participating actors thus serves two masters: increasing legitimacy of standardization processes and shielding them from unwanted foreign influence.

20 The aforementioned issues are particularly salient for AI standardization. AI systems and technologies integrate different components, which requires not only technical knowledge, but also expertise on fundamental rights and ethics to define and assess such concepts as "bias" and "fairness." In the EU, enabling the involvement of different stakeholders in AI regulation and governance goes beyond opening up ESOs, and includes the establishment of new institutions and processes.[56] However, such outwards-looking policy is a double-edge sword as

46 SFS Suomen Standardit ry, 'Standardointityö On Jaettu Usealle Organisaatiolle' (Standardization Work is Divided Among Several Organisations) (*SFS*) <https://sfs.fi/sfs-ry/meista/toimialayhteisot/> (machine-translated), accessed 8 January 2026.

47 Ibid.

48 See the analysis in Medzmariashvili (n 8).

49 Senden (n 8), 352.

50 See on this in relation to the delegated and implemented acts under Articles 290 and 291, Joana Mendes, 'Delegated and Implementing Rule Making: Proceduralisation and Constitutional Design' (2013) 19 European Law Journal 22.

51 See 2022 Standardization Strategy (n 6), 5.

52 See Annalisa Volpato and 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.

53 See generally, Avinash Dixit, *Lawlessness and Economics: Alternative Modes of Governance* (Princeton University Press: 2007).

54 European Commission, 'Entrepreneurship and Small and Medium-sized Enterprises (SMEs)' (*European Commission*) < https://single-market-economy.ec.europa.eu/smes_en> accessed 6 June 2025.

55 See more generally on SMEs in standardization, Kirti Gupta, 'The Role of SMEs and Startups in Standards Development' (2017) < https://ssrn.com/abstract=3001513> accessed 6 June 2025.

56 The AI Act, for instance, establishes the European AI Board, that among other things, will consult the Commission when preparing standardization requests (Article 65), and the AI Office, which will help ensuring consistent implementation and enforcement of AI Act in the EU (Article 64).

the development of AI standards seems to take longer than expected, leaving the markets in a limbo.[57]

I. Stakeholder Participation at the EU Level

21 In general, there are two avenues through which stakeholders can get involved in the development of European HSs: 1) through Annex III of Regulation 1025/2010 as a European stakeholder organization receiving EU financing in accordance with Article 16 of this Regulation; or 2) through becoming an NSO member or participating in national standardization committees in any other way (e.g. as a stakeholder with voting rights limited to a particular committee or working group). The former seems to be preferred by the European legislator, as Article 5(1) of the Regulation 1025/2012 mandates wide participation and involvement of the relevant stakeholders in different stages of standardization. This obligation is clearly directed to the ESOs, which shall "*encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders, including SMEs, consumer organisations and environmental and social stakeholders in their standardisation activities,*"[58] i.e., standards proposals, technical discussions, commenting, as well as in disseminating information about standards (but not standards themselves!). The wording of this provision suggests that not only should these stakeholders be able to attend the meetings of standardization committees ("appropriate representation") but also to meaningfully contribute to these meetings and, possibly, influence the outcomes ("effective participation").[59] This obligation is also echoed in the "Vademecum on European Standardization", which provides that ESOs have a reporting requirement to indicate how they have encouraged and facilitated, on the basis of Article 5, appropriate and effective participation of all relevant stakeholders, and furthermore provide the list of the categories of stakeholders participating in the development of harmonized standards.[60]

22 While the "European" avenue seemingly guarantees meaningful participation, it also has certain pitfalls. The beneficiaries of Annex III are limited to four types of organizations representing 1) SMEs; 2) consumers; 3) the environment and 4) social interests. To qualify for the funding of Article 16, these organizations must be non-governmental and not-for-profit, tailored to representing the respective stakeholders in European standardization and have a mandate to do so from at least two third of the Member States. Annex III thus does not enable direct participation, but rather a *collective* voice of a particular segment of stakeholders. Yet, SMEs' interest may vary per sector or even per Member State. Similarly, the overarching term "social interests" or "civil society" comprises divergent types of stakeholders whose positions may not always align, and who may experience participation barriers differently. As an example, while Regulation 1025/2012 encourages representation and participation of people with disabilities, Disabled Persons Organizations do not have voting powers in ESOs and are moreover faced with such challenges as a lack of adequate accommodation for participation in standardization meetings.[61] Even if some non-governmental organizations (NGOs) may be well equipped to represent the interests of these four types of stakeholders in European standardization processes, they are in an evident minority in ESOs technical committees, where the balance is typically tilted towards large technical companies. And while the recent reforms in the European standards bodies, notably ETSI, enhanced participatory rights of Annex III organizations, they are still far from being on an equal footing with technical actors.[62]

23 Furthermore, and notwithstanding the recent increase in EU funding for Annex III organizations and the Commission's subsidy to SMEs' representatives,[63] participation in ESOs remains costly for the both types of stakeholders, who moreover view the processes as too complex and time-consuming.[64] On

57 As such, CEN/CENELEC did not meet the initial deadline to adopt HSs for high-risk AI systems. While initially, the HS was supposed to build on the existing ISO/IEC 42001 standard on AI Management System, the discussions at the EU level revealed the incompatibility of this standard with the requirements of the Commission, leading to a longer standardization process. Such an assessment requires specialized knowledge and expertise to take part in the deliberations, while the market players would typically prefer efficient and fast standards development.

58 Regulation 1025/2012, 5(1).

59 See, in parallel, the concept of "meaningful" participation in WTO, 'Decision of the Committee on Technical Barriers to Trade on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement' (1 November 2000) WTO Doc G/TBT/9 TBT, Annex 4, para C (7).

