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The Private Administrative Law of Technical Standardization

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Abstract: The nature and place of technical standards has remained an enigma for EU law and legal thought, despite their ubiquitous part and growing importance in market-building processes within and beyond Europe. The significance and intractability of this enigma has been heightened by the landmark *Fra.bo* (2012) and *James Elliot* (2016) judgments of the ECJ. These judgments have prompted contradictory positions regarding the publicity and justiciability of technical standards among European legal scholarship and even between the European Commission and the European Parliament. The enigma and these contradictory positions have recently reached the ECJ again through the *Stichting Rookpreventie* case currently under review by its Grand Chamber. Drawing upon a reconstructive analysis of these and other relevant legal sources concerning technical standardization in Europe, this paper surmounts these seeming contradictions by advancing a new account of these legal developments. Contrary to the mainstream positions nowadays in tension, the article argues that these judgments have reaffirmed the New Approach and the distinctive place of technical standardization organizations in the European legal order while avoiding dysfunctional modes of judicialization. It has done so by acknowledging the techno-political character of technical standards and aptly delineating institutional competences between the government and the judiciary throughout technical standardization processes. To guide future legal thinking and reasoning on these processes, the paper recasts these legal developments through the idea of a 'private administrative law' as signifying the way that EU Law has transformed the nature and place of technical standardization in the internal market and as an eventual means for the global reach of EU law.

'The internal administrative law of standardisation, after all, was hardly developed by a sense of civic awakening among industrial circles, or by a spontaneous due process

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revolution in the engineering profession. Rather, it has been the result of a long and intricate process of normative borrowing—and sometimes imposition—of norms and principles from different legal sources.' Harm Schepel, *The Constitution of Private Governance—Product Standards in the Regulation of Integrating Markets* (Hart Publishing, 2005), 414.
'. . . ironically, standards have not been completely standardized.' David Hemenway, *Industry Wide Voluntary Product Standards* (Ballinger Publishing, 1975), 8.

I. The enigma of technical standards in EU law and legal thought

Technical standardization norms and processes have become prominent features of post-national policy making. These norms are produced by an array of supranational standard-setting organizations (SSOs), such as ISO (International Organization for Standardization), CEN (European Centre for Standardization), or CENELEC (European Electrotechnical Committee for Standardization), which have attained significant degrees of regulatory authority to shape markets within and beyond the state. At the European Union (EU) level, this regulatory empowerment gradually took off after the development of the so-called 'new approach to technical harmonisation' in 1985 (the New Approach). At the global level, it proliferated since the reference to 'international standards' became crystallized in the World Trade Organisation (WTO) Agreement of Technical Barriers to Trade in 1995 (the TBT Agreement), notwithstanding the experimental role that the Standards Code of 1979 developed under the General Agreement on Tariffs and Trade (GATT) already had in these respects. Nowadays, the regulatory powers and authority of these SSOs have not only consolidated. As some recent announcements of the EU indicate, these powers are steadily increasing in scope, substance, and geographical reach.

Regarding their scope, while typically associated with industrial goods and processes, technical standards have recently been extending into the realm of services.[1] In terms of substance, for a long time, the focus of technical standardization had been on reconciling the values of free trade and social protection by ensuring the compatibility or quality of products. Today, technical standards are rather informed by a much wider set of policy goals, such as promoting sustainability, competitiveness, and innovation in the transition towards a digital and circular economy.[2] Furthermore, technical standardization processes have also become a

[1] See 'service standards' (*European Commission*) https://ec.europa.eu/growth/single-market/services/service-standards_en; and Commission, 'Standardisation Package 2016: European standards for the 21st Century' COM (2016) 358 final, pp. 9–11 justifying the extension by the fact that 'services account for 70% of the EU economy, yet service standards only account for 2% of all European standards . . . [and] national service standards can constitute barriers to cross-borders service provision'.
[2] See, for example, Commission, 'A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020' COM (2011) 311

strategic pillar in the EU's path towards a 'global reach', operating as a vehicle to purportedly re-configure foreign and transnational markets.[3] Technical standards have thus attained a pivotal place and role in the contemporary law of political economy.[4]

Despite their growing importance in public policy and transnational governance, technical standardization used to be a relatively marginal topic in law and legal studies. The topic was normally approached, if at all, in a fragmented way: whether from the perspective of tort law, antitrust law, copyright law, trade law, contract law, or administrative law. This neglect has been increasingly addressed during the last years through several legal studies that have examined technical standardization practices in encompassing and multi-dimensional manners.[5] Harm Schepel's 2005 monograph on the topic may fairly be given a seminal place in overcoming such opacity and marginality, as it pioneered the elaboration of technical standardization as an object of systematic legal inquiry by drawing upon the tradition of critical social theory and pluralist approaches to law and legal thought.[6] Yet, if the technical standardization phenomenon was already problematic from a legal perspective within the EU by the turn of the

final; and, more recently, Commission, 'ICT Standardisation Priorities for the Digital Single Market' COM (2016) 176 final. For its context and subsequent implementation until 2020, see also 'ICT standardisation' (*European Commission*) <https://ec.europa.eu/growth/single-market/european-standards/ict-standardisation_en>.

[3] See the Commission, 'Joint Standardisation Initiative under the Single Market Strategy' (2016) <https://ec.europa.eu/growth/content/joint-initiative-standardisation-responding-changing-marketplace_en> established in collaboration with several European standardization bodies, member states, and industry representatives promoting, among other priorities, 'the European regulatory model supported by voluntary standards and its close link to international standardisation in third countries' (at p. 7). See also, the European Parliament's resolution of 4 July 2017 on European standards for the 21st century [2018] 2016/2274(INI) OJ C334/2, para. 9 stressing 'the importance of promoting European standards at a global level when negotiating trade agreements with third countries'.

[4] For an overview, Poul F Kjaer, 'The law of political economy: An introduction' in P F Kjaer (ed.), *The Law of Political Economy: Transformation in the Function of Law* (Cambridge University Press, 2020); and David Kennedy, 'Law and the political economy of the world' in G de Búrca, C Kilpatrick, and J Scott (eds), *Critical Legal Perspectives on Global Governance: Liber Amicorum David M Trubek* (Hart Publishing, 2014).

[5] See, *inter alia*, P Delimatsis (ed.), *The Law, Economics and Politics of International Standardisation* (Cambridge University Press, 2015); J L Contreras (ed.), *The Cambridge Handbook of Technical Standardization Law: Volume 2: Further Intersections of Public and Private Law* (Cambridge University Press, 2019); and M Cantero and H-W Micklitz (eds), *The Role of the EU in Transnational Legal Ordering: Standards, Contracts and Codes* (Edward Elgar Publishing, 2020).

[6] See, H Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Hart Publishing, 2005): presenting the whole monograph as a constructivist project of articulating 'the non-existent discipline of "standards-law"'. In this sense, see also the latest contribution by M Eliantonio and C Cauffman, 'The legitimacy of standardisation as a regulatory technique a cross-disciplinary and multi-level analysis: An introduction' in M Eliantonio and C Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique A Cross-disciplinary and Multi-level Analysis* (Edward Elgar, 2020): reviewing a much wider range of contemporary legal approaches to technical standardization, and acknowledging how 'Schepel's contribution remains a major book in the area of standardisation'.

century,[7] in the light of more recent legal developments, it has become a veritable legal conundrum.

This conundrum is manifested in at least three puzzles that are currently pervading EU law and legal thought on technical standards. The first puzzle is that although it is generally accepted that after the European Standardisation Regulation 2012 and *Fra.bo* (2012) technical standardization processes in the EU have become 'juridified',[8] paradoxically, these processes have been at the same time regarded 'in essence' as 'immune to judicial control' and thereby are in breach of 'the principle of effective judicial protection'.[9] The second puzzle is that while the European Court of Justice (ECJ) established in *Fra.bo* that under certain circumstances SSOs must be regarded as exercising public powers,[10] access to these standards nevertheless remains protected by copyright and thereby fails to meet basic parameters of publicity in law making.[11] The final puzzle stems from the landmark *James Elliot* judgment by the ECJ in 2016. In spite of the ECJ declaring in *James Elliot* that harmonized technical standards (HTSs) are 'part of EU Law' as 'measures implementing or applying an act of EU Law',[12] oddly the rule-making practices of European standard-setting organizations (ESOs) are not subject to equivalent legal requirements applicable to analogous EU bodies.[13] The purported justiciability, publicity, and legal status of technical standards are thus three salient puzzles currently vexing EU legal ordering in this field.

These puzzles in turn elicit an overarching conundrum that is impinging on the arrested development of technical standardization in EU law and legal thought. This conundrum builds upon some relatively uncontroversial

[7] C Joerges, H Schepel, and E Vos, 'The law's problems with the involvement of non-governmental actors in Europe's legislative processes: The case of standardisation under the "New Approach"' (European University Institute, 1999) Working Paper <http://cadmus.eui.eu//handle/1814/154> accessed 28 April 2018.

[8] H Schepel, 'The new approach to the New Approach: The juridification of harmonized standards in EU law' (2013) 12 *Maastricht Journal of European and Comparative Law*, 521.

[9] M Eliantonio, 'Judicial control of the EU harmonized standards: Entering a black hole?' (2017) 44 *Legal Issues of Economic Integration*, 395: analysing eventual procedural paths to challenge harmonized technical standards in the EU legal order and emphatically concluding that 'the current system of judicial protection of the EU standardization process does not respect the principle of effective judicial protection' (at p. 407).

[10] Case C-171/11 *Fra.bo* [2012] ECLI : EU : C:2012:453.

[11] R van Gestel and H-W Micklitz, 'European integration through standardization: How judicial review is breaking down the club house of private standardization bodies' (2013) 50 *CML Rev*, 145, 158–60, 175–7: arguing that if 'the line of *Fra.bo* [is to be followed] it is hard to imagine why the normal rules with respect to the publication of laws and regulations would not apply to standards that *de facto* determine the scope or content of these rules'.

[12] Case C-613/14, *James Elliott* [2016] EU : C:2016:821, paras 40 and 34 respectively.

[13] L Senden, 'The constitutional fit of European standardization put to the test' (2017) 44 *Legal Issues of Economic Integration*, 337, 352: discussing *James Elliot* and concurrent decisions to conclude that, while the EU legal order has lately 'set some conditions for the lawful delegation of powers to—both public and private—bodies other than the Commission, . . . the lack of constitutional safeguards in the Treaties for this type of delegation is in sharp contrast with those that have been put into place by the Treaty of Lisbon regarding the Commission's own exercise of power'.

observations. The primary observation is that HTSs have been officially bestowed with the exercise of 'public powers' of a regulatory character (*Fra.bo*). In addition, HTSs have also been regarded as 'part of EU Law' and specifically given an administrative function in 'implementing or applying [acts] of EU Law' (*James Elliot*). Given the acknowledged regulatory character and administrative functions that technical standards perform in EU law, this overarching conundrum thus concerns the question of why technical standardization powers are not subject to the types of conditions of validity and accountability mechanisms (such as publicity and judicial review) applicable to comparable EU administrative bodies or agencies when exerting analogous regulatory powers in the EU legal order?

The political significance and intractability of this conundrum is perhaps best epitomized by the contradictory positions that leading EU institutions have taken in this respect. The European Commission has expressed in official instruments the view that HTSs have become fully justiciable in their 'validity and interpretation' after the *James Elliot* judgment.[14] Conversely, the European Parliament has at the same time issued an official resolution in response to the *James Elliot* judgment declaring that '. . . *standards cannot be seen as EU law*, since legislation and policies regarding the level of consumer, health, safety, environment and data protection and the level of social inclusion are determined by the legislator'.[15] Likewise, the ECJ itself has voiced a similar bewilderment with the nature and place of technical standards in the EU legal order when inviting interested parties in the *Stichting Rookpreventie* case currently pending at its Grand Chamber to comment on the relevance of *James Elliot* 'in order to establish the legal status of [technical] standards'.[16] Although the nature and place of technical standards have been a perennial *problematique* for modern legal orderings, after the *James Elliot* judgment they have become an outright enigma in EU law and legal thought.[17]

This paper elaborates an account that surmounts this entrenched enigma by drawing upon 'the idea of a private administrative law'. As I have articulated elsewhere, in synthesis, this idea signifies the way that the EU has transformed through different legal means the nature and roles of several modes of private regulatory authorities that are currently operating within and beyond the internal market. Alongside the acknowledgement of the regulatory nature of their powers

[14] Commission 'Better Regulation Toolbox: Tool 18—The choice of policy instruments', sec. 3.2 on 'technical standards' (2017) <https://ec.europa.eu/info/sites/info/files/file_import/better-regulation-toolbox-18_en_0.pdf>, p. 114 fn 161.

[15] European Parliament resolution of 4 July 2017 on European standards for the 21st century [2018] 2016/2274(INI) OJ C334/2, para. 4 (emphasis added).

[16] Case C-160/20, *Stichting Rookpreventie Jeugd and Others* [Case in Progress]: 'Questions for written answers' on file with the author.

[17] 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*, 323, 335: noting how 'the contributions to this special issue have shown that EU law, while embracing hybridity, has not yet found a way to come to terms with it' and that technical standardization within EU Law currently amounts to an 'unresolved dillemma'.

in an array of policy fields, this idea highlights how the EU has consistently reconfigured how those powers must be exercised through a range of formal and substantive conditions of validity (or 'rules of recognition'), which are neither equivalent to those applicable to 'governmental' (public) agents nor to 'civil or commercial' (private) actors. I argue that these reconfigurations instead convey a new legal grammar that the EU has been incrementally creating with respect to ubiquitous modes of private regulation, in between the realms of private and public law, which can be productively conceptualized as an emergent field of 'private administrative law'.[18]

Via the prism of private administrative law, this article overcomes the referred enigma that is nowadays halting the understanding of technical standardization in EU law and legal thought. It does so by explaining and vindicating why HTSs can be regarded as 'part of EU Law' (*James Elliot*) and at the same time subject to different conditions of validity than those applicable to EU administrative agencies when exercising similar—but not identical—modes of 'regulatory powers' (*Fra.bo*). This entails several interventions in the ongoing debate regarding the relationship between EU law and technical standardization processes outlined above. *With* Schepel, I argue that a functionalist approach to technical standardization within the EU is worth preserving. However, *contra* Schepel, I contend that this requires a move away from the 'pluralist' paradigm about private regulatory authority of SSOs that Schepel has explicitly embraced. Rather, one can transcend the seeming contradiction between the functionalist configuration of HTSs within the EU legal order and their subsequent 'juridification' by representing these modes of private regulatory authority through the category of 'administration' and the idea of a 'private administrative law' more generally.

Against Schepel and much contemporary EU legal scholarship in the field of technical standards, furthermore, I argue that when placed in this frame of reference the *James Elliot* judgment can be read as reaffirming rather than undermining (or liquidating) the modernist model of private regulatory authority that the EU established under the New Approach. As this paper emphasizes, the appeal of this argument does not solely stem from its explanatory merits. This appeal also derives from its normative capacity of concurrently acknowledging the techno-political character of HTS processes, while avoiding dysfunctional modes of judicialization. Finally, *beyond* Schepel, the article stresses how the idea of a private administrative law brings to light crucial aspects about HTSs that were not considered within the scope of Schepel's book nor in the 'pluralist' vision of law

[18] I have elaborated upon the jurisprudential and doctrinal bases of this idea, as well as some of its main analytical parameters, in R Vallejo, 'After governance? The idea of a private administrative law' in P F Kjaer (ed.), *The Law of Political Economy: Transformation in the Function of Law* (Cambridge University Press, 2020); and R Vallejo, 'Voyaging through standards, contracts, and codes: The transnational quest of European regulatory private law' in M Cantero and H-W Micklitz (eds), *The Role of the EU in Transnational Legal Ordering: Standards, Contracts and Codes* (Edward Elgar Publishing, 2020).

informing it, namely questions concerning the effectiveness and material impacts of HTS processes. In elaborating the idea of a private administrative law as the EU approach to HTSs, I thus offer an innovative interpretation of the latest legal developments in the field and a conceptual frame that seeks to push the debate beyond its current gridlock.

In substantiating these propositions, the paper proceeds as follows. After clarifying the object and context of analysis, Section II revisits Schepel's seminal conception of HTS processes. In the light of certain dissenting opinions in contemporary legal scholarship, I first review its foundations and aims to clarify why Schepel's monograph has had a seminal place in structuring much of contemporary legal thinking about technical standardization processes. Yet, I also underscore some key contradictions in Schepel's analysis. The section concludes by stressing how these contradictions have markedly contributed to the current enigma regarding the nature and place of technical standards in the EU legal order.

On these bases, the rest of the article discusses how the idea of a private administrative law overcomes this enigma. Section III elaborates a historiographical analysis of the development of technical standardization in the internal market, explaining how and why the EU has been incrementally (re-)configuring the terms of private regulatory authority exercised by ESOs through HTSs since the establishment of the New Approach. Throughout this analysis, my overall argument is that the EU has been incrementally constituting what can be productively conceived as a private administrative law of technical standardization based on the legal recognition of their regulatory authority and the progressive institutionalization of transparency, participation, rationality, and a complex scheme of non-judicial review regarding the terms of their exercise. This argument nuances the current widespread view once advanced by van Gestel and Micklitz regarding how European courts were 'breaking down the club house of technical standardisation bodies'.[19] In contrast, I underscore the leading role that the EU legislator and government had been consistently taking long ago in this respect *vis-à-vis* the courts.

Section IV, in turn, addresses the significance of the ECJ's *Fra.bo* and *James Elliot* judgments within this overall scheme. In contrast with the vast attention that *Fra.bo* has received as a purportedly landmark case in EU internal market law, I argue that the judgment is rather cryptic in its foundations and not particularly innovative in its outcomes from the perspective of technical standardization law. *James Elliot* is the truly landmark case from this perspective, yet not for the reasons that have usually been attributed to it in European legal studies. Through an in-depth analysis of the opinion of AG Sánchez-Bordona and the reasoning of the ECJ, the section shows that, instead of 'judicializing' technical standards by an outright subjection of HTSs to judicial review, the ECJ aptly delineated

[19] Gestel and Micklitz (n 11).

institutional competences between the government and the judiciary regarding HTS processes. It did so by limiting its jurisdiction over HTSs to interpretative questions—in ways that are consistent with its previous case law on the matter—thereby deferring issues of their abstract validity to the political process. More importantly, in *James Elliot* the ECJ explicitly acknowledged for the first time the peculiar nature and place of HTSs in the European legal order, as modes of private regulatory authority conducive to the implementation of public policy programmes that are neither equivalent to public nor private action. I thus take *James Elliot* as giving formal legal recognition to the idea of a private administrative law within the European legal order. To make it clear, my argument is not that private administrative law is something that should happen. My argument is that private administrative law is already happening; private administrative law is positive law.

The final section concludes by discussing how this idea of a private administrative law not only addresses the contradictions and overarching conundrum of HTSs in the EU legal order, but also provides an appraisal of the technical standardization phenomenon and the number of its challenges ahead. These challenges include how to realize their immanent commitments to principles of the transparency, participation, and publicity of technical standardization processes, as well as to ensure their regulatory effectiveness and legitimacy in safeguarding social needs, which have been revamped into the EU Law agenda by the *PIP* cases litigated in several European courts and the referred *Stichting Rookprevent* ie case. As this concluding section explains, the idea of a private administrative law does not have ready-made answers to these challenges. Instead, the idea of a private administrative law provides the structure upon which the socio-political conflicts and deeds regarding these challenges continues to unfold within and beyond the European legal space.

It is important to stress that underlying and interconnecting these different legal propositions there is a distinctive jurisprudential thread. Through the perspective of critical social theory, Harm Schepel has influentially advanced a 'legal constructivist' approach to technical standardization processes. This approach essentially underscores the juris-generative properties of these processes without or beyond the state.[20] By illuminating how these juris-generative properties are to a relevant extent enabled, shaped, and constrained by legal or political officials of the state (or member states, such as the EU), in contrast, the idea of a private administrative law that this article advances can thereby be understood as an exercise in 'legal reconstructivism'.[21]

[20] See mainly H Schepel, 'Rules of recognition: A legal constructivist approach to transnational private regulation' in H Muir Watt and D P Fernández Arroyo (eds), *Private International Law and Global Governance* (Oxford University Press, 2014).

[21] On the distinction between legal constructivism and legal reconstructivism in contemporary legal thought, see S Tschorne, The Theoretical Turn in British Public Law Scholarship PHD, The

II. Schepel's vision of 'standards-law' and its contradictions

We live in 'a world of standards'.[22] Nowadays, almost every product we buy, service we receive or perform, and transaction we make relies upon some mode orf standard or are themselves part of broader standardization cycles.[23] As a result, a large part of our daily lives whether as producers, investors, traders, workers, patients, students, or consumers are actually 'governed through standards'.[24] In this sense, standards currently have an almost ontological role, assigning identities or generating new modes of subjectivities that contribute to define who we 'are' or each of us may potentially 'become'.[25] In an era when 'free markets' and 'free movement' appear to rule, ironically it is standards that hold an ubiquitous place and pervasive role in disciplining almost each and every aspect of our socio-economic lives.[26]

Within this vast 'world of standards', the realm of technical standardization conveys a prominent region or microcosm.[27] One explanation comes from its long history in national legal systems, which makes technical standards probably the most emblematic example of standardization practices (and of private

London School of Economics and Political Science (LSE) (2016) <http://etheses.lse.ac.uk/3441/> accessed 17 February 2017.

[22] N Brunsson and B Jacobsson, *A World of Standards* (Oxford University Press, 2002).

[23] S Botzem and L Dobusch, 'Standardization cycles: A process perspective on the formation and diffusion of transnational standards' (2012) 33 *Organization Studies*, 737. See further, T M Egyedi and K Blind (eds), *The Dynamics of Standards* (Edward Elgar Publishing, 2008).

[24] S Ponte, P Gibbon, and J Vestergaard, 'Governing through standards: An introduction' in S Ponte, P Gibbon, and J Vestergaard (eds), *Governing through Standards: Origins, Drivers and Limitations* (Palgrave Macmillan, 2011). See further, S Timmermans and S Epstein, 'A world of standards but not a standard world: Toward a sociology of standards and standardization' (2010) 36 *Annual Review of Sociology*, 69, 72: stressing how modern life is governed by a 'plethora of standards' that include 'labor standards, the standard of living, sexual double standards, grading standards, human rights standards, standards of proof in court, food standards, animal welfare standards, standard time, safety standards, gold standards, standards of decency, national standards in education, and many more'.

[25] M Lampland and S Leigh Star, 'Reckoning with standards' in M Lampland and S Leigh Star (eds), *Standards and Their Stories: How Quantifying, Classifying, and Formalizing Practices Shape Everyday Life* (Cornell University Press, 2009); V Higgins and W Larner (eds), *Calculating the Social: Standards and the Reconfiguration of Governing* (Springer, 2010).

[26] M Power, *The Audit Society: Rituals of Verification* (Oxford University Press, 1999); J Vestergaard, *Discipline in the Global Economy?: International Finance and the End of Liberalism* (Routledge, 2009); and B Hibou, *The Bureaucratization of the World in the Neoliberal Era: An International and Comparative Perspective* (Springer, 2015).

[27] For the purposes of this paper, I take as a baseline the definition of a 'standard' given by European Standardisation Regulation 2012, articles 2.1 and 4 as 'a document that prescribes technical requirements to be fulfilled by a product, process, service or system, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory'. In this same vein, see also the WTO TBT Agreement, annex 1, paras 1–2 and the Market Surveillance Regulation 2008, article 2 n. 9; and the Information Directive 2015, Article 1 n. 1 (g) and (f). For different permutations in the notion of standards across disciplines, see H De Vries, 'Standardization—what's in a name?' (1997) 4 *Terminology—International Journal of Theoretical and Applied Issues in Specialized Communication*, 55.

regulatory authority in general) throughout the development of modern law.[28] Another reason is that their enduring pedigree as customary or expertocratic norms, embodying the 'state-of-the-art' or the 'acknowledged-rules-of-technology' in politically unproblematic ways, has been increasingly eroding due to at least two distinctive factors. The first factor is geopolitical. Whether at the European (CEN, Cenelec, ETSI) or international levels (ISO, IEC, and ITU), the supranational harmonization of technical requirements usually entails transplanting, adapting, or overriding established national positions and regulatory traditions, which inevitably make HTS processes prone to interest representation and harsh political disputes.[29] The second factor is the renewed substantive focus that HTSs have attained. HTSs have markedly moved from a focus on mere 'technicalities', such as the sizes or compositions of electrical plugs, automobile tyres, or computer interfaces, towards more qualitative aspects of goods or services that are more evidently 'political'. These qualitative aspects include health and safety requirements, and increasingly also stringent questions regarding the sustainability and accessibility in the development of goods, services, or processes (including the use of personal data).[30]

[28] This history is mainly connected to the establishment of several standard-setting organizations at a national level during the early twentieth century, including the Bristish Standards Institution (BSI) in the UK in 1901, the Deutsches Institut für Normung (DIN) in Germany in 1917, the American National Standards Institute (ANSI) in the USA in 1918, and the Association Française de Normalisation (AFNOR) in France in 1926. For an overview of their evolution in modern legal imaginaries, see K-H Ladeur, 'The changing role of the private in public governance: The erosion of hierarchy and the rise of a new administrative law of cooperation. A comparative approach' (2002) 9 EUI Working Paper LAW 7–17 <https://cadmus.eui.eu/handle/1814/187> accessed 30 June 2020.

[29] T Büthe and W Mattli, *The New Global Rulers: The Privatization of Regulation in the World Economy* (Princeton University Press, 2011) 8, 10–11: explaining that standard-setting processes at the supranational level: 'typically [have] important distributional implications, generating winners and losers. To lose may mean higher production costs, steeper costs of swtiching to international standards, lower international competitiveness, loss of export markets, and even risk of corporate demise … In short, global private regulation should be understood and analysed as an intensely political process, even if the politics may be hidden beneath a veneer of technical rethoric'. With respect to the EU level, see likewise M Egan, *Constructing a European Market: Standards, Regulation, and Governance* (Oxford University Press, 2001) 134–6, 144: 'Though discussions are defined by functional areas, with different sets of interests and constituencies mobilized by different issues, the technical becomes political when it becomes policy relevant. Divergent notions of safety, risk assessment, and the unwillingness of participants to accept different national concepts and administrative practices raises numerous difficulties for those involved in standard-setting'.

[30] See, for example, European Standardisation Regulation 2012, recital 19 stating how: 'Standards can contribute to helping Union policy address the major societal challenges such as climate change, sustainable resource use, innovation, ageing population, integration of people with disabilities, consumer protection, workers' safety and working conditions'. Moreover 'by driving the development of European or international standards for goods and technologies in the expanding markets in those areas, the Union could create a competitive advantage for its enterprises and facilitate trade, in particular for SMEs, which account for a large part of European enterprises'. At the international level, see also in this sense the 'ISO 14000 series on environmental management' (*ISO*) <https://www.iso.org/iso-14001-environmental-management.html> and the set of technical standards that are being developed by ISO in order to meet the 'UN sustainable development goals' (*ISO*) <https://www.iso.org/sdgs.html>; or, regarding data protection, the 'ISO/IEC 2700

Alongside this ubiquitous place and expanding regulatory authority of SSOs at the European and global levels, the seminal place that Schepel's 2005 monograph has achieved in contemporary EU law and legal studies about HTSs is a well-deserved one. More than 15 years after its publication, Schepel's monograph is still considered 'a major book' as it is 'perhaps even the only one, so far, dealing exclusively with standardization in the context of law and governance'.[31] Yet, at the same time, the wide scope of Schepel's book has been read as too dispersed in the geographical scope of its analysis and thereby as signalling a perceived 'gap' in the understanding of the nature and place of HTSs within EU law and governance.[32]

I disagree. This section explains why Schepel's monograph is best understood as an incisive intervention and comprehensive re-framing of prevalent modes of legal and technocratic thinking about HTSs in Europe. I first argue that there is no gap in Schepel's analysis: by duly combining EU law analysis with an extensive range of comparative references, Schepel's 2005 monograph articulates what can be regarded as a complete theory about the nature and place of European standardization within EU law and governance. As Section II.A explains, what makes the monograph particularly innovative is how Schepel transcended the ubiquitous technocratic or legalistic representation of technical standardization processes, by elaborating a 'pluralist' account of technical standardization as regulatory spaces of para-constitutional politics aligned with the functionalist tradition of modern law and legal thought.[33]

However, once this content and aim of the monograph is clarified, Section II.B points to at least two aspects in Schepel's argument that are contradictory and problematic. The first aspect is that Schepel's argument is internally inconsistent with the alleged legal pluralist premises that are deemed to sustain it (and especially the Teubnerian variety of legal pluralism that Schepel endorses). Schepel's argument is actually much closer to the legal republicanism of Habermas than Schepel would like to acknowledge. More importantly, this internal inconsistency is relevant because it has largely contributed to the perplexity and overall enigma that HTS processes hold nowadays in EU law and

series on information security management' (*ISO*) <https://www.iso.org/isoiec-27001-information-security.html>.