60 European Commission, 'Commission Staff Working Document: Vademecum on European Standardisation in Support of Union Legislation and Policies – Part III: Guidelines for the Execution of Standardisation Requests' (Staff Working Document) SWD(2015) 205 final, 2.6. Note that Vademecum merely serves as a guiding document in a form of soft law and does not impose any legal obligations.

61 'Evaluation of Regulation (EU) No 1025/2012' (n 17), 33-34.

62 For a "Standardisation Governance Act," (n 13); Volpato and Eliantonio(n 53).

63 'Evaluation of Regulation (EU) No 1025/2012' (n 17), 21-23.

64 Evaluation of Regulation (EU) No 1025/2012'(n 17), 33; see also High-Level Forum on European Standardisation, Workstream 3: NSBs Peer-Review (including SMEs and Civil

top of that, the scope of ESOs work has also expanded through the years, covering additional sectors and technologies, and thus requiring even more specialized knowledge and skills from stakeholders in ESOs' technical bodies.

II. Stakeholder Participation at the National Level

24 NSOs would typically agree on a national position among their stakeholders and then send (a) representative(s) to bring this position to ESOs, for instance through contributing to the discussions or voting on a standard's approval. This brings certain advantages: in ETSI, for instance, participation through NSOs allows direct voting power on the adoption of harmonized standards, while the votes of Annex III organizations are not counted in the new Approval Process.[65] What's more, NSOs can participate and vote in the international standards bodies: this means that they can take part in the JTC21, a joint technical committee of CEN/CENELEC which is focused on European standardization in the field of AI.

25 From this vantage point, participation in European standardization through the "national" avenue seems more attractive. For organizations that are not included in Annex III, this is the only option to be involved in standards development. In turn, SMEs enjoy enhanced participation guarantees at the national level, as Article 6(1)(b) of Regulation 1025/2012 explicitly requires NSOs to enable their participation in standardization activities even without NSO membership, while Article 6(1)(d) also requires to provide SMEs with free access to draft standards (which is currently the case only for 54% of NSOs).[66]

26 Yet, while NSOs largely follow the applicable CEN/CENELEC Guides, they establish their own participation rules, operational frameworks, and stakeholder strategies. NEN, for instance, distinguishes between the "regular" and "reduced" membership fees, with the latter applying equally to such categories as SMEs, NGOs and academia.[67] AFNOR, the French NSO, offers different membership packages tailored for different types of stakeholders, and even provides waivers to societal actors.[68] Such price differentiation is typically either enabled by agreements concluded between NSOs and national governments, i.e., ministries responsible for standardization policies, or by tailored subsidies that, again, are granted by the public sector. Financing models thus play a crucial role in providing meaningful opportunities for stakeholders' involvement in NSOs.

27 Furthermore, NSOs across the EU have different operational capacities. To illustrate, NSOs of larger Western Member States, like NEN, AFNOR, and German DIN, have a considerable standardization experience and are active players at the European and global levels; this is different for NSOs from smaller countries like Malta or Lithuania. Hence, an SME from the Netherlands would technically have more chances for their position to be heard in ESOs than a comparable SME in, for instance, Lithuania. This only exacerbates the already existent discrepancies between Member States. As a consequence, the involvement of underrepresented stakeholders in ESOs is fragmented and varies significantly across the NSOs. Recent numbers suggest that SMEs are represented in 31 out of 34 CEN/CENELEC members and 26 out of 39 ETSI members, while participation of societal stakeholders in NSOs varies between 47% and 77%.[69]

28 Most importantly, participation through the "national" route does not solve the issue of balance in stakeholder representation: after all, the majority of AI standards developers in JTC21 are corporate actors, with some large companies having more than one representative.[70] Rather, in the absence of effective opportunities under the "European route", the problem shifts to the national level. The effectiveness of stakeholder participation in European standardization thus hinges on the rules and processes of national standards bodies that are embedded in the legal systems and standardization policies of the Member States, and on the national financial instruments.

Society Inclusiveness) – Recommendations on National Inclusiveness (September 2024) < https://sbs-sme.eu/wp-content/uploads/2024/09/FINAL-Recommendations-HLF-WS-3-NSB-peer-review_v2.pdf> accessed 30 June 2025.

65 Mariolina Eliantonio and Annalisa Volpato, 'The European System of Harmonised Standards. Legal Opinion for EOCS' (2022) < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4055292> accessed 6 June 2025, 32.

66 'Evaluation of Regulation (EU) No 1025/2012' (n 17), 22-23.

67 NEN, 'Normcommissielidmaatschap' (Standardization Committee Membership) (*NEN*) < https://www.nen.nl/normcommissielidmaatschap> (machine translated) accessed 6 June 2025.

68 AFNOR Group, 'Join AFNOR' (*AFNOR Group*, 2025) <https://www.afnor.org/en/about-us/join-the-association/#decouverte > accessed 6 June 2025.

69 'Evaluation of Regulation (EU) No 1025/2012' (n 17), 21-22.

70 Corporate Europe Observatory, 'Bias Baked in: How Big Tech Sets Its Own AI Standards' (*Corporate Europe Observatory*, 9 January 2025) < https://corporateeurope.org/en/2025/01/bias-baked > accessed 6 June 2025.

D. Access to Standards: Copyright and Distribution of Harmonized Standards

29 Public access to HSs has become a much-debated topic in the aftermath of the *PublicResourceOrg* judgement, where the CJEU held that HSs should be disclosed due to an overriding public interest.[71] These discussions are however not new at the national level, as courts of several Member States have previously ruled on the issue of access to national standards that have been equated to law.[72] The puzzle that the European and national courts are trying to solve boils down to the following: while standards bodies have legal ownership of the documents they create, and thus derive part of their income from their sales,[73] once their standards are used for regulatory purposes they acquire a "law-like" function and create binding obligations upon a wide range of actors. Hence, following democratic principles and the rule of law,[74] the texts of such standards should be available to those that are bound by obligations that these standards create. In other words, the law is not for sale.