[31] Eliantonio and Medzmariashvili (n 17), 327–8.

[32] Ibid 328: noting that 'However, the scope of [Schepel's] book is quite wide and covers standardization in various jurisdictions: the EU, the US and Mexico. Only two chapters discuss standardization in Europe, including six Member States, as well as standardization at the EU level'. This is taken as a basis to conclude that 'To date, despite, on the one hand, its importance for the process of European integration and for the global competitiveness of the European economic and, on the other hand, its dubious legal nature, there is no comprehensive scholarly work attempting to place the process of European standardization within the system of European governance'.

[33] For a contemporary retrospective about the functionalist tradition in modern law and legal thought, see M Loughlin, 'The functionalist style in public law' (2005) 55 *The University of Toronto Law Journal*, 361, and, from a private law perspective, P Zumbansen, 'Law after the welfare state: Formalism, Functionalism, and the ironic turn of reflexive law' (2008) 56 *The American Journal of Comparative Law*, 769.

governance. The second aspect moves from the internal construction to the external impact of the monograph, by discussing how Schepel's argument has been used in contemporary EU legal thought. As the section shows, this points to a more acute level of contradiction, as Schepel's account of HTSs has been ironically invoked to sustain the very same 'juridification' that Schepel had once so vehemently opposed.

A. Schepel's vision of 'Standards-Law' . . .

To understand the purpose and arc of Schepel's argument, it is helpful to reconstruct his argument in two main contributions. The first contribution challenges the law/non-law distinction as applied to HTSs. Writing in the tradition of critical social theory, in representing these policy choices as law-making choices, Schepel's book sought to defetishize technical standardization processes and awaken the EU legal consciousness from the lethargy of unproblematically relegating these processes either to the realm of customary facts or scientific truths (ie non-law). As Schepel's target is prevalent legalistic ideologies informing the concept of law in Europe, the project is framed from the very beginning against *denialist* approaches to private regulatory authority in contemporary legal studies.[34] In this way, Schepel provocatively aimed to raise awareness among EU law and legal thinking about the importance of technical standardization processes and the ubiquity of normative and policy choices they usually entail.[35]

Even though HTS processes may be represented as instances of law-making, Schepel's second contribution is to guard against the temptation of 'juridifying' these processes.[36] Schepel's main claim here is that the legal fiction about the 'private' and 'voluntary' character of HTSs in EU law serves an important function: to avoid the judicialization (ie 'juridification') of technical questions that through slow, costly litigation would largely hamper the political project of building an internal market and the contentious political question of how to reconcile free trade and social protection among varied national economies that inform HTS processes. Against some prevalent technocratic interpretations of the

[34] Schepel (n 6), 2: 'From the Crawford-court to Jürgen Habermas, the dominant position in legal theory and practice is that law cannot accept norms as law if they are not made according to the procedures and passed through the institutions prescribed by law'.

[35] Ibid 5–6: noting how 'standards are products of discussion, negotiation, deliberation and compromise between engineers, manufacturers, academic experts, professionals, trade unionists, representatives of consumer organisations and public officials meeting in boards, committees, task forces and working groups in associations and other organisations. They bring to the table economic, political, moral and technical arguments and ultimately arrive at a solution that will to some extent hurt some groups and in some degree benefit others—consumers or producers, importers or domestic manufacturers. Standardisation is a microcosm of social practices, political preferences, economic calculation, scientific necessity, and professional judgment. Standardisation looks a lot like lawmaking'. See further, ibid 404.

[36] On the notion of 'juridification', see, in general, G Teubner, 'Juridification: Concepts, aspects, limits, solutions' in R Baldwin, C Scott, and C Hood (eds), *A Reader on Regulation* (Oxford University Press, 1998).

phenomenon in Europe, and despite the technical language informing the debates pursuant to the adoption of HTSs, therefore, from the outset, Schepel stresses their political nature.[37] Moreover, and in rigorous functionalist style, he also deploys socio-legal methods to uncover the mechanisms and dynamics of legal and political accountability already in place within HTS processes that aims to ensure sound policy making within the EU.[38] For these reasons, according to Schepel, any tendencies towards judicializing (ie 'juridifying') these political processes informing HTSs is a temptation to be resisted[39] or (in the light of some recent legal developments) to be strongly lamented.[40]

However, this does not mean that EU law and judicial institutions have no role in the HTS regime. Conversely, in Schepel's view, law and legal institutions have an important place and function in the New Approach. This function is to structure these techno-political processes in a way that enhances political engagement and contestation over the contentious question of how to reconcile the set of public interests at stake in a given situation. Rather than 'domesticating' HTS processes, by formally integrating them into the EU hierarchy of norms, Schepel thus envisaged the role of EU law as enhancing their responsiveness or 'public-regardedness' to the range of public interests involved.[41] As the evocative title of the monograph asserts, Schepel's key argument is that the role of EU law is best understood as one of 'constituting private governance' by institutionalizing HTS processes as terrains of socio-political enfranchisement towards sound policy making.

Two legal realms hold a central place in Schepel's vision of standards law. One is competition law scrutiny of HTSs, tailored through a 'procedural public

[37] See, in particular, Schepel (n 6), 23–8: cautioning that 'standards bodies should hence not be conceptualised so much as hybrids of science and policy, but rather as sites for the mutual construction of science and policy. The importance of associational governance in globalised risk regulation lies not in its capacity of delivering "universal, secular truths"; its importance lies in its capacity to internalise and renegotiate the boundaries between science and politics, and to tie expert knowledge to local professional judgments, institutional structures, social relationships and economic conditions. Associational governance is perhaps as close as we can come to the agora, that mythical place, as elusive as necessary, neither state nor market, neither exclusively public nor exclusively private, where societal and scientific problems are framed and defined, and where what will be accepted as "solution" is being negotiated' (at 28).

[38] See, in particular, ibid 2 and 4: reviewing a range of accountability mechanisms of a 'vertical', 'horizontal', and 'diagonal' reach already operating in EU technical standardisation processes. See further, ibid 234–46.

[39] Schepel (n 6), ch. 7: quarrelling with a range of positions towards the juridification of HTSs taken by EU scholars (particularly German).

[40] In this sense, Schepel (n 8); H Schepel, 'Between standards and regulation: On the Concept of 'de facto mandatory standards' after Tuna II and Frabo' in P Delimatsis (ed.), *The Law Economics and Politics of International Standardisation* (Cambridge University Press, 2015).

[41] Schepel (n 6), 257: 'the central problem with standardisation under the New Approach is not the privatisation of public lawmaking, but the political instrumentalisation of private rulemaking. And the normative answer to that problem is not the reinvigoration of the public, but, rather, the reinvigoration of the public-regardingness of responsive self-regulation'.

interest test'.[42] The second one is European tort law, albeit ingrained with a regulatory function suitable for these purposes.[43] In this way, EU law would prompt mechanisms to enhance technical research and development and socio-political contestation about the contents and aims of HTSs in their development and implementation.[44] Schepel thus powerfully concludes (against Habermas) that there is a need to invert the centre–periphery correlation between the state and civil society institutions. In particular, Schepel proclaims that is only 'from the periphery' that law 'can and must contribute to the constitutionalisation' of technical standardization processes and other modes of global private governance more generally.[45]

B . . . And its contradictions

As this brief reconstruction illustrates, the vision of 'standards-law' that Schepel articulates is far from fragmentary or dispersed. On the contrary, Schepel elaborated a wide-ranging and encompassing account of the nature and place of HTSs in the EU legal order. It is this very same vision that nowadays seems to be crumbling though, due to the relentless path towards 'juridification' signalled by the European Standardisation Regulation 2012, *Fra.bo* (2012), and *James Elliot* (2016). In this context, I point to a fundamental aspect in the legal constructivist vision advanced by Schepel about 'standards law' in Europe that has come to undermine its whole objective in the light of these later legal developments. My contention is that Schepel's embrace of the 'pluralist' paradigm to address 'the law's problem' with HTSs is both internally inconsistent and has also become contradictory in terms of its consequences by contributing to legitimize the very same 'juridification' process that it once sought to oppose.

First, it is internally inconsistent because, if analysed carefully, Schepel's vision of 'standards law' in Europe does not correspond with the Teubnerian model of legal/constitutional pluralism that Schepel purports to embrace.[46] One of the distinctive (and most landmark) aspects of the legal/constitutional pluralist theory

[42] Ibid 9. In anticipation, see also H Schepel, 'Delegation of regulatory powers to private parties under EC competition law: Towards a procedural public interest test' (2002) 39 *CML Rev*, 31.
[43] Schepel (n 6), ch. 10.
[44] Ibid 413: 'The legal imperative, then, is to promote the procedural integrity of autonomous private standardisation, to diversify its membership, to enhance its knowledge base, and to broaden its ethos'.
[45] Schepel (n 6), ch. 11, and 414.
[46] Ibid 28–35, 403–14 drawing upon the sociological jurisprudence of Gunther Teubner (and against Habermas) in sustaining his approach to technical standardization processes in contemporary law and legal thought. See further Schepel (n 20), 404: acknowledging how his 'argument, it should be obvious, owes an enormous debt to various strands of the work of Gunther Teubner, for now culminated in Constitutional Fragments. Legal pluralism, reflexive law, and a constructivist epistemology of law make up elements of "societal constitutionalism", rendered here in a debased and systems-theoretically suspect version that insists that law production by private associations should be politicized from within by the operations of normative orders recognizing or denying each other as law according to criteria that are intrinsic to law'.

developed by Teubner is that the legal status that the rule-making practices by civil society institutions may attain, does not necessarily depend upon acts of legal recognition by legal officials of the state. Conversely, this legal nature or status is somehow attained autonomously ('autopoietically'), through communicative processes developed within that very same realm of social practices that render the institutionalisation of a law/non-law distinction and a legal/illegal coding by its own participants. The social practices by civil society institutions may themselves become 'juris generative' to the extent these institutions develop a relatively settled mode of legal/illegal coding about the behaviours performed therein. Therefore, according to Teubner, the prospect of a 'law beyond the state' is premised upon the possibility of a 'law without the state' that somehow comes into being (mysteriously, magically, and *ex nihilo*) through a self-validating dynamic.[47]

Yet, this is neither the view nor the position that Schepel takes with respect to HTSs.[48] In his 2005 book, the whole argument that Schepel develops is about how the legal officials of the EU (the WTO or the USA) have, can, and should 'constitute' technical standardization processes as a site of 'private governance'. In other words, the whole argument is premised upon the existence of a competent legal official that has the legal and political authority to give (and, one assumes, also not to give) recognition to HTSs according to certain conditions of legal validity established in general and abstract terms by such an official. And indeed, the main objective of Schepel's book has been to offer persuasive guidance on how those competences ought to be conceived and exercised by EU legal officials in light of the applicable legal framework and relevant comparable experiences. Therefore, while one may well attribute HTSs some legal status within the EU, according to Schepel's book this legal status ultimately depends upon a relation of legal recognition between SSOs and competent EU legal officials that can thereby be characterized as inherently asymmetrical.[49]

[47] G Teubner, 'Global Bukowina: Legal pluralism in the world society' in G Teubner (ed.), *Global Law Without a State* (Dartmouth. 1997). s III–V: characterizing the dynamic as one where ' "rules of recognition" need not necessarily be produced hetero-referentially by an independent "public" legal order and then be applied to "private" contractual arrangements. What we face here is a "self-legitimating" situation, comparable only to authentic revolutions in which the violence of the first distinction is law-creating'. See further, G Teubner, *Constitutional Fragments: Societal Constitutionalism and Globalization* (Oxford University Press, 2012), passim, 45–59: explaining how 'we come up against a strange new phenomenon: *the self-constitutionalization of global orders without a state*'.

[48] In contrast, for example, to the one taken in these respects by H Lindahl, 'ISO Standards and Authoritative Collective Action: Conceptual and Normative Issues' in P Delimatsis (ed.), *The Law Economics and Politics of International Standardisation* (Cambridge University Press, 2015).

[49] On asymmetrical recognition, see H Lindahl, *Authority and the Globalisation of Inclusion and Exclusion* (Cambridge University Press, 2018) chs 5–6. Just for the sake of the exercise, one can find support for this interpretation of the monograph, among other passages, in the assessment that Schepel provides of how 'the New Approach [established by the EU through legal and infra-legal means] has moved far beyond these formal arguments [regarding the "private" and "voluntary" nature of HTSs] and has developed a rather sophisticated arsenal of regulatory

Likewise, when Schepel has iterated his argument in the context of subsequent legal developments, the argument has consistently relied upon that very same premise or structure. For instance, when arguing why some legal orders have (and should) transit from a 'bright line' to a 'grey zone' approach to private regulatory authority, Schepel illustrates the point through ample references to whether (or not) legal officials of the EU, the USA, or the WTO have proceeded in one or the other way.[50] Similarly, when criticizing latest legal developments regarding technical standardization at the international level, Schepel explicitly acknowledges that the authority to determine the conditions of validity of technical standards ultimately lies with WTO legal officials.[51] In all its legal pluralist commitments, therefore, every time that Schepel has sustained the legal status that ought to be attributed to modes of private regulatory authority (and HTSs in particular), the legal status is structurally dependent upon the terms of legal recognition given by some competent legal official of the state (or representative of the respective member states).

Schepel's argument is thereby premised upon the existence of some competent official—whether of the EU, the USA, or the WTO—holding (and exercising) an asymmetrical mode of legal and political authority in the name of its citizens or signatory states. This authority mainly has an expressive function. It determines whether and under what conditions the primary rules of obligation issued by SSOs through HTSs ought to be given legal recognition within its territory and thereby backed by the 'force of (its peoples') law'. The argument thus presupposes sovereignty, and thus comes much closer to the republican vision of law in contemporary political economies articulated by Habermas that Schepel himself would like to acknowledge.[52] Of course, this does not mean that Schepel is wrong. Actually, I think that this functionalist representation of technical standardization processes in the EU is right at both explanatory and normative levels. However, my point is that from a legal pluralist perspective Schepel's argument is internally inconsistent (and not only from the post-modern pluralist turn that Teubner has taken after the programme of 'reflexive law').[53]

mechanisms seeing both to the link between legal requirements and technical standards and to the internal procedural legitimacy of the standardisation process itself'. Schepel (n 6), 246.