30 The CJEU in *James Elliott* seemingly put an end to any doubts whether the presumption of conformity makes HSs truly binding by stating that HSs are a part of EU law owing to their legal effects.[75] The appeal decision in *PublicResourceOrg* confirmed it,[76] but left many issues unanswered, including the copyright protection of HSs and how and by whom should these standards be distributed to comply with the judgement. The following attempts to unpack some of these questions.

I. Access to Harmonized Standards at the European Level

31 The fact that the ESOs can hold copyright over HSs is as such not disputed by the New Approach.[77] In fact, the European Commission has previously recognized the sales of HSs as a legitimate mechanism of financing ESOs activities;[78] this recognition however came in times when standards' voluntary nature has not been questioned. CEN and CENELEC's exclusive copyrights over their standards are codified in Article 3 of CEN/CENELEC Guide 10.[79] The exclusive licenses for "publishing, reproducing and distributing" of HSs are however held by their NSO members, who are moreover responsible for making HSs, or their

71 *Public.Resource.Org,* para 85.

72 One of the very few systematic comparative studies on national case law, even though currently dated, was perfomed by Schepel and Falke. Their findings illustrate the divergent approaches and reasonings behind the national courts' decisions: in France, for instance, AFNOR holds a "monopoly" of standard distribution due to its public mission to develop and publish standards, but can nevertheless hold copyright under the French law, while in Austria, Greece, Belgium and Italy, the national courts ruled against the copyright retention. Harm Schepel and Josef Falke, *Legal Aspects of Standardisation in the Member States of the EC and EFTA,* Volume 1: Comparative Report (European Commission 2000) 168. Van Gestel and Micklitz, above n 23, followed later with the analysis of German and Dutch case law on the matter, noting the different conclusions of the courts. The German *Bundesgerichsthof* decision that DIN looses its copyright over private standards that are referenced in law, since their content is attributable to governmental officials who accepted and incorporated the standard, is particularly curious. Had this reasoning is applied to HSs, where the Commission plays a major role in approving, ESOs copyright over HSs may be seriously questioned. However, while public access justifies the exclusion of copyright in Germany, this does not seem to be the case in the EU where, as seen with ETSI, copyright does not preclude free availability.

73 The exact numbers remain unclear, although according to the figures reported by CEN, a loss of revenue from HSs sales would result in a significant deficit. See Davies and Van Wayenberge, above n 10, 169, citing CEN Annual Report 2021 and 2022, both available at < https://www.cencenelec.eu/news-and-events/news/?News%20types[]=3690>. Most recent numbers sugges that for all three ESOs, harmonised standards account for 11% of all standardisation deliverables produced between 2013 and 2024, 'Evaluation of Regulation (EU) No 1025/2012' above n 17, 11. See also annual report 2024 https://www.cencenelec.eu/news-events/news/?News%20types%5b%5d=3690.

74 See the discussion in Volpato, above n 8.

75 *James Elliott,* para 40.

76 *Public.Resource.Org,* para 70.

77 Although it was challenged by some academic commentators, see Alexandru Soroiu, 'The CJEU Dismantles EU Standardisation in C-588/21 P (Public.Resource.Org)" (Verfassungsblog, 19 March 2024) < verfassungsblog.de/eu-harmonised-standards/> accessed 7 June 2025; Sunimal Mendis and Olia Kanevskaia, 'Harmonized technical standards under EU copyright: the Public.Resource.Org judgement' (IPKat, 22 July 2024) <https://ipkitten.blogspot.com/2024/07/harmonized-technical-standards-under-eu.html> [date accessed].

78 Harm Schepel and Josef Falke, Legal Aspects of Standardisation in the Member States of the EC and EFTA, Volume 1: Comparative Report (European Commission 2000) 168, note 10, citing M. Bangemann, in response to Written Question No. 822/91, MEP M. Welsh, (1992) OJ C 2/10.

79 CEN-CENELEC, *Guide 10: Policy on the Distribution, Sale and Copyright of CEN and CENELEC Content*, 5th edn (2024). Specific rules apply to 'Eurocodes', HSs supporting the construction sector; CEN-CENELEC, *Guide 28: Guidelines for the Public Access of Eurocodes and Their National Annexes and Harmonised European Standards under the Construction Products Regulation*, 1st edn (19 June 2014).

translations, available nationally.[80] The licensing terms are defined in the agreements between the ESOs and NSOs,[81] and prices are generally based on the number of pages per document. In this regard, while NSOs enjoy a considerable freedom to set their prices and sales conditions (e.g. discounts for standards bundles), revenues yielded from these sales are given to CEN/CENELEC as their legal owners.[82] This disconnect between rights holders and distributors is not uncommon in copyright law,[83] but in the context of the New Approach, it presents challenges to public availability of *European* standards that, apparently, should be manifested at the national level.

32 These challenges particularly concern NSOs since, without the revenue from standards' sales, they should find an alternative source of income to support their activities and/or to pay dues to CEN/CENELEC.[84] What's more, CEN/CENELEC Guide 10 provides NSOs that do not comply with the copyright and distribution policy risk being excluded from participation in standardization activities or even expelled from the ESOs membership.[85] At the same time, when a breach of ESOs' copyright through unauthorized reproduction or distribution of standards is suspected in the Member States territory, the responsibility to start an individual action lies with the Member State concerned.[86] In this regard, NSOs also have a "last resort mechanism" for the purpose of responding to requests for free access to the standards to the general public: in fact, CEN/CENELEC Guide 10 prescribes that its Members first should use all reasonable efforts to reject such requests, and only grant a sponsored conditional access in close consultation with CEN/CENELEC.[87] It should be noted that, while these provisions are clearly not in compliance with the *PublicResourceOrg,* the current version of the Guide at the moment of writing is the one of January 2024, and thus predates the CJEU decision; accordingly, significant updates of these provisions may be expected in the new versions of the guide.

33 Furthermore, akin to many national standards, HSs implement or are based on standards developed by other bodies, such as ISO and IEC.[88] Making HSs publicly available thus automatically triggers these bodies' copyright, possibly resulting in potential breach of contract and violation of intellectual property rights and affecting the ecosystem of international standardization.[89] Curiously, Guide 10 states that each participant or contributor, including, under specific terms ISO and IEC, that is involved in the development of European standards must grant the rights to their contribution to CEN/CENELEC, which then have the rights to exploit this content worldwide in any format and grant exploitation rights to NSOs and partner organizations.[90] This provision, however, seems to concern contribution of these bodies to HSs development processes and does not stretch to standards that are used as a basis for such HSs.

34 Yet and as confirmed in the recent *Stichting Rookpreventie II* judgement of the Court of Justice[91], ESOs copyrights over HSs, while seemingly undisputed, do not preclude standards availability: for instance, ETSI's standards can be accessed free of charge, and ETSI still retains copyright over them. Hence, whether ESOs will indeed suffer financial consequences as a result of their standards being made publicly available, as it was claimed by CEN/CENELEC in the General Court,[92] largely depends on their business model.

80 CEN-CENELEC, *Guide 1: Status of European Standards*, 1st edn (December 2001), 1; see also Guide 10.

81 CEN-CENELEC, *Internal Regulations, Part 1: Organization and Structure* (1 January 2025), clause 1.5

82 Guide 10, Annex A.

83 Think, for instance, of commercial publishing industry, where the author of the original work is a right holder, but the revenues from distribution largely go to the publishing house.

84 Van Gestel and Micklitz, above n 23, 147, note that previously, NSOs were not able to provide figures for sales of HSs and revenues from them.

85 Guide 10, 1; see also CENELEC, *The Statutes of CENELEC* (adopted 27 June 2024, entered into force 1 January 2025), 9.1.2.

86 Guide 10, 7 (e).

87 Guide 10, 9.

88 Davies and Van Wayenberge, above n 10, 154, note that based on the figures reported by CEN and CENELEC for the first quarter of 2024, approximately 44 percent of all HSs developed by these ESOs were identical to (circa 38 percent) or based on (circa 6 percent) standards published by the ISO or the IEC. More recent data from CEN and CENELEC 2024 Annual Report demonstrates that 62,1% of HSs (779 out of 1.355 HSs published in 2024) were identical to those of ISO and IEC, making the percentage of total standards developed by CEN and CENELEC and that are identical to ISO and IEC international standarrds about 49,6 % (11.129 out of 22.457). CEN and CENELEC, *Annual Report 2024,* < https://ar2024.cencenelec.eu/ > accessed 8 January 2026.

89 At the moment of writing, a case is pending before the EU General Court brought by IEC and ISO against the European Commission, alleging a breach of copyright resulting from the distribution of harmonised standards based on IEC and ISO materials. Case T-631/24 *International Electrotechnical Commission and ISO v Commission* OJ C/919.

90 Guide 10, 3.

91 Case C-155/24, Nederlandse Voedsel- en Warenautoriteit and Others v Stichting Rookpreventie Jeugd EU:C:2026:327 ("Stichting Rookpreventie II").

92 Case T-185/19 *Public.Resource.Org, Inc. and Right to Know CLG v European Commission* EU:T:2021:445, para 66.

35 In this regard, the question that *should* be asked is who is responsible for providing access to these standards.[93] Pursuant to the Vademecum on European standardization, both ESOs and NSOs are expected to seek suitable ways of to make publicly available information that indicates legal requirements covered by a HS as well as information on significant changes to harmonized standards, especially when it comes to providing these to SMEs.[94] This transparency requirement is not an obligation to make the *content* of these standards publicly available, although it is unclear how information on standards' modifications can be useful to stakeholders who do not have access to the text of these standards. It is also in conflict with the earlier Communication of the European Commission on Intellectual Property Rights and Standardization, which provides that standards bodies may lose their status as an ESO if they fail to ensure non-discriminatory access to standards,[95] as well as with Article 6 of Regulation 1025/2012, which lays on the NSOs the obligation to ensure SMEs' access to HSs and, given the lack of any enforcement mechanisms at the EU level, leaves NSOs with a broad discretion to decide how this access should be facilitated. That said, parts of the legal framework that provides these obligations are, again, outdated, since the current version of Vademecum predates the landmark rulings on CJEU. Hence, as it is the case with CEN/CENELEC Guide 10, an update can be expected that will clarify transparency obligations of ESOs and NSOs .

36 The aforementioned Commission's IPR communication introduces yet another important actor in this equation, namely the European Commission itself, which should ensure that all interested parties have access to standards on "fair, reasonable and non-discriminatory basis"[96] when these standards are referred in legislation as mandatory requirements or "as one which confers a particular status under Community law" (possibly meaning the presumption of conformity). What's more, if the Commission believes that a standard is not being made available on these terms, it must withhold or withdraw the standards' approval as a HSs. While this seemingly puts the Commission in the driving seat (which largely follows the line of reasoning of Advocate General Medina),[97] the Commission acting as a catalyst of access to HSs does not square with ESOs' exclusive ownership rights, and NSOs exclusive rights of distribution and reproduction.