[50] H Schepel, 'Private regulators in law' in J Pauwelyn, R Wessel, and J Wouters (eds), *Informal International Lawmaking* (Oxford University Press, 2012).

[51] Schepel (n 20), passim at 211.

[52] For a discussion, see especially Schepel (n 6), 406–11.

[53] See, for example, for a similar point E Meidinger, 'Law and constitutionalism in the mirror of non-governmental standards: Comments on Harm Schepel' in C Joerges, I-J Sand and G Teubner (eds), *Transnational Governance and Constitutionalism* (Hart Publishing, 2004) 192–3: illustrating why it is contradictory to sustain a putatively legal pluralist vision of law solely on the basis of legal decisions coming from the legal officials of the purported legal hegemon by powerfully invoking US Supreme Court Chief Justice John Marshall's opinion in *Johnson v M'Intosh* (1823) 21 U.S. 543, 588 who observed that '[c]onquest gives a title which the Courts of the conqueror cannot deny, whatever the private and speculative opinions of individuals may be, respecting the original justice of the claim'.

My second point is that Schepel's argument is not only internally inconsistent, but in the light of the latest EU legal developments in the field, it has become contradictory in its consequences as well. This is because, in the way it has been formulated, ironically, the argument leads towards the very same 'juridification' of HTSs that Schepel has so adamantly sought to prevent. To understand this point, it is important first to retrieve the conundrum pervading the nature and place of technical standardization within the EU legal order. As explained in the introduction to this paper, the conundrum is to explain how HTSs can be officially regarded as 'measures implementing or applying an act of EU Law', and thereby understood as 'part of EU Law' (*James Elliot*), but at the same time are not subject to the equivalent legal requirements and accountability mechanisms applicable to analogous EU administrative authorities.

The pluralist paradigm advanced by Schepel to represent the legal authority of HTSs cannot resolve that puzzle. According to this paradigm, to the extent that HTSs can be regarded as 'law' (or given even some purported 'constitutional' status), logically, they could not, at the same time, be considered part of EU Law. Conversely, and to the extent that EU legal officials have integrated HTSs into the hierarchy of EU legal norms by rendering them as 'measures implementing or applying an act of EU Law', thereby locking HTSs within the EU's constitutional frame of legitimacy, HTSs could no longer be regarded as a manifestation of legal pluralism but as subjected to the authority of EU legal or political officials. For these reasons, under the pluralist paradigm embraced by Schepel to represent the legal authority of HTSs, the *James Elliot* decision can only be lamented as signifying an unequivocal path towards the 'juridification' of HTSs within EU law.

The predominant interpretation that the *James Elliot* judgment has generated within EU law and legal studies reaffirms this observation. Among EU legal scholarship, the judgment has mostly been read as leading towards the 'agencification' of SSOs and the overall 'juridification' of technical standardization processes within the EU. Contrary to Schepel, however, this juridification has been generally received with enthusiasm by EU legal scholarship as symbolizing the final triumph of the 'rule of law', the de-privatization/publicity of HTSs as their accessibility could no longer be restrained by copyright, or as enhancing the 'legitimacy' of technical standardization processes by rendering HTSs amenable to judicial review.[54] Some even refer to Schepel's scholarship as somehow

[54] For different variations of these arguments, see, for example, Senden (n 13); Eliantonio and Cauffman (n 6); B 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; M Medzmariashvili, 'Delegation of rulemaking power to European Standards Organizations: reconsidered' (2017) 44 *Legal Issues of Economic Integration*, 353; and C Tovo, 'Judicial Review of Harmonized Standards: Changing the Paradigms of Legality and Legitimacy of Private rulemaking under EU law' (2018) 55 *CML Rev*, 1.187.

envisioning this whole 'juridification' process in seemingly laudable terms.[55] Likewise, others echo Schepel's 'new approach to the new approach' in order to approvingly represent the pathways towards an agencification of SSOs that *James Elliot* would have ascertained through similar neologisms.[56] As these references illustrate, ironically, Schepel's scholarship has become a recurrent point of reference to uphold the pathways towards the judicialization of technical standardization processes through the very same type of arguments that Schepel himself had once so vehemently opposed.[57]

This is a perplexing scenario. In the EU legal canon, a canon that largely remains trapped between neo-classicist and post-modern representations of technical standardization, this is the scenario that provides the backdrop against which the overall enigma of HTSs in contemporary EU law and legal thinking has unfolded. Nonetheless, one fact is at least relevant to highlight in this scenario: despite this dominant interpretation that the *James Elliot* judgment has generally prompted within EU Law and legal thought, none of these putative legal effects have actually materialized in practice (yet). The legal puzzle generated by *James Elliot* thus still remains in place: how can HTSs be considered as 'measures implementing or applying an act of EU Law', and thereby 'part of EU Law', and yet not be subject to the legal requirements and accountability mechanisms applicable to similar EU legal acts or bodies?

For most EU legal doctrine this seems to be a logical impossibility, so the necessary conclusion is that the regulatory authority exerted by SSOs have to be understood under the metaphor of 'delegation', subject to the *Meroni* requirements, and thereby assimilated to EU administrative agencies in their nature and place within the EU legal order. For a large part of EU legal doctrine, the 'agencification' of SSOs and consequent judicialization of HTSs would thus seem if not an inevitable conclusion at least a desirable horizon that needs to be followed

[55] See, for example, C Colombo and M Eliantonio, 'Harmonized technical standards as part of EU law: Juridification with a number of unresolved legitimacy concerns?: Case C-613/14 James Elliot Construction Limited v. Irish Asphalt Limited, EU : C:2016:821' (2017) 24 *Maastricht Journal of European and Comparative Law*, 323, 325; M Gnes, 'Do administrative law principles apply to European standardization: Agencification or privatization?' (2017) 44 *Legal Issues of Economic Integration*, 367, 377; A Volpato, 'The harmonized standards before the ECJ: James Elliott Construction' (2017) 54 *CML Rev*, 591; and S Roettger-Wirtz, 'Standardisation of health products in search of legitimacy: Rethinking judicial review?' in M Eliantonio and C Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique A Cross-disciplinary and Multilevel Analysis* (Edward Elgar, 2020).

[56] A van Waeyenberge and D Restrepo, 'James Elliot Construction: A 'new(ish) approach' to judicial review of standardisation' (2017) 42 *ELR*, 882; and J Hettne, 'Standards, barriers to trade and EU internal market rules: Need for a renewed approach?' (2017) 44 *Legal Issues of Economic Integration*, 409, 419: calling for a 'renewed approach [that] must be more flexible and possible to apply in different areas depending on the different broader political and societal interests at stake [among other aspects, based upon] . . . a larger scope of ex ante control of the standard-making process which will in turn facilitate ex post judicial review'.

[57] Schepel (n 6), 246–58.

after *James Elliot*.[58] Conversely, for those sceptical about the absorption of HTSs within the hierarchies of EU legal norms and the dysfunctional intervention of judges in HTS processes, the alternative would be to mourne the *James Elliot* judgment as a 'jurispathetic' judgment that consolidates an undesirable 'juridification' of HTS processes within the EU. But is it so? Does *James Elliot* necessarily lead towards a 'juridification' of HTSs within EU Law and therefore can it be either celebrated or lamented for doing so? *Tertium non datur*?

In the remainder of this article, I offer an account that overcomes this perceived dilemma while addressing the referred legal puzzles and overarching conundrum. Curiously, this requires the development of an idea that Schepel himself articulated, but (to my understanding) has never systematically pursued: the idea of a 'private administrative law'.[59] As I argue in the rest of the paper, this idea can contribute to understanding how and why HTSs can be given a regulatory character (*Fra.bo*) and be considered part of EU Law as 'measures implementing or applying an act of EU Law' (*James Elliot*), but nonetheless entailing a different *kind* of law within the EU not assimilable to the one applicable to EU administrative agencies nor to private parties in their mere private relations. For these reasons, against Schepel and most of contemporary legal thinking in the EU, I claim that the *James Elliot* judgment rather than undermining (or liquidating) the distinctive EU model to HTS processes established through the New Approach, has come to reaffirm it. Yet, in order to sustain this claim, I first place the judgment in an overall reconstruction of how the EU has been incrementally transforming the terms of private regulatory authority exerted by ESOs through HTSs since the establishment of the New Approach.

III. EU law and the transformation of technical standardization processes: a reconstruction

The New Approach holds a pivotal place in the current legal configuration and overall understanding of HTS processes within the EU.[60] Established as an integral part of the internal market completion programme during the 1980s, the

[58] Notably, in contrast with, M Simoncini, *Administrative Regulation Beyond the Non-Delegation Doctrine: A Study on EU Agencies* (Bloomsbury Publishing, 2018) 117: 'The application of the *Meroni* doctrine seems to be inappropriate, as standardisation powers are not delegated, but are only regulated by EU law'.

[59] As signalled by this article's epigraph, this idea was originally articulated in Schepel's seminal monograph and has then been reiterated in some of his latest publications, but to my knowledge it has never been theoretically pursued in any systematic way. See, Schepel (n 6), 305–9, 320–38, 400, 409–10, and 6, 8, 284, and 414 with respect to the 'internal administrative law' of SSOs; and Schepel (n 50), 366.

[60] The basic set-up of the New Approach was established by the Commission, 'Completing the Internal Market: White Paper from the Commission to the European Parliament' COM(85)310 final, pp. 19–22; and Council resolution of 7 May 1985 on a New Approach to Technical Harmonization and Standards [1985] OJ C136/1 (the New Approach Resolution 1985).

context leading towards the New Approach and the type of policy challenges it has raised since its adoption have been well analysed by now.[61] From a legal perspective, the debate about the New Approach has generally been centred upon the constitutionality of the initiative (typically based upon the *Meroni* parameters of 'delegation'). This debate has also extended to issues of accessibility, justiciability, and the overall integrity of HTS processes.[62]

In this section, I take up this debate by elaborating an alternative account about the legal meaning of these transformations based upon the idea of a private administrative law. To this end, I trace the institutional trajectories of EU technical standardization processes from the so-called 'old approach' (1969), to the 'new approach' (1985), the partial institutional reforms triggered in ESOs during the 1990s after some policy controversies (1990, 1998), and the final consolidation of a distinctive EU approach to technical standardization processes alongside new governance lines (2003). The argument is that these transformations evidence a distinctively modernist approximation to the private regulatory authority exerted by SSOs through HTSs that has been followed by the EU, in a way that can be productively understood as constituting a private administrative law of technical standardization. This model became formally institutionalized in EU Law by the so-called 'new legislative framework' on conformity assessment (2008), section 7 of the EC Guidelines on Article 101 TFEU (2011), and in the European Standardisation Regulation 2012.

In Section IV, I draw upon the private administrative law apparatus to examine the controversial turn that the EU approach to technical standardization has taken following *Fra.bo* (2012) and discuss some of the latest legal developments including the standardization package of 2016 and *James Elliot* (2016). Throughout this reconstruction, the objective is not only to show how the idea of a private administrative law can provide a distinctive and consistent way to understand this range of legal developments concerning technical standardization processes in Europe. I also show why it can additionally provide a compelling explanation of them in the light of its immanent ideals. Therefore, this section aims to position the idea of private administrative law as the best interpretation of the EU approach to technical standardization, noting, in particular, its explanatory power and normative commitments.

A. The 'old approach'

As a point of departure, it is important to underscore that from an economic perspective, technical standards are generally conceived as means to facilitate

[61] A classical reference is J Pelkmans, 'The new approach to technical harmonization and standardization' (1987) 25 *Journal of Common Market Studies*, 249. For a more recent and significantly expanded account, including empirical analysis of technical standardization practices, see Egan (n 29).

[62] Within contemporary EU legal studies, the terms of the debate are very much set by Gestel and Micklitz (n 11); with a reply by Schepel (n 8). See also Senden (n 13).

commerce by enabling exchange (compatibility standards) or mitigating negative externalities (quality standards) throughout industrial processes. Generally modelled as a result of coordination games, where convergence towards a single norm would seem *prima facie* optimal and desirable in resolving collective action problems, in this sense, technical standards are regarded as inherently welfare enhancing.[63] Under certain circumstances, however, technical standards may curtail competition and hamper innovation by reducing variety, fragmenting markets, or generating lock-in effects.[64] In addition, the *de jure* or *de facto* need to comply with a variety of technical standards in order to access markets can also harm trade. To a relevant extent, these socio-economic functions explain why SSOs emerged during the early twentieth century, as key actors in the development of economic and industrial policy for the growing administrative bodies at a national level.[65] It also explains why, after completing the customs union (1968), a significant part of EU law and policy in building the internal market came to be focused on tackling technical standards and regulations, as the ample divergences that existed among its member states were one of the most burdensome non-tariff barriers to trade.[66]

[63] But see Egan (n 29), 160–5: explaining that 'this instrumental view is largely indifferent to the decision-making constraints posed by bounded rationality, information costs, and the way in which organizational culture may affect the ease or ability of those involved to pursue a particular strategy. As a result, communicative rationality is at least as important as instrumental rationality in understanding the dynamics of standardization processes … The outcome of the standardization process depends partly on the pay-off structure but also on the organizational dynamics, norms, and synergies within the organization'.

[64] For an analysis in this sense, see, for example, the ABA Section on Antitrust Law, *Handbook on the Antitrust Aspects of Standards Setting* (American Bar Association, 2004). With respect to innovation policy, see the specialized volume by R Hawkins, K Blind, and R Page (eds), *Handbook of Innovation and Standards* (Edward Elgar Publishing, 2017).

[65] There are significant differences though between USA and European traditions of technical standardization and among European countries in these respects. In general, the USA has followed a more decentralized model of technical standardization, largely based on regulatory competition among standard-setters, where ANSI (established in 1918) accredits standard-developers and approves standards as 'American National Standards', but it does not itself develop technical standards. In contrast, technical standardization practices in Europe follow a much more integrated model, along neo-corporatist lines and generally based on 'peak associations' that coordinate existent practices by directly engaging in the production of technical norms. The status of these European standard-setters institutions nevertheless differ: while AFNOR (France) is more integrated into the French administrative system, considered as an 'administrative association' even if formally remaining a private organization, DIN (Germany) has a more independent status from the government, as a non-profit organization producing German standards 'in the public interest'. In the case of the UK, due to the internationalization of technical standardization, BSI was transformed into BSI Group and is now more focused on consultancy, certification, and inspection services rather than in producing technical standards. For an instructive comparative analysis, see Schepel (n 6), chs 4–5. See also, more generally, S Krislov, *How Nations Choose Product Standards and Standards Change Nations* (University of Pittsburgh Press, 1997); J Tate, 'National Varieties of Standardization' in P A Hall and D W Soskice (eds), *Varieties of Capitalism: the institutional Foundations of Comparative Advantage* (Oxford University Press, 2001).

[66] For a specialized study of this context, see mainly, Egan (n 29), ch. 3.

The original strategy pursued by EU authorities was to overcome those technical barriers to trade through legislative harmonization. The strategy was based upon the explicit competence to address disparities between national laws that 'directly affect the establishment or functioning of the internal market' as given to EU legislative bodies (ex-Article 100 EEC). On this basis, the Commission embarked upon an ambitious policy programme seeking to harmonize these divergent technical requirements in national laws through several EU Directives.[67] However, this strategy, which became widely known as the traditional approach to technical harmonization (or the 'old approach'), proved unsuccessful.

Originally, the programme projected that 124 EU Directives would be enacted in 18 months, but after three years of its operation only 24 Directives had been adopted. The slow progress continued throughout the 1970s, to the extent that the content and timelines of the programme had to be adapted several times in order to reflect more modest expectations (1973, 1977).[68] Everything that was wrong with the 'old approach' is perhaps best epitomized by an anecdote published in the *Wall Street Journal* chronicling the difficulties of standardizing jam:[69] (i) legislative initiatives that exclusively focused on single products; (ii) formulated in extremely detailed terms so as to avoid discretion by member states in their implementation; (iii) where any political agreement was hard to reach due to the unanimity required in the Council; or (iv), once they have been finally adopted, their technical specifications in order to ensure health or safety were probably already outdated; and (v), even if formally binding, these agreements were hardly respected in practice.[70] By the end of the 1970s, the Commission

[67] See Council resolution of 28 May 1969 drawing up a Programme for the Elimination of Technical Barriers to Trade in Industrial Products which result from disparities between the provisions laid down by Law, Regulation or Administrative Action in Member States [1969] OJ C076/1.

[68] See, for example, Council resolution of 21 May 1973 concerning the Elimination of Technical Obstacles to Trade in Industrial Products [1973] OJ C38/1.

[69] 'First some essential background. The Dutch spread jam on bread for breakfast, so they like it smooth. Sugary, too. Most Frenchmen, however, wouldn't touch smooth jam with a barge pole, much less a butter knife. They commonly eat their jam straight from the jar, with a spoon. . . . The negotiators spent years getting the Dutch who want more sugar in their jam and the French who want more fruit, to compromise. But just as that happened, Britain, Europe's largest jam consumer joined the EC—and tossed a spanner into the works. Its name is marmalade. It seems the low-quality jam in much of Continental Europe was called marmalade, a confusion Britons refused to tolerate. In the end Continental Europe changed their terminology, and low-grade jam simply became jam. After two decades of haggling everyone finally agreed what jam was and what should be in it, and the Eurocrats proudly unveiled a jam standard in 1979. Then the French, who have been eating jam since the thirteenth century and who are extremely picky about it, decided to mediate on the matter for an additional four years or so. It wasn't until 1984 that they got on board. It did not escape the Eurocrats that it had taken twenty-five years to decide on jam, it could take centuries to do the same nit-picking for the many thousands of other products involved in Continental trade' *Wall Street Journal*, 2 September 1989, referenced by Egan (n 29), 75.

[70] For a thorough analysis of the original strategy, diagnosing a 'regulatory mismatch', ibid 4: noting how 'Not surprisingly, programme deadlines slipped by and criticism mounted regarding efforts to unify the market at the expense of existing national rules. . . . It took, for example, fifteen years to reach agreement on mineral water standards and eight years to agree on standards for

'was exasperated' as it became clear that the programme of overcoming technical barriers to trade through legislative harmonization had 'failed miserably'.[71]

Against the backdrop of these shortcomings in reducing technical barriers to trade through political negotiations, the ECJ famously stepped in and took a leading role in fostering market integration through law and legal reasoning. The landmark judgments are *Dassonville* (1974) and *Cassis de Dijon* (1979) where, alongside the constitutionalization of the EU legal order already asserted by the ECJ through *Costa* ('supremacy')[72] and *Van Gend en Loos* ('direct effect'),[73] the ECJ now audaciously expanded its authority to review the very same regulatory powers and policies of (its) member states. First. in *Dassonville* the ECJ justified such an authority by giving a broad definition of trade restraints that encompassed technical requirements as 'measures having an equivalent effect to a quantitative restriction' under Article 30 EEC.[74] Then, in *Cassis*, the ECJ further established the basic parameters under which these regulatory powers could be validly exercised by member states in the pursuit of legitimate regulatory objectives.[75]

These bold interpretative moves by the ECJ changed the whole dynamic informing the programme of overcoming technical barriers to trade. From a configuration mainly based on 'positive integration' through the political process, the programme now largely relied upon 'negative integration' through free movement law and reciprocal expectations of mutual recognition among member states. In this way, the ECJ came to restructure through legal means the socio-economic relationship between markets and regulation and the political relationships between the EU and its member states. In a move that reaffirms the constitutive place of law in socio-political relations, in fact, these ECJ judgments have largely been understood as having a transformative significance at a historical and cultural level within the EU. At a social-consciousness level, these judgments are regarded as laying a pathway towards the development of a European community not only committed to economic integration through individual rights, but one that through the norm of reciprocity underlying the principle of mutual recognition could also start to conceive itself as a kind of 'non-unitary polity'.[76]

windscreen wipers. A broad range of similar examples confirmed that harmonization was bound up in trivia and red tape. These "Euro-scandals" were dramatized and often exaggerated in the popular press, and the Commission's efforts to standardize products throughout Europe became the object of derision'. In this sense, see also Schepel (n 6), 63.

[71] See, respectively, R Schütze, *From International to Federal Market: The Changing Structure of European Law* (Oxford University Press, 2017) 125; Joerges, Schepel, and Vos (n 7), 7.

[72] Case C-6/64 *Flaminio Costa v E.N.E.L.* [1964] ECLI : EU : C:1964:66.

[73] Case C-26-62 *NV Algemene Transporten Expeditie Onderneming van Gend & Loos v Netherlands Inland Revenue Administration* [1963] ECLI : EU : C:1963:1.

[74] Case C-8-74 *Procureur du Roi v Benoît and Gustave Dassonville* [1974] ECLI : EU : C:1974:82.

[75] Case C-120-78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* [1979] ECLI : EU : C:1979:42. But see, for a revisionist and more nuanced account of this conventional narrative, R Schütze, 'From Dassonville to Cassis: The revolution that did not take place' in A Albors-Llorens, C Barnard, and B Leucht (eds), *Cassis de Dijon: 40 Years On* (Bloomsbury Publishing, 2021).

[76] JHH Weiler, 'The transformation of Europe' (1991) 100 *The Yale Law Journal*, 2403, 2.408. In this sense, albeit with differing interpretations about the meaning of these transformations, see also

B. The 'New Approach'

This legal reconfiguration generated a relatively neat division of labour between EU legal and political institutions with respect to the policy question of how best to overcome prevailing technical barriers to trade in the EU internal market. While protectionist regulations were to be addressed through free movement law and mutual recognition, the EU legislative bodies could now focus their harmonization initiatives on targeting those strategic sectors where established technical measures by member states could not be regarded as mutually equivalent.[77] Alongside a changing socio-political climate that increasingly favoured market liberalization as a path towards economic growth, the programme of completing the internal market thus gained a new momentum and impetus during the 1980s. After intense negotiations and much soft law experimentation, the White Paper on Completing the Internal Market (1985) and the Single European Act (1987) became the pillars of a reinvigorated single market programme to be achieved by 1992 through a range of innovative policy strategies.[78]

Technical standards held an important role in these innovative strategies. Originally, technical standards had an unclear position within the relevant division of labour, as widespread divergences among NSOs could neither be tackled by positive integration (as the 'old approach' had blatantly shown), nor be consistently disciplined through negative integration as, due to their 'private' and 'voluntary' nature, they could not be subject to free movement discipline.[79] In order to prevent new technical barriers to trade from emerging, national SSOs were initially included within the notification duties and standstill commitments established by the new Information Directive 1983. This was done to enable horizontal harmonization and the development of mutual recognition dynamics among these organizations.[80]

M Maduro, *We the Court: The European Court of Justice and the European Economic Constitution* (Bloomsbury Publishing, 1998); and, more recently, Schütze (n 71); S Weatherill, *The Internal Market as a Legal Concept* (Oxford University Press, 2017); J Zglinski, *Europe's Passive Virtues: Deference to National Authorities in EU Free Movement Law* (Oxford University Press, 2020).

[77] Or at least this is how the Commission devised the strategy in its (controversial) interpretation of the *Cassis de Dijon* judgment: see Commision, 'Communication from the Commission concerning the Consequences of the Judgment given by the Court of 20 Feb. 1979 in Case C-120/78 (*Cassis de Dijon*)' (1980) OJL C256/2. The assertive interpretation of the judgment by the Commission generated harsh criticism among member states' representatives and some consumer associations, as instigating a de-regulatory 'race to the bottom' and undermining consumer protection within the internal market: see, for example, Consumer Consultative Council, Opinion on the consequences of the judgment of the *Cassis de Dijon* case' (1981) CCC/29/31 Rev 4 and further references in Egan (n 29), 110–11. See also, for a specialized study, B Leucht, 'The Cassis de Dijon Judgment and the European Commission' in A Albors-Llorens, C Barnard, and B Leucht (eds), *Cassis de Dijon: 40 Years On* (Bloomsbury Publishing, 2021).

[78] See Commission, 'Completing the Internal Market: White Paper from the Commission to the European Parliament' COM(85)310 final; and the Single European Act [1987] OJ L169/1.

[79] For a legal analysis, Schepel (n 6), 39–63. From a policy perspective, Egan (n 29), 109–10, 116–22: noting the difficulties that EU authorities had in tackling widespread divergences standards issued by national bodies among EU member states.

[80] For an explanation, S Weatherill, 'Compulsory notification of draft technical regulations: The contribution of directive 83/189 to the management of the internal market' (1996) 16 *Yearbook of*

Although this scheme already gave a background role to ESOs, the Commission at the same time developed a supplementary scheme that upgraded the role of ESOs in overcoming technical barriers to trade by generalizing the technique of making legislative reference to technical standards, which had first been developed (atypically, at least at the EU level) in the Low Voltage Directive 1973. In this way, the so called New Approach to technical harmonisation became established.[81]

The basic tenets informing the New Approach contrasted markedly with the 'old approach'.[82] Instead of vertical directives addressing single products, the legislative programme was developed through horizontal directives encompassing 'wide product categories and types of risk'. Instead of detailed technical specifications about each of these products, directives focused only on establishing their 'essential requirements' to be concretized by ESOs through technical standardization mandates. Moreover, products certified in compliance with technical standards (ie the 'CE' mark) gained a 'presumption of conformity' with those essential requirements and thereby move freely in the internal market without being subject to additional testing, verification, or other modes of conformity assessment by member states. Yet, technical standards remain voluntary or non-binding in their application as producers may select other means to prove compliance with those essential requirements.[83] From being an intractable problem to overcome non-tariff barriers to trade, in this way, technical standards suddenly became an important part of the solution to reach the policy goal of completing the internal market.[84]

C. The 'New Approach': its legal meaning and original configuration

From the perspective of market integration, at least, the new approach has been widely regarded as a 'success story of the European Union'.[85] What under the old approach had usually taken decades, under the new approach took months or

European Law, 129. But see Schepel (n 6), 60: noting how 'in practice, this "horizontal" harmonisation has been an abysmal failure'.

[81] See, the the New Approach Resolution 1985. Vestiges of how the New Approach relates to the assertive interpretation of *Cassis* can still be officially found nowadays: see, for example, Commission, 'Commission Notice—The "Blue Guide" on the implementation of EU products rules 2016' (2016) OJ C 272/1, sec. 1.1.3 stating how 'the New Approach legislative technique approved by the Council of Ministers on 7 May 1985 in its Resolution on a new approach to technical harmonisation and standards was the logical legislative follow up to the *Cassis de Dijon* case'.

[82] These basic tenets were established in the Model Directive 1985, set out in the New Approach resolution 1985, annex II.

[83] As Egan explains 'this provided firms with a degree of flexibility, particularly in areas of rapid innovation and change, although it was assumed that meeting designated European standards would be the easiest route for compliance'. Egan (n 29), 124.

[84] Schepel (n 6), 63–7: noting how 'in practice, the Community has resolved the problem of decisional supranationalism by handing over the task of hammering out agreement on technical details to private intergovernmentalism'.

[85] Gestel and Micklitz (n 11), 156–7; M Mataija, *Private Regulation and the Internal Market: Sports, Legal Services, and Standard Setting in EU Economic Law* (Oxford University Press, 2016), 231–2; Schepel (n 6), 66–7. See also, European Commission 'Vademecum on European

only a few years. Already by 1992, there were 10 New Approach directives in force covering wide-ranging categories of products, and by the turn of the century the number had risen to more than 20, leading (at least officially) towards considerable gains in trade alongside the attainment of other public policy objectives within the internal market.[86] However, at the same time, the New Approach has been a controversial 'success story' that still remains, in many ways, legally and normatively problematic. On the one hand, since its very beginning one significant part of the controversy has been centred upon whether the New Approach scheme entails an unconstitutional (*ultra vires*) delegation of regulatory powers to private actors. Usually, the parameters of analysis in this respect are the so-called *Meroni* doctrine and the principle of institutional balance.[87] On the other hand, a significant part of the controversy has also been centred on the policy implications of the New Approach scheme and, in particular, on whether it entails an overall marketization of regulation that will lead towards a deregulatory turn in social protection within the EU.[88] In this way, an enduring tension between the perceived success of the new approach and sustained misgivings about its constitutional validity and normative desirability have largely dominated the terms of the legal debate.