II. Access to Standards at the National Level: The Netherlands

37 At the national level, some remarkable discussions on the legal force and accessibility of private standards referenced in law took place in Court rooms and legislative chambers in the Netherlands, making this a good case study for the purpose of this paper. As other EU Member States, the Netherlands has its own legal understanding of standards, rooted in its constituonal traditions and national legislation. Not all standards refenced or cited in the Dutch legislation are considered mandatory. The Dutch Building Decree[98] – a textbook case of the reliance on private standards in safety regulation –,[99] is an illustrative example. While the provisions of the Building Decree refer to a number of NEN standards and convey an impression that the use of these standards is mandatory, the "equivalence clause" of Article 2.5 stipulates that other means of compliance may be used to demonstrate compliance with the requirements of the decree: accordingly, standards in the Dutch building legislation merely raise a presumption of conformity but are not equal to law.

38 The non-mandatory nature of such standards has been confirmed in case law. In 2012, some years before *James Elliott*, the Dutch Supreme Court ruled in *Knooble* that the reference to NEN standards in the Building Decree indeed pulls these standards into the public domain due to their legal effects, but does not make them "laws", since these standards were not published following the procedure that published laws and NEN's function of standards developer is not based on the delegation of public authority.[100] Rather, the Court held that such standards are "outwards applicable general rules"

93 The CJEU in its recent decision Stichting Rookpreventie II ruled that it is irrelevant whether such acccess should be ensured by the EU or its Member States resources, but that it is the EU which has to bear the costs associated with access., see Stichting Rookpreventie II, para 40.

94 Vademecum, above n 61, 2.10.

95 Commission of the European Communities, 'Communication from the Commission: Intellectual Property Rights and Standardisation' COM(92) 445 final (Brussels, 27 October 1992), 6.3.2 and 6.3.3.

96 Fair, reasonable, and non-discriminatory terms (FRAND) refers to the obligation to provide access to property subject to exclusive rights, and is commonly used, for instance, in the licensing of standard-essential patents.

97 AG Opinion in *PublicResourceOrg,* above n 26, para 28.

98 Besluit bouwwerken leefomgeving (Stb 2021, 71), in force from 21 May 2025.

99 See, among others, Richard Neerhof, *Bindende werking van private normen en regels in het privaatrechtelijke bouwrecht* (IBR Publications 2023).

100 Gerechtshof 's-Gravenhage, 16 November 2010, ECLI:NL:GHSGR:2010:BO4175, case nos 200.029.693-01 and 200.031.136-01, 8-9 and 14; confirmed on appeal in Hoge Raad, 22 June 2012, ECLI:NL:HR:2012:BW0393, case no 11/01017 Reference. See also the discussion in van Gestel and Micklitz, above n 23.

that are established on the basis of private law agreements, and it is sufficient if they are available for commercial firms against a "reasonable fee" (without specifying what is reasonable) or can be viewed publicly without hindrance, for instance at the NEN library. [101] Hence, unlike claimed by the plaintiffs, it was not required for the text of these standards to be published in the Dutch State Gazette (*Staatscourant*) as laws and governmental regulations. In a parallel case adjudicated by the Administrative Division of the Council of State, the judges followed the similar reasoning and found that standards that do become binding as a consequence of their reference in the Building Decree, are "outwards generally binding rules", and thus should be announced in *Staatscourant.*[102]

39 In the aftermath of *Knooble,* the practice of referencing NEN standards in national laws and regulations have been brought to the attention of the Dutch Parliament.[103] Two important outcomes of this discussion, that also shaped the current Dutch policy on standardization, were the following: Firstly, standards referred to in national laws and regulations should in principle remain voluntary.[104] However, and secondly, once standards *do* become mandatory as a consequence of this reference, they should be made publicly available free of charge and published as law pursuant to Article 89(4) of the Dutch Constitution. In this regard, the Dutch Drafting Instructions for Legislators name certain cases when the legislator may opt for mandatory compliance with the standard, i.e., when such mandatory obligations are required by EU law, Treaties and decisions of international organizations; or when the regulations at issue are directed towards the governmental institutions where the exclusive application of such standards is desirable or concern the enforcement of criminal norm (for instance in case of measuring methods).[105] In any case, such mandatory reference should be motivated and foreseen by information about where the standard can be found. The requirement of public availability thus only applies to standards that have acquired a public-law character through their citation, or reference to them, in the legislative or regulatory text.

40 Figure 1 schematically illustrates the requirements for standards availability in the Netherlands,

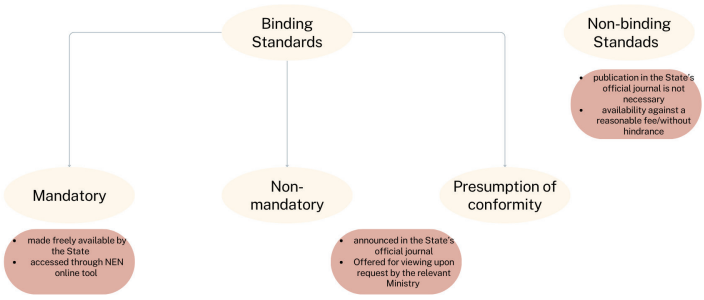

Figure 1: requirements for access to standards in the Netherlands

41 But even if these law-like standards are equated to law, NEN does not cease to hold copyright over them meaning that, at least in theory, offering these standards free of charge inevitably results in the loss of income and affects NEN's ability to finance its standardization activities. As a solution, the Ministry of Economic Affairs in the Netherlands "buys off" NEN's standards that have become mandatory through their reference in the text of law, hence compensating NEN for the (potential) loss of income.[106] In turn, NEN provides such mandatory national standards, and, in the aftermath of *PublicResourceOrg,* HSs free of charge through its online tool upon a free registration.[107]

42 That said, this agreement is only valid between the Ministry and NEN, and hence only applies to NEN homegrown standards. A similar arrangement will not work for HSs and international standards that have been made mandatory through their incorporation and hence, according to Dutch law, should be made publicly available; what's more, placing these standards into public domain will result in the breach of the copyright policy of standards bodies that issued these standards in the first place (although the situation is different for ESOs after the *PublicResourceOrg* ruling).[108] Hence, the Drafting Instructions for Legislators provides that if a mandatory reference is made to an *international*

101 Gerechtshof 's-Gravenhage, 7.

102 Raad van State, 2 February 2011, ECLI:NL:RVS:2011:BP2750, case no 201002804/1/H1, 2.4.5 and 2.4.6.

103 Minister van Economische Zaken, Landbouw en Innovatie, *Brief aan de Voorzitter van de Tweede Kamer der Staten-Generaal: De kenniseconomie in zicht*, Kamerstukken II, 27 406, nr 193 (30 June 2011).