Part of the problem with this scholarly focus on the New Approach is that it has come at the cost of overlooking how EU Law has been incrementally transforming technical standardization processes since the New Approach inception and the legal meaning of these transformations. By drawing upon a reconstructive analysis of relevant empirical data and policy assessments of technical standardization in Europe, I seek to shift the scholarly focus from abstract concerns with the constitutional validity or normative desirability of HTSs towards an engagement with aspects of technical standardization processes in practice. This

Standardisation' (2004): stressing how European standardization policy has been 'a great success story of the European Union'.

[86] See, Commission, 'Efficiency and Accountability in European Standardisation Under the New Approach' (COM/98/291), pp. 2, 16–18 <http://aei.pitt.edu/id/eprint/42995>. This is a view largely shared by the Council, see Council Resolution of 28 October 1999 on the role of standardization in Europe [2000] OJ C141/01, paras 5 and 20 acknowledging how 'the new approach has contributed in a significant way to the functioning of the single market, the protection of health and safety, the competitiveness of industry and the promotion of international trade, and has been supporting an increasing range of Community policies' and inviting the Comission to 'examine systematically whether the New Approach can be applied to sectors not yet covered as a means of improving and simplifying legislation whenever possible' among other improvements. This sense of accomplishment is still vivid: see Commission, 'Commission Notice—The "Blue Guide" on the implementation of EU products rules 2016' (2016) OJ C 272/1, sec. 1.1.3 stating how 'some 27 directives [are] being adopted on the basis of New Approach elements. They are far fewer in number than traditional directives in the field of industrial products (some 700), but their wide hazard-based scope means that entire industrial sectors have benefited from free movement through this legislative technique'.

[87] For a thorough review (and positioning) of the legal debate in these respects, see Joerges, Schepel, and Vos (n 7), 26 ff. For a retrieval in light of some latest legal developments, see also Senden (n 13).

[88] Some of the relevant literature in these respects is indicated by, Schepel (n 6), 67 n. 144.

analysis unveils how the New Approach could be considered a 'success' only when reducing the analysis to the number of directives enacted. However, focusing solely on such a legislative standpoint fails to notice how much of the political disputes, stalemates, and gridlocks that had affected the old approach became reproduced throughout the technical standardization processes themselves.[89] The analysis also unveils how the EU has been addressing these difficulties by incrementally institutionalizing the principles of transparency, participation, rationality, and modalities of non-judicial review, among other accountability mechanisms, within those technical standardization processes. Alongside these transformations, I claim, a private administrative law of technical standardization has started to emerge and has been consolidated through the 'visible hand' of EU Law.[90]

From the time of its original set-up, the New Approach had several components that typically characterize modern administrative governance. First, standardization tasks are formalized through a 'standardization mandate', which operates as a policy/political mandate to implement (execute) legislative provisions by specifying the type of requirements that goods need to comply with in order to freely circulate and be commercialized in the internal market.[91] Yet this does not entail that ESOs nor national SSOs have become executive bodies of the EU. According to the New Approach, the mandate has to be formally 'accepted' by ESOs.[92] Moreover, ESOs and national SSOs remain entitled to autonomously develop standardization projects that do not overlap or contradict standardization mandates or HTSs that are in force. In fact, mandated standardization remains only a minor fraction of the total standardization projects that

[89] For example, by 1999, from 2,905 standardization mandates issued by EU legislative authorities, only 914 had been accomplished: see Commission, 'Economic Reform: Report on the Functioning of Community Product and Capital Markets' (COM/99/10) <http://aei.pitt.edu/id/eprint/12641>.

[90] In this practical/empirical line, see Egan (n 29), chs 7–8. From the perspective of legal methodology, the implicit reference (and inspiration) for this reconstruction comes from H-W Micklitz, 'The visible hand of European Regulatory Private Law—The Transformation of European private law from autonomy to functionalism in competition and regulation' (2009) 28 *Yearbook of European Law*, 3.

[91] According to the Model Directive 1985: 'The quality of harmonized standards must be ensured by standardization mandates, conferred by the Commission, the execution of which must conform to the general guidelines which have been the subject of agreement between the Commission and the European standardization organizations'. The standardization mandate still remains a central component of the European standardization process: see, for a latest account, P Cuccuru, 'Regulating by Request: On the Role and Status of the "Standardisation Mandate" under the New Approach' in M Eliantonio and C Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique: A Cross-disciplinary and Multi-level Analysis* (Edward Elgar, 2020).

[92] For an updated account about the role and the process for issuing standardization mandates and the so-called 'follow-up' mandates by the EU, see the Commission, 'Vademecum on European standardisation in support of Union legislation and policies—standardisation requests (role, adoption and execution)' SWD (2015) 205 final <https://ec.europa.eu/growth/single-market/european-standards/vademecum_en>.

ESOs and national SSOs regularly develop.[93] In this sense, standardization mandates are better placed within the paradigm of 'distributed administration' or collaborative administrative governance.[94]

A second component is that New Approach directives must themselves contain at least the 'essential requirements' to be fulfilled by the respective products.[95] In this way, a so called principle of autonomous legal requirements was established by the Model Directive 1985. This typically corresponds with the distinction between legislation and regulation within the European tradition of administrative law.[96] Indeed, one of the objectives of including the principle of autonomous legal requirements in the development of the New Approach was to avoid the constitutional controversies that had once surrounded the broad references to technical standards made in the Low Voltage Directive 1973.[97] Yet, originally, the clause responded to more pragmatic justifications as well. With the aim of completing the internal market by 1992, the purpose was to make the New Approach directives directly operationalizable by competent bodies at the national level in case ESOs could not fulfil their standardization mandates in time—a concern that the evidence soon demonstrated to be justified.[98]

A third component is the non-judicial review mechanism of HTSs that the Model Directive 1985 established within EU technical standardization

[93] See, for example, E Vardakas, 'Technical Regulations and Standards in Europe: A Historical Background', *Vademecum on European Standardisation* (2004) 9 <https://law.resource.org/pub/eu/vademecum/complete.vademecum.pdf> accessed 30 July 2020: noting how 'according to statistics made available by the European Standards Bodies, about two-thirds of their work are initiated and adopted independently of the European Union's mandates'. More recently, it has been documented that from the *circa* 20,000 standards that CEN and CENELEC had produced by 2016, only 4,000 correspond to HTSs. In the case of ETSI, the relation is 35,000 to 500: see Commission, 'Standardisation Package 2016: European standards for the 21st Century' COM (2016) 358 final, p. 5.

[94] Simoncini (n 58), 113, 117. See also, more generally, on 'collaborative administrative governance' J Freeman, 'Private parties, public functions and the new administrative law' (2000) 52 *Administrative Law Review*, 813, 826–31. On 'distributed administration', see B Kingsbury, N Krisch, and R B Stewart, 'The emergence of global administrative law' (2005) 68 *Law and Contemporary Problems*, 15.

[95] Model Directive 1985, section B, III.

[96] On such a distinction within the European tradition and its relevance throughout the European integration context, see P L Lindseth, 'The "Law-Regulation Distinction" and European Integration: Reflections on the German Jurisprudence from the 1960s to the Present' (2010) 4 *Jus Politicum*, <http://juspoliticum.com/article/The-Law-Regulation-Distinction-and-European-Integration-Reflections-on-the-German-Jurisprudence-from-the-1960s-to-the-Present-214.html>.

[97] Egan (n 29), 125–6.

[98] For this reasons, the Model Directive 1985 explicitly stated that 'The essential safety requirements . . . shall be worded precisely enough in order to create, on transposition into national law, legally binding obligations which can be enforced. They should be so formulated as to enable the certification bodies straight away to certify products as being in conformity having regard to those requirements in the absence of standards' (section B, III). Albeit this 'principle of autonomous legal requirements' has been acknowledged to be 'unstable' throughout the New Approach, this is nothing new for administrative lawyers: for a detailed analysis, see H C H Hofmann, G C Rowe, and A H Türk, *Administrative Law and Policy of the European Union* (Oxford University Press, 2011), 598–605.

processes. This review mechanism, known as the 'safeguard procedure' (and complemented by the 'safeguard clause'), could be activated by 'competent public authorities' before or after an HTS has been issued, in order to contest 'the conformity of a product, the validity of a certificate, or the quality of a standard'.[99] Although in its original design it was conceived as a mechanism to be used in exceptional circumstances, in practice it has been revealed to play an important role as an instance of legal and political accountability or administrative review concerning the quality or effectiveness of HTS processes.[100] The ECJ has explicitly contributed to its distinctive significance. Since *Cremonini and Vrankovich*, the Court has consistently established that the 'safeguard procedure' is the only means through which the presumption of conformity granted to products certified as compliant with HTSs can be legally rebutted, thereby forbidding Member States to impose, *de jure* or *de facto*, any modes of additional conformity assessments for these products in order to access national markets.[101] This is an important component of the New Approach regime, to which I will return in my analysis in Section IV of the ECJ judgments in *Fra.bo* (2012) and *James Elliot* (2016).

A fourth component is some minimum benchmark of publicity that has been institutionalized since the beginning of the New Approach by requiring that HTSs be published in the *Official Journal of the European Union* as a condition for such a presumption of conformity to become effective.[102] Finally, all of this original set-up was initially complemented by 'memorandums of understanding' (MoU) and the 'General Guidelines for Cooperation' subscribed between the Commission and CEN and Cenelec.[103] These General Guidelines are relevant for many reasons. First, the Guidelines, since their adoption, acknowledged the

[99] Model Directive 1985, introduction, and section VII (or 'safeguard clause') concerning the way to legally withdraw the commercialization of products that 'might compromise the safety of individuals, domestic animals or property'.

[100] For a review of their uses in practice, Schepel (n 6), 235–9: remarking how 'the safeguard procedure has thus been transformed *de facto* from an instrument dealing with emergency situations and market surveillance to an extra layer of administrative verification of the technical contents of standards'.

[101] See Case C-815/79 *Cremonini and Vrankovich* [1980] ECLI : EU : C:1980:273. See further Case C–365/97 *Commission v Italy* [1999] ECLI : EU : C:1999:544; Case C–100/00 *Commission v Italy* [2001] ECLI : EU : C:2001:211; and Case C–103/01 *Commission v Germany* [2003] ECLI : EU : C:2003:301. More recently, see also, Case C-100/13 *Commission v Germany* [2013] EU : C:2014:2293.

[102] Model Directive 1985, section V.1.A. Although the publication had traditionally been deemed to be a mere formality, devoid of any significance, some of the latest innovations by EU legal authorities may end up proving consequential: for a discussion, see A Volpato and M Eliantonio, 'The butterfly effect of publishing references to harmonised standards in the L Series' (*European Law Blog*, 7 March 2019) <http://europeanlawblog.eu/2019/03/07/the-butterfly-effect-of-publishing-references-to-harmonised-standards-in-the-l-series/> accessed 7 March 2019.

[103] Commission, 'General Guidelines for Cooperation between the European Commission and CEN and Cenelec' (1984) < http://aei.pitt.edu/10921/1/10921.pdf>, pp. 191–197 (the 1984 Guidelines for Cooperation).

exclusive authority of CEN and Cenelec (and later ETSI) to develop European standards as 'recognized' ESOs. From the outset, this feature differentiated the technical standardization model devised by the EU from the one largely based on regulatory competition established by the USA.[104]

The Guidelines are also relevant because they established the commitment of CEN and Cenelec to duly implement EU policy mandates by issuing technical standards in the public interest. This declared commitment to regulate in the public interest raised a key challenge to the whole policy scheme set up through the New Approach. Given that HTS processes were largely developed by industry representatives integrating technical committees, the challenge was how to prevent situations of regulatory drift or special interest capture, while at the same time safeguarding the technical expertise and operational autonomy of ESOs from political instrumentalization by EU political officials. Among other mechanisms, the Guidelines originally established that for these purposes Commission officials could attend the meetings of the respective technical committees as 'observers' with no voting rights. As the Commission lacked the capacity to monitor such meetings, the Commission soon made this possibility operational through the designation of specialized 'consultants' who started to participate in technical committees as 'independent experts'. Rather than controlling the standardization process, these consultants were formally regarded as exercising an 'advisory role' by 'clarifying the terms of the essential requirements and/or mandates and to make sure that these are taken account of in every step of the process' in order to ensure coherence between legal requirements and draft HTSs.[105] Finally, the voluntary character of the Guidelines has been seen as a further indication of why ESOs ought not to be regarded as executive bodies of the EU nor simply assimilated to EU administrative agencies.[106]

As all these original features of the New Approach demonstrate, from the outset, the EU integrated a number of incipient governance and accountability mechanisms in HTS processes that, in their organization and operations, share similarities with administrative rulemaking. Even if initially limited in their reach or practical impact, these mechanisms aimed to ensure that the expanded

[104] Stressing this point, Egan (n 29), 269–73: explaining how, in contrast to the 'more pluralist route [taken by the USA that] allows 'standards competition' among a number of different public and private organizations and agencies, the European Union has fostered a strategic regulation approach around a single set of European standards'.

[105] Schepel (n 6), 240–3.

[106] Simoncini (n 58), 117: 'As no hierarchical relation exists, the Commission engages in a contractual relationship with the European standardisation bodies. The mandate for setting standards in conformity with the essential requirements of the Directives is an agreement that requires the acceptance of both the parties. Likewise, the general guidelines for cooperation between the Commission and these standardisation bodies provide a contractual framework that aims to maximise the protection of the general interest in question by granting the full support of EU and European Free Trade Association (EFTA) institutions to the functional duties of the European standardisation bodies'.

regulatory authority attained by ESOs was exercised in a way that safeguarded the public interests contained in various legislative provisions and policy mandates.[107] The legal recognition given by the EU to the regulatory authority exercised by ESOs to pursue policy ends in the name of its citizens entailed, at the same time, an acknowledgement of a certain degree of (asymmetrical, not hierarchical) control by EU officials over how those regulatory powers are exercised. These modes of control were expressed in an incipient set of 'rules of recognition' and internal accountability mechanisms established by the EU through legal means. These rules and mechanisms sought to balance their regulatory autonomy with their socio-political integration by preventing regulatory drift or capture while attempting to avoid straightforward political instrumentalization. In this way, and as the subsequent development of the New Approach denotes, the EU started to incipiently (but incrementally) re-configure the terms of organization and operation of ESOs and a 'private administrative law of technical standardization' gradually started to emerge.[108]

D. The developments of the 'New Approach' during the 1990s

One indication that a private administrative law of technical standardization was beginning to emerge is that soon after the original formulation of the New Approach a certain basic commitment to openness and participation by civil society representatives of marginalized groups was integrated into technical standardization processes.[109] In particular, at an early stage, the integration of consumer representatives in standardization processes received explicit support by EU authorities.[110] Nonetheless, it is important to stress that the institutionalization of a principle of openness and participation in HTS processes has been a gradual achievement (and is still in an ongoing challenge) rather than a first principle, as primacy had traditionally been given to the internal circles of national SSOs.

[107] Egan (n 29), 132–3: remarking how early-on 'fears that such private decision-making would dilute the public interest, and to perceptions of regulatory capture . . . fostered increased attention on monitoring and oversight functions . . . aimed at ensuring that the private standards bodies are responsive to public goals and objectives'.

[108] For a specialized study of similar dynamics on technical standards at the internationational level, resembling the paths taken by the EU: M Mataija, 'Private standard setting in the TBT Agreement: Control and recognition' in M Cantero and H-W Micklitz (eds), *The Role of the EU in Transnational Legal Ordering: Standards, Contracts and Codes* (Edward Elgar Publishing, 2020).

[109] The 1984 Guidelines for Cooperation established the following in these respects: 'In order to establish the grounds for a large recognition of the importance of European Standards, CEN and Cenelec will ensure that the interested circles, especially public authorities, manufacturers, users, consumers, trade unions, can, if they so wish, be effectively associated in the drawing-up of European Standards: the Commission will, should the case arise, help in the definition of the appropriate modalities'.

[110] See, for example, Commission, 'Commission Recommendation 88/41/EEC of 10 December 1987 on the involvement and improvement of consumer participation in standardization' (1987) OJ L23/26; and the Council resolution of 4 November 1988 on the improvement of consumer involvement in standardization [1988] OJ C293/01.

Indeed, it has been widely documented how national SSOs have usually been given a noticeably more important role in these respects. Throughout HTS processes, national SSOs have regularly operated as fora to coordinate and articulate national positions among diverse societal interests, but also to link the technical committees working at a European level with relevant constituents. These were the (largely opaque) mechanisms originally established by the New Approach to make such a commitment to develop standardization mandates that are in the public interest both possible and contestable.[111]

A step forward in the involvement of societal representatives was made in 1992 when, in light of further political criticism, CEN agreed to formally create the category of 'associate members' involving consumer, workers, and SMEs' representatives within their processes (extended later to environmental representatives).[112] Moreover, by 1996 some basic commitments to transparency, participation, and rationality in technical standardization processes became formally institutionalized as a criteria of recognition of ESOs.[113] Nevertheless, consistent calls to 'improve existing mechanisms' continued to proliferate in 1998,[114] 1999,[115] and 2002.[116] Yet this commitment to opening technical standardization processes to broader societal representatives was initially in tension with the policy interest to ensure a suitable and timely fulfilment of standardization mandates.[117]

In fact, the regulatory capacity of ESOs to deliver standardization mandates became a central concern during the 1990s. This concern triggered several initiatives for the institutional recalibration of technical standardization processes, two

[111] Joerges, Schepel, and Vos (n 7), 48–9, and for detailed analysis and case studies, Egan (n 29), chs 6–8.

[112] G Howells, 'Consumer safety and standardisation—protection through representation?' in L Krämer, H-W Micklitz, and K Tonner (eds), *Law and Diffuse Interests in the European Legal Order: Liber Amicorum Norbert Reich* (Nomos, 1997).

[113] Commission, 'Commission Decision 96/139 amending the list of national standardisation bodies in Annex II to Council Directive 83/189/EEC' (1996) OJ L32/31.

[114] See, Commission, 'Efficiency and Accountability in European Standardisation Under the New Approach' (COM/98/291) < http://aei.pitt.edu/id/eprint/42995>, paras 8 and 19: stating that 'CEN and CENELEC should consider further opening their structures to representative European-based interested parties, such as workers, consumers, environmental interests and industry, allowing them to participate in strategic discussions and the elaboration of policy. In contrast to ETSI, in CEN and CENELEC policy decisions and strategic discussion remain limited to their Boards and national standards bodies'.

[115] In this sense, see Council Resolution of 28 October 1999 on the role of standardization in Europe [2000] OJ C141/01, para. 39.

[116] See, Council Conclusions of 1 March 2002 on standardization [2002] OJ C66/1. For an earlier assessment in this line, see J Falke, 'Achievements and unresolved problems of European standardisation: The ingenuity of practice and the queries of lawyers' in C Joerges, K-H Ladeur, and E Vos (eds), *Integrating Scientific Expertise into Regulatory Decision-making: National Traditions and European Innovations* (Nomos, 1997), 208–15. For an updated account, see also, in general, Schepel (n 6), 242–6; and J Mendes, *Participation in EU Rule-Making: A Rights-Based Approach* (Oxford University Press, 2011), 121–4.

[117] For a review of how this tension became manifested and in different aspects of the regime, see Egan (n 29), 160, 166, and 209–10.

of which are worth highlighting. First, these concerns prompted the issuance of a Green Paper (1990), which advanced a series of ambitious proposals regarding the terms of organization and operation of ESOs in order to foster 'faster integration in Europe'.[118] Among other proposals, this institutional re-design initiative sought to streamline technical standardization processes by establishing 'project teams' (instead of national delegations); inserting majority voting as a regular practice of decision making (and thereby replacing the principle of 'consensus' traditionally informing technical standardization processes that was prone to stalemate); and establishing a 'European Standardisation Council' that aimed to replace national SSOs in their coordinating role through broad interest representation. Labelled as an attempt to insert a 'retrograde' *dirigisme* in technical standardization processes by establishing a new euro-bureaucratic layer that altered the whole working norms and culture of ESOs, this initiative generated wide opposition among almost every relevant player and was thus ultimately diluted.[119] Yet, the initiative did subsequently translate into a range of optimizations to HTS processes. These improvements included budgetary incentives for the quicker delivery of standardization mandates; a strengthening of 'consultant' positions within those processes; and, more importantly, in a change to their decisional rules by contemplating the possibility of resorting to qualified majority in resolving policy gridlocks as an alternative to the principle of 'consensus'.[120]

However, as concerns about the regulatory capacities of ESOs remained, and alongside the declared intention of the Commission to expand the role of technical standardization in reaching a broader set of EU policy goals,[121] by the end of the 1990s a second initiative for institutional reform emerged. This initiative sought to insert elements of regulatory competition within HTS processes, thereby emulating the model that largely informs technical standardization in the USA.[122] However, the proposal was roundly rejected by EU authorities.[123] The

[118] Commission, 'Green Paper—Action for faster integration in Europe' COM (1990) 456 final.
[119] Joerges, Schepel, and Vos (n 7), 20–3; Schepel (n 6), 68–70: explaining 'no one had anything to gain from the Commission's proposals. The national standards bodies would see their position undermined; national authorities their venues of influence further narrowed, and European industry would have to invest vast quantities of time, expertise, and money. Unsurprisingly then, the Green paper stands as one of the most widely and savagely trashed policy papers in the history of the Commission'
[120] Schepel (n 6), 243–4. See also, Egan (n 29), 224–5.
[121] Commission, 'On the broader use of standardisation in community policy' COM (1995) 412 final.
[122] In particular, as Joerges, Schepel, and Vos have documented, this was a proposal at least discussed (if not generated) at the Meeting of Internal Market Ministers in February, 1998: see Joerges, Schepel, and Vos (n 7), 24.
[123] See Commission, 'Efficiency and Accountability in European Standardisation Under the New Approach' (COM/98/291), paras 28–29: where the European Commission states that 'Efficiency is not likely to be enhanced by the recognition of new standards bodies. New organisations would have to cope with the same tension between efficiency and accountability as CEN, CENELEC and ETSL As they would not be members of the international standards organisations ISO/IEC/ITU, they would not be in a position to represent Europe's interest at the international level, which is becoming increasingly important'.

failure of both institutional re-design initiatives is significant because it had the effect of consolidating the model devised by the New Approach through the new Information Directive 1998 as a distinctive EU approach to technical standardization processes that was increasingly aligned with an emergent 'new governance' paradigm.[124] Moreover, the failure of both reforms eventually also proved to be significant at a global level (just as the 1998 Report by the Commission had foreseen). Indeed, as the influential empirical study by Büthe and Mattli demonstrates, the dominant position that EU standards and norms have currently attained in the global political economy of product standardization *vis-à-vis* the USA may well be explained by the 'institutional complementarity' between ESOs and ISO/IEC that this consolidation of the New Approach strengthened.[125]

E. The 'New Approach' meets 'new governance'

The beginning of the 2000s was marked by intense debate and negotiation about the place and role of ESOs within the European legal order and the overall meaning of the New Approach against the backdrop of the EU's turn to 'new governance'. Alongside the White Paper on Governance, the New Approach became a benchmark for other areas of policy making where a 'framework of co-regulation' could also successfully apply.[126] This gave the New Approach new status in European policy making. On the one hand, and against the backdrop of growing doubts about the effectiveness of regulatory interventionism through 'command-and-control', the New Approach became a symbol of 'better law making' prompting more flexible and responsive regulatory styles that bolstered 'light touch regulation and devolving regulatory responsibilities'.[127] On the other hand, the period was also characterized by criticisms of HTS processes on several fronts, including the timeliness, viability, transparency, and effectiveness of participation by relevant stakeholders.[128]

In fact, this whole reformist process ended up with the formulation of new General Guidelines for Cooperation between the Commission and ESOs. While acknowledging the 'high political profile' that technical standardization processes had already attained by that time, and its important role in pursuing several EU

[124] See, Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations [1998] OJ L204/37 (the Information Directive 1998).
[125] Büthe and Mattli (n 29), 6–7, 11–12, and ch. 3: empirically documenting how EU norms and positions have attained predominance in global product standardization through ISO/IEC, and formulating an 'institutional complimentarity theory' to explain this predominance. In this sense, see also Hofmann, Rowe, and Türk (n 98), 597–8.
[126] Commission, 'European Governance: A White Paper' COM (2001) 428 final, p. 20.
[127] Schepel (n 6), 71. See also, Egan (n 29), 262–4.
[128] See Council Conclusions of 1 March 2002 on standardization [2002] OJ C66/1.

policy challenges, these guidelines notably advanced their 'correspondingly enhanced obligation to observe the principles of transparency, openness, consensus, independence, efficiency and coherence'.[129] Therefore, despite the pioneering status that the New Approach had attained in broad EU imaginaries as an early commitment to new governance ideals of procedural integrity and civil society engagement in regulatory processes, it was only by the 2000s that the New Approach more decisively started to mimic the good governance parameters in technical standardization processes that, by that time, were also being integrated at the WTO level.[130]

It must be stressed that many of these institutional re-configurations of technical standardization processes had been achieved through 'soft law' methods by this time.[131] This made the task of EU law and legal thought even more difficult because it was still largely reasoning behind the formalist, legalistic veil of strict binary distinctions between law/non-law = public/private = political/technical.[132] This was the backdrop against which Harm Schepel's intervention in EU legal thought about technical standardization was shown to be influential in at least three ways. As discussed in the previous section, in synthesis, Schepel first stressed the importance of 'removing the clout of formalism' so as to acknowledge the political/policy nature of technical standardization processes that resemble 'much of lawmaking', albeit avoiding its concurrent 'juridification'.[133] Second,

[129] See the Commission, 'General Guidelines for the Cooperation between CEN, Cenelec and ETSI and The European Commission and the European Free Trade Association—28 March 2003' (2003) OJ C91/7. The overall sentiment is well captured by Schepel (n 6), 72–3: noting how 'In this climate, standardisation takes on a new significance. Instead of either the obvious way of removing barriers to trade represented by national standards or replacing political supranationalism with technical private transnationalism, European standards now take on an autonomous value in the project of European integration. In the bitter debates of Community competences versus Member States' sovereignty, the idea of European-wide industry self-regulation disarms both sides by introducing the notion that bottom-up integration generates its own normative frameworks. European standardisation dissolves the tension between negative and positive integration'.

[130] See Annex 3 of the TBT Agreement, establishing a 'Code of Good Practice for the Preparation, Adoption and Application of Standards'. The reforms can be understood as part of a larger dynamics of institutional isomorphism in standardization processes by civil society institutions, already anticipated by the ISO/IEC Guide 59, 'Code of good practice for standardisation' (1994) and continued by the ISEAL, 'Code of good practice for setting social and environmental standards' (2004).

[131] Still, all of these soft law measures largely relied upon the structure provided by the Information Directive 1983. In practice, though, they depended at the same time on the number of Directives developed under this New Aproach framework, which respectively gave the legal basis for these standardization mandates.

[132] For a thorough examination of EU legal thought about technical standardization at the end of the twentieth century, Joerges, Schepel, and Vos (n 7): diagnosing a stage where 'the obstinacy of [EU] lawyers in their search for an answer to the delegation problem and their readiness to content themselves with overly formalistic responses needs to be understood in the light of the difficulties of developing alternatives' (at p. 45).

[133] Schepel (n 6), 6, 234, 405. In this sense, see Joerges, Schepel, and Vos (n 7), 55–6: 'standardisation is—public and private—"governance"; it can neither be reduced to the application of legal rules and principles nor to a purely technocratic exercise but requires political decisions over normative issues and economic interests'.