104 Rijksoverheid, Aanwijzingen voor de regelgeving (Stcrt. 1992, 230), 3.48.

105 Ibid.

106 The invoice is provided on the basis of the downloads through online tool, NEN connect.

107 While functional, the tool still has certain limitations. See the case study conducted by (2025) <Linda Zhou, Bas Tissing and Freek van den Oetelaar, 'Project Report: Copyright and Standards' (ILP Lab 2025).<https://ilplab.nl/projects/report-on-opening-technical-standards-and-copyright/> accessed 8 January 2026.

108 See above n 89 and accompanied text.

standard, the price of this standard should not be "unreasonably high"[109] – without, again, defining what "unreasonably high" is and whether, in case the costs of access prove too burdensome for certain stakeholders, they will be mitigated by the State.

43 There is a striking difference between the treatment of the legal effects and presumption of conformity stemming from private standards by the Dutch and European Courts. While in the EU, the fact that standards have legal effects seems to place them into the domain of lawmaking, and thus require these standards to be publicly accessibly based on the rule of law principles and transparency requirements, the Dutch Supreme and Administrative Courts appear not to consider the legal effect of standards sufficient to equate them with the law, and base their decisions on the *source* of the rulemaking authority and their delegated powers. From this vantage point, the conclusion of the Dutch Courts that such standards retain their copyright and should not be made publicly accessible is not astonishing, although the reliance on the vague terms as "reasonable fees" or "reasonable availability" for access to these standards ideally requires further refinement. It is curious however, whether the reasoning of the CJEU would have led it to arrive at the different conclusion than the Dutch Court regarding the copyright protection of HSs. Either way, the question remains whether the Dutch case law, and thus also Dutch standardization policy, will still hold in the aftermath of *PublicResourceOrg* and *Stichting II.*

E. The Expanding Accountability Gap of European Standardization

44 A closer look at the New Approach reveals that it is full of paradoxes that are not easy to resolve. Free access to HSs is desirable yet will likely obstruct the proper functioning of the European standardization system. ESOs' and NSOs' funding depends on the sales of HSs through NSOs yet little research has been done to verify whether and to what extent this is actually the case, as consolidated figures of overall annual EU expenses for standardisation are also unavailable.[110] Most importantly, while providing access to standards and standardization processes is a European requirement, the institutional settings and lack of enforcement of Regulation 1025/2012 at the EU level leaves the *onus* of this obligation on NSOs and Member States. There is nothing "European" about access to European standardization.

45 Even bigger disconnect lies in the shared obligations of European and national bodies, where the Commission requests and approves HSs, ESOs owns HSs and are responsible for the their content, and NSOs distribute HSs while operating within the framework set by national governments. The accountability of governmental bodies appears to be triggered only when standards acquire legal effect through a governmental action, either by the Commission's approval and publication of a standards' reference in the Official Journal of the EU (OJEU) or, in case of Member States, by a regulators' decision to cite a standard in a regulatory document and, at least in the Netherlands, couple this citation with an obligation of compliance.[111]

46 Being the sole license holders for selling HSs in their respective Member States, NSOs find themselves in a bind, bearing the ultimately responsibility of correctly implementing the *European* standardization policy through *national* measures that are often divergence, if not contradictory, to the European requirements.

47 It should not be forgotten that Member States can exercise influence over the HSs even before those are formally adopted into the European legislation and cited in the OJEU, for instance through Articles 10[112] and 11 (formal objection) of Regulation 1025/2012. Similarly, the Commission's power to direct the private ordering of European standardization seems to have grown in prominence over the years: while in past, reforms proposed by the Commission in its Green paper were fiercely opposed by the industry and ultimately abandoned, institutional amendments introduced in the 2022 Standardization Strategy and Regulation 2022/2480 have been, even though reluctantly, implemented by ESOs.[113] But when it comes to providing access as a part of wider transparency obligations, both the Commission and Member States appear hesitant to use the tools available in their regulatory toolbox.

48 On top of that, this already fragile system of interplay between private and public, national and European, hinges on stretched competences conferred upon bodies whose status under EU law remains uncertain. This is an important point from the constitutional perspective, as the legitimization of the New Approach in its current form appears to rest, on

109 Aanwijzingen voor de regelgeving, 3.48.

110 'Evaluation of Regulation (EU) No 1025/2012' above n 17, 43.

111 This entanglement into natinal legal systems may be not to the liking of constitutional pluralists. See the discussion in Vallejo, above n 34, at 184 and 210, engaging with Schepel's seemingly pluralistic take on the legal status of HSs.

112 According to Senden, the rationale behind Article 10 is to mitigate insufficient public and democratic control, and prevent the risks of capture by business interests, Senden, above n 8, 343.

113 See Panagiotis Delimatsis and Zuno Verghese, '"To Antipolis, my sisters!": ETSI as a forum of contestation, collaboration and orchestration' (2024) 37 Innovation: The European Journal of Social Science Research 1305.

the one hand, on voluntarism, and on the other, on checks and balances ensured through administrative and judicial control. In a rather paradoxical manner, the former seems to have diminished as the latter has expanded, revealing the flaws in the system's design.