Schepel argued how EU Competition Law could and should contribute to structure such a political process by embracing a 'procedural public interest test' as a condition of validity for standardi\ation agreements that enhances participation, contestation, deliberation, and the overall responsiveness of these agreements to social needs.[134] Finally, Schepel also stressed how European Tort Law could, at the same time, contribute to enhancing the quality of deliberation and policy making by incentivizing a technical standardization process that engages in thorough scientific studies towards the very same frontiers of knowledge.[135]

Retrieving these claims made at the dawn of the twenty-first century is important as it demonstrates how much of Schepel's vision about technical standardization processes became officially institutionalized through legal means during the period 2005–2012. First, in light of the growing significance for EU policy making, by 2006 a new legal framework was enacted in order to rationalize the budgetary support and incentives given by the EU to technical standardization processes.[136] Second, by 2011 the 'procedural public interest test' had been officially institutionalized through the EC Guidelines on the Applicability of Article 101 TFEU to standardization agreements, which generally exempts these agreements from competition law scrutiny to the extent that their processes of adoption are informed by some basic parameters of 'good governance' among other specific requirements.[137] Third, Schepel's view of a tort law system as a

[134] Schepel (n 42); Schepel (n 6), ch. 9.
[135] Schepel (n 6), ch. 10.
[136] See the Decision 1673/2006/EC by the European Parliament and European Council of 24 October 2006 on the financing of European standardization [2006] OJ L315/9, justifying the financial contributions to technical standardization processes due to their importance in enhancing the 'health, safety and environmental and consumer protection' and boosting 'the competitiveness of enterprises by facilitating in particular the free movement of goods and services, network interoperability, means of communication, technological development and innovation in activities such as information technology' (recital 3).
[137] See Commission, 'Guidelines on the Applicability of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Co-operation Agreements' (2011) OJ C11/1, article 7 establishing, for example, that 'where participation in standard-setting is unrestricted and the procedure for adopting the standard in question is transparent, standardisation agreements which contain no obligation to comply with the standard and provide access to the standard on fair, reasonable and non-discriminatory terms will normally not restrict competition within the meaning of Article 101(1)' (para. 280 ff). For a earlier assessment, see I Maher, 'Competition law and transnational private regulatory regimes: Marking the cartel boundary' (2011) 38 *Journal of Law and Society*, 119, 128–31, 134–5: noting how standardization agreements within the EU have thereby become 'co-regulatory in nature and characterized by four features: openness (of decision making and membership for all interested actors), consensus (no particular stakeholder interest favoured), balance (participation is available at any stage in the decision-making process), and transparency'. For a latest assessment beyond the 'law in books', see C Cauffman and M Gérardy, 'Competition law as a tool to ensure the legitimacy of standard-setting by European standardisation organizations?' in M Eliantonio and C Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique A Cross-disciplinary and Multi-level Analysis* (Edward Elgar, 2020): I will return to their important insights below in the conclusion.

frameworok that provides the necessary incentives to ensure HTS processes safeguard social needs has largely become a reality.[138]

F. The European Standardisation Regulation 2012

This overall transformation of HTS processes was finally consolidated by the enactment of the European Standardisation Regulation 2012. Its significance is at least twofold. By integrating a number of dispersed rules on standard-setting into a single body of law, on the one hand the European Standardisation Regulation 2012 institutionalized this set of normative commitments to principles of transparency, participation, rationality, and review in HTS processes at a legislative level. On the other hand, the European Standardisation Regulation 2012 also upgraded these commitments in a number of ways.[139]

Among other rules ensuring the transparency and stakeholder participation in HTS processes, for instance, the European Standardisation Regulation 2012 was innovative in that it established specific means of technical and financial support to ensure the active involvement of consumers, environmental concerns, workers, and SME representatives. It also formally integrated the representative organizations of these stakeholders throughout the standardization process.[140] Moreover, the European Standardisation Regulation 2012 established new modes of review and other accountability mechanisms by the Commission and member states over the content of HTSs—and extended them to the European Parliament—in order to assess whether standardization mandates have been duly fulfilled.[141] With these reforms, the European Standardisation Regulation 2012 aimed to create new modes of checks and balances within HTS processes as an way to politically assert public interests and thereby mitigate situations of regulatory drift or

[138] See, for a latest assessment, C Glinski and P Rott, 'Deficient standards by European standardisation organisations: Between state liability and tort liability' in M Eliantonio and C Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique A Cross-disciplinary and Multilevel Analysis* (Edward Elgar, 2020).

[139] See especially the European Standardisation Regulation 2012, recital 7 stating some of the existent legal provisions that had to be 'simplified and adapted in order to cover new aspects of standardisation to reflect those latest developments and future challenges in European standardisation'. On the foundations of this legislative reform, see European Parliament Resolution of 21 October 2010 on the future of European standardization [2010] OJ C70/56 and the Report of the Expert Panel for the Review of the European Standardisation System, 'Standardization for a competitive and innovative Europe: a vision for 2020' (2010) <http://www.anec.eu/attachments/Definitive%20EXPRESS%20report.pdf>.

[140] See, in particular, articles 3–6, 12, 16, 17.4 (b), and especially Annex III of the European Standardisation Regulation 2012.

[141] In this sense, article 10 of the European Standardisation Regulation 2012 instructs the Commission to examine whether HTSs 'satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation' before they are published in the Official Journal and thereby attain legal effects. In turn, its article 11 institutionalizes an 'advisory procedure' and an 'examination procedure' that can be triggered by the European Parliament or by Member States to raise objections against HTSs for these very same reasons. See also, in this sense, the European Standardisation Regulation 2012, recitals 25, 29, and 49–50.

special interest capture, while preserving the necessary levels of regulatory autonomy from political instrumentalization.

Finally, the European Standardisation Regulation 2012 also prompted new information and coordination mechanisms.[142] These mechanisms are meant to enhance the overall responsiveness of the standardization system to social needs and new policy challenges. In this sense, the European Standardisation Regulation 2012 not only consolidated previous developments regarding the accessibility and functionality of HTS processes in the EU. In many ways, it also upgraded the structure of HTS processes in order to 'provide a flexible and transparent platform for consensus building between all participants and which is financially viable'.[143]

To the extent that technical standardization processes in Europe were 'originally organised at the national level around the industrial sector . . . [and] no third parties were allowed to participate, nor the administration . . . nor third parties representing public interests',[144] it is thus remarkable to note the extent to which, by 2012, the terms of organization and operation of HTS processes have been largely transformed by the visible hand of EU law.[145] Yet, throughout this reconstruction even more remarkable is how this 'breaking down the club house (mentality) of private standardisation bodies' had mostly been achieved by EU political authorities through legislation and infra-legal instruments rather than through modes of judicial review. In this sense, by 2012 the processes of technical standardization within the EU very much came to resemble Schepel's seminal vision—an EU legal structure prompting highly politicized HTS processes. These processes offered ample opportunity for engagement with relevant societal

[142] Among other mechanisms, see its article 24 on the annual report by ESOs and article 8 instituting the adoption of an 'annual work programme for European standardisation' to be adopted by the European Commission 'after broad consultation with relevant stakeholders' identifying 'strategic priorities for European standardisation, taking into account Union long-term strategies for growth' and 'objectives for the international dimension of European standardisation' (see also recital 27). For its latest version, see Commission, 'The Annual Union work programme for European standardisation 2020' COM (2019) 486 final, outlining different proposals to enhance sustainability, cybersecurity, and social rights in industrial processes through standardization.

[143] European Standardisation Regulation 2012, recital 9. By 2016, these aims were largely evaluated as successfully accomplished: see the Commission, 'Report from the Commission to the European Parliament and the Council on the implementation of the Regulation (EU) No 1025/2012 from 2013 to 2015' SWD (2016) 126 final, stressing how 'overall, standardisation activities are coherent with the EU's policy objectives—notably the digital single market (DSM), a fairer and deeper single market, energy union, growth and investments, the role of the EU as a global actor. On a practical level, coherence is achieved through the use of the AUWP (which is in line with the Commission priorities 15), and subsequently through close monitoring of the process inside the Commission as well as through interaction with the Member States and relevant stakeholders' (at p. 8).

[144] Gestel and Micklitz (n 11), 149.

[145] See, in this sense, European Parliament resolution of 4 July 2017 on European standards for the twenty-first century [2018] 2016/2274(INI) OJ C334/2 stating how: 'Regulation (EU) No 1025/2012 has brought improvements to the standardisation process by integrating, for the first time, societal stakeholders and SMEs under the legal basis of the European standardisation system'.

representatives and established mechanisms for EU officials to assert the public interest. At the same time, any dysfunctional judicialization (i.e. 'juridification') of these policy controversies had been avoided.[146]

As this brief historiographical reconstruction shows, the EU has incrementally transformed through legal means HTS processes into a regulatory space where several societal representatives converge with techno-political authorities in making and contesting policy choices pursuant to the implementation of standardization mandates. Central to this transformation has been the institutionalization of principles of good governance, expressed in a growing commitment to principles of transparency, participation, rationality, and modalities of review throughout these processes, in ways that sought to make them compatible with the overall efficiency and effectiveness in meeting policy objectives and social needs. In this way, through several legal means, the EU has incrementally re-configured the terms of organization and operation of ESOs akin to the model of 'private administrative law'. While consistently expanding its meta-regulatory authority over ESO activities through evolving rules of recognition seeking to foster their social integration and political responsiveness, the EU has sought to preserve the regulatory autonomy of ESOs by generally restraining its intervention in HTS processes to ensuring a commitment to procedural principles of good governance.[147]

Therefore, a fully fledged regime of 'private administrative law' of HTSs only became legally institutionalized (constituted) through the visible hand of EU law by 2012. This legal transformation noticeably contrasts not only with the opaque 'club mentality' that used to inform technical standardization processes in Europe. In some significant way, it is also in contrast with the model of regulatory competition that has been established in these respects by the USA,[148] and the 'pluralist' metaphor of law-making by civil society institutions that informs postmodern approaches to private regulatory authority in much of contemporary legal studies. *Pace* Schepel and with Habermas, as my analysis reveals, EU law has incrementally institutionalized a number mechanisms seeking to ensure that HTS processes 'remain linked to [EU] legislative programs in a transparent, comprehensible, and controllable way' with the possibility of EU legal officials 'asserting public interests' when appropriate and thereby maintaining their

[146] See, in this sense, the Commission, 'Report from the Commission to the European Parliament and the Council on the implementation of the Regulation (EU) No 1025/2012 from 2013 to 2015' SWD (2016) 126 final: concluding how the European Standardisation Regulation 2012 'has brought significant improvements in the ESS [European Standardisation System] due to the timely availability of standards requested by the Commission, the early involvement of the stakeholders, the creation of consensus around the standardisation requests under preparation, and the improvement in the quality and detail of the requests issued' (at p. 10).

[147] See, in a similar sense, Mataija (n 85), 252–3.

[148] Stressing these comparative differences in institutional design and philosophy of technical standardization processes, see Gestel and Micklitz (n 11), 155–6; Mataija (n 85), 227. See also Egan (n 29), ch. 10: noting how 'comparisons with the construction of the American single market reveal a counterpart in the European Union'.

'asymmetrical position that results from their obligation to represent the whole of an absent citizenry, whose will is embodied in the wording of the statutes' without necessarily entailing or falling prey to political instrumentalization.[149]

IV. The end of the New Approach?

A. *Fra.bo*

In what may well become another instantiation of a 'rise and fall' dynamics in the historiography of legal change, the very same year that the idea of a private administrative law in technical standardization informing the New Approach attained an enhanced legal status in EU Law, its whole architecture seemingly started to crumble. The ECJ's judgment in *Fra.bo* was the first stroke, which has been widely read as a decision that (at least under certain circumstances) subjected technical standardization processes to free movement discipline and thereby to judicial review.[150] Some received this ECJ judgment with optimism, as finally ensuring the accessibility to HTSs that now (logically) could no longer be subject to copyright,[151] or as subjecting HTSs to the principle of effective judicial protection under free movement law and thereby to essential parameters of the rule of law in Europe.[152] However, others viewed the judgment as opening the way for a problematic 'juridification' (ie judicialization) of technical standardization processes that would swamp the effective and efficient safeguarding of social needs that the EU had attained through this political/policy process in a costly and slow litigation before courts that do not have, nor properly could access, the necessary knowledge to address these technical issues.[153]

Fra.bo must be treated with circumspection though, as it has neither generated the optimistic nor the fatalistic scenarios that have been anticipated. *Fra.bo* is a

[149] J Habermas, *Between Facts and Norms: Contributions to a Discourse Theory of Law and Democracy [1992]* (The MIT Press, 1996) 350–1, 441–2. In contrast, see Schepel (n 6), 406–10; Schepel (n 50), 367–8; Schepel, 'Rules of Recognition: A Legal Constructivist Approach to Transnational Private Regulation' (n 20), 207: where Schepel elaborates a pluralist approach to the private regulatory authority of technical standardization bodies largely set against the legal republicanism of Jürgen Habermas.

[150] Case C-171/11 *Fra.bo* [2012] ECLI : EU : C:2012:453.

[151] Gestel and Micklitz (n 11): reasoning on the basis of *Fra.bo* that according to EU Law 'if standards bodies must be regarded as public bodies when having de facto public powers, what they produce is "law" and therefore cannot be protected via copyrights' (at p. 175–6).

[152] P Verbruggen and B Van Leeuwen, 'The liability of notified bodies under the EU's New Approach: The implications of the PIP breast implants case' (2018) 43 *European Law Review*, 394: 'While the CJEU had previously held that art.34 TFEU did not have horizontal direct effect and could therefore not apply to contractual arrangements, in Fra.bo it opened the door for art.34 TFEU to have horizontal direct effect' and in this sense holding that a '"constitutionalisation" of private regulation clearly emerged in *Fra.bo* and, more recently, in *James Elliott*'.

[153] Schepel (n 8): concluding that 'There may be a lot wrong with European standardization, but it is hard to see how clogging up the system with litigation will remedy much of it'.

strange and in many ways an ambivalent judgment. The 'de facto' test that the ECJ devised is not really useful.[154] The reasoning also undermines the type of normative expectations that sustains the delicate balance between the aims of ensuring social protection through conformity assessments and at the same time safeguarding free movement in the internal market through mutual recognition.[155] It is also a decision that hardly takes seriously the entrenched distinction between (voluntary) technical standards and (mandatory) technical regulations, with all the associated legal implications, nor the historical reasons that necessitated the institutionalization of that distinction in the EU legal order in the first place.[156] For these reasons, *Fra.bo* must not be overestimated in neither its legal nor policy implications beyond its particular facts.[157]

Nevertheless, and against the backdrop of the attention that *Fra.bo* has drawn in EU legal thinking and analysis, it is important to stress at least one point. In *Fra.bo* the ECJ decided that the measure was subject to free movement discipline because in that particular case, and under those particular circumstances, the measure *de facto* operated as a technical regulation and thereby had to be regarded as subject to Article 34 TFEU. One might well disagree with the framing of the case or the reasoning that led the court to such a conclusion, but it seems far-fetched to extract from this judgment a general rule that each and every technical standard or conformity assessment measure would now be subject to judicial review through free movement discipline. Actually, one could read *Fra.bo* as disciplining technical standards that were an integral part of co-regulatory arrangements, as, for example, the German 'Regulation on General Conditions for Water Supply' (the *AVBWasserV*) at stake in the case could be interpreted.[158] In this reading, the judgment would not be really a landmark one or seen as innovative at all. When placed within this framework, the *Fra.bo* judgment would instead become part of a relatively settled line of case law where the ECJ has already extended free movement discipline to technical standardization that is part of co-regulatory regimes that produce trade restrictive