49 It follows thus that the current institutional and legal landscapes of the New Approach points towards NSOs as the ultimate actors capable of resolving this accountability gap. But such solution comes with criticism and limitations. Firstly, NSOs operate within the national frameworks and in principle can only create rules applicable to national standards. Even if disentangling national standards from European and international ones presents a challenge, overstepping NSOs' competences may trigger legal actions against them or even a Member State. Secondly, and as demonstrated in Section D, Member States' approaches to access to standards documents and processes are intrenched in national laws and differ in terms of funding and resources available nationally to support and promote standardization activities. This inevitably prevents a common approach across all 27 Member States, potentially rising constitutional issues at the national level and risking divergent interpretation and implementation of European standardization policy.

50 In particular, the differences in prices and sales conditions for HSs across NSO lead to inequalities among the Member States when it comes to transparency and access to normative material that, per CJEU case law, has become "a part of EU law." Firstly, it enables forum-shopping among standards users, some of which may be inclined to acquire technical documents by cost-friendly NSO (a practice that anecdotally does not occur too often due to the "gentlemen' s agreements" among NSOs and domestic industry players.) Secondly, these differences preclude correct implementation of Article 6(1) of the Regulation 1025/2012, as the issue of SMEs' access to standards becomes a matter of agreements between NSOs and national governments, where the latter may decide to compensate an NSO for the loss of income that occurred due to the privileged prices for certain stakeholders. This makes national governments intermediaries that fix the lacunae in the agreements between ESOs and NSOs. Such practice of State compensation is common in some European countries, like France and Spain, but is not applied in others, like the Netherlands which, again, adds to discrepancies between national implementation of European rules. Member States thus enjoy a wide discretion when designing their standardization policies and applying their administrative laws to both national and European or international standards. These national regulations, together with the terms of agreements between NSOs and ESOs or national governments, shape the NSOs policies and practices on access to standards documents and standards processes.

51 From a different viewpoint, leaving the matters in hands of NSOs also comes with certain benefits. At the outset of the EU project, national governments have already been asked once to give up some of their regulatory powers in favour of the European Commission; with the New Approach, these powers are once again being wielded, this time to private actors, arguably without a proper act of delegation and with even less control and oversight. The fact that the role of the NSOs has been gradually increasing throughout the years, first moving from merely advising to approving the HSs,[114] and recently gaining the exclusive powers to vote on HSs,[115] are some steps in the direction of inviting more national power and constitutional checks and balances to the New Approach.

F. Fixing, Not Fixating

52 Discussions on access to standards and standardization processes have animated legal scholarship long before *PublicResourceOrg* and, more recently, *Stichting II*;[116] with the Court's rulings, however, the need for pragmatic solutions has become even more evident. One thing is clear: the system of the New Approach, however deficient, has proven to work well for the European integration. The alternatives are gloomy: in the absence of standards, it is the EU and its Member States that will have to develop detailed technical specifications – a task for which they inherently lack time and resources. At the same time, letting standards slip into the domain of private ordering without any public oversight risks fragmenting markets and defeating technical harmonization. Given the institutional and regulatory complexities, how should the New Approach be revived to remain functional yet respect the rule of law?

53 The only solution that has been adopted so far, namely a read-only online portal developed by CEN/CENELEC to be used by NSOs, once again illustrated the tendency of shifting European challenges to the national level. The functionality of this tool allows anyone to consult the text of HSs but precludes from making any copies or screenshots of the document. This tool, I argue, is a lip service to the

114 Joerges and others, above n 8, 48.

115 See Regulation 2022/2480.

116 See, for instance, Bjorn Lundqvist, 'European Harmonized Standards as Part of EU Law: The Implications of the *James Elliott* Case for Copyright Protection and, Possibly, for EU Competition Law' (2017) 44 Legal Issues of Economic Integration 421.

PublicResourceOrg judgement: it only solves the problem of access, and not distribution, missing the bigger picture of free availability of legal texts and the rule of law. Furthermore, and due to the lack of feasible European alternatives, NSOs may consider revisiting their financing model, focusing for instance on producing and selling value-added versions or documents essential for standards' implementation. While understandable from the business viewpoint, such practice risks rendering HSs incomplete or even futile without those additional documents and thus negates the very core of the argument that legal obligations should be known to the public. It seems that the current cure for European standardization is worse than its ailment.

54 Though not intended as a panacea for all flaws of the New Approach, this Article proposes several remedies for fixing the issues of access.

55 Firstly, there is a need to update the current legal framework and policy documents in which European standardization is grounded. Given the case law developments of the past decade, it is striking that the Vademecum has not been updated since 2015, and that Regulation 1025/2012 refers to standards as "voluntary".[117] Article 5 of the Regulation should also be clarified as to the degree of responsibilities that the ESOs and NSOs bear for ensuring a wide stakeholder participation, as should be the role and responsibilities of the European Commission. Furthermore, the Commission should formulate a clear position regarding the consequences of *PublicResourceOrg* decision for ESOs' copyrights and accessibility of standards, which would help clarify the obligations of different actors and institutions of the European standardization ecosystem and fill in the gaps left by the CJEU.[118] Of course, legal and policy changes are notoriously slow to implement, and by the time amendments have been adopted, many acutely needed HSs, such as those in the field of AI, will be already developed and on the market. Nonetheless, greater coherence in European standardization policy could strengthen both the policy framework and the European project, by articulating a clear common position without altering Member States' laws.

56 Secondly, this Article suggests that the inevitable reliance of the EU standardization on agreements between ESOs and NSOs on the one hand, and NSOs and States on the other, artificially fragments the system of standardization. Rather, or additionally, this type of agreements should be concluded between the Commission and Member States. The existing agreements between ESOs and NSOs should also specify conditions for privileged access to HSs standards and to ESOs' processes, strengthened by the commitment of funding from either Member States or the Commission. While ESOs and NSOs may initially be expected to resist this intervention or view it as encroaching on their contractual relationships, they may also consider it a welcome a shift of access and allocation of responsibilities discussions to those with the actual power to address these challenges.

57 Thirdly, HSs should be made available directly through ESOs, rather than NSOs.[119] Currently, once HSs or international standards are referenced in legislation, they become a subject of national administrative law. The issues as accessibility, distribution and reproduction of such standards then become tied to the question whether they acquire a legal force and result in a binding obligation. In this situation, national legislation and judiciary decisions may clash with NSOs' contractual obligations to ESOs and other standards bodies in case they prescribe for their standards to be freely available.[120] While this may indeed put more burden on the ESOs, it also opens opportunities for their increased cooperation with NSOs on such issues as translation and distribution of standards document. Such cooperation could then level the playing field for the European industry and citizens by setting similar conditions for HSs accessibility. This is of course easier said than done, since national differences in administrative and copyright laws remain applicable to HSs that are cited in national regulations. For these reasons, the terms of this arrangement should, again, be prescribed in the agreements between ESOs and NSOs.

58 Finally, there are always options for Member States to streamlining their standardization policies, and for NSOs to make their processes more inclusive. In

117 In contrast, at the national level, landmark case law has led to more prominent legislative changes to access policies, or even amendment of national copyright laws and introduction of compulsory licensing, see discussion in van Gestel and Micklitz, above n 23. On top of that, the definition of HSs appears inconsistent with the terminology of the General Product Safety Regulation (GPSR), leading to incoherences for standards requesting processes, 'Evaluation of Regulation (EU) No 1025/2012' above n 17, 57. It should also be noted that at the moment of writing, the amendment process of Regulation 1025/2010 is still ongoing.

118 See, for a similar argument, Davies and Van Wayenberge, above n 10, 165.

119 This resonates with the advanced financing mechanisms and the increasing role of ESOs in sellings standards proposed in the 1990 Commission's Green Paper.

120 On top of that, interpretation of "public availability" seem to differ in national laws: for instance, in France "public availability" seems to include paywalls, while in the Netherlands, it also covers physical-only access at the NSO premises. Zhou et al, above n 106.

this regard, ESOs, but also the European Commission, can continue serving as facilitators, inviting NSOs and Member States to share their best practices and to learn from each other. In this context, stronger and more experienced NSOs can play a meaningful role in supporting less experienced ones through agreements, capacity-building, education, and exchanges. While changes to national laws are neither feasible nor desirable, such streamlining can nonetheless promote greater coherence across the system. This coherence is crucial especially in the rapidly developing field as AI, where the EU ambition is to become a global standard setter while also preserve its European values[121] requires Member States to speak with one voice.

59 Although each of these solutions entails costs, they offer greater durability and bring standardization closer to the rule of law, while preserving the balance between private expertise and public accountability.

G. Conclusion

60 The New Approach exemplifies a fundamental tension between private expertise and public accountability, in which traditional boundaries are deliberately blurred. Private expertise is indispensable, and one of the principal strengths of the New Approach has been its ability to preserve and mobilize such expertise—an attribute that remains essential for AI and standardization more broadly. At the same time, public accountability has become increasingly salient as standards, including AI standards, acquire greater public significance. Even if the New Approach was conceived not as a form of delegation but as a system of accountability, it is evident that the system is now failing.

61 In this light, access to HSs and standardization processes becomes particularly crucial. To comply with the legal requirements for high-risk AI systems and anticipate market developments, industry actors need HSs before the relevant provisions of the AI Act are fully enforceable. At the same time, the increased participation of Annex III organizations and SMEs in standards development, while necessary due to the specifics of AI as well as for the alignment of these standards with EU democratic values and interests, delays the speed with which HSs for AI are created. What's more, AI in itself is a moving target: the recent soar of Large Language Models (LLMs) and Generative AIs, and the consequent hasty changes to the draft AI Act in 2023, confirmed yet again how technology development outpaces regulatory efforts. Hence, if we are to regulate AI with the New Approach, we need to preserve its benefits, and to release what no longer serves us.

62 In this regard, the recent line of case law raises a lot of questions on the limits of private ordering of European standardization, the legal value of European standards and the role of ESOs as semi-regulators. These questions touch upon some very fundamental constitutional issues, such as competences to regulate and shared accountability for the legal material produced outside public bodies. While these questions are not without merit, it should be recalled that the European standardization has never been about the delegation of powers in the first place, but rather about bring private powers into the public sphere.[122] In this context, HSs have been meant as opposites to the law: a non-binding product of the industry, for the industry, aiming to bring agility to public policy, but not to replace it. By a curious chain of contradictions, it is the very voluntary nature of HSs that led them to have legal effects and cause the current impasses, where the challenges of integrating private expertise into law-making became a discussion on the rule of law and, eventually, should be solved through financing.

63 But while rooted in technical complexities and layers of regulation, this discussion also runs deeper, illustrating a common EU problem of safeguarding "European" through "national". In this regard, as the New Approach generated path dependencies that in a way limit the flexibilities of future regulatory reforms, it is also likely to pass on the issues of transparency into different domains, adding to the urgency of addressing these issues now. Fixing the system is not just about making HS publicly available, but revisiting deep-rooted problems stemming from past intentions.

64 It will most likely take a long time and a chain of litigation processes and policy changes before this impasse is resolved. In the meantime, it is worth remembering a common aim that underlies the effort to find the solution: a strong Internal Market in the EU that is based on the rule of law.

121 See AI Act, 40 (3) and recitals 1,2,6; Mario Draghi, *The Future of European Competitiveness: Part A – A Competitiveness Strategy for Europe* (Publications Office of the European Union 2024) 5 < https://commission.europa.eu/document/download/97e481fd-2dc3-412d-be4c-f152a8232961_en> 5, accessed 7 June 2025.

122 See, in this regard, Joerges and others, above n 8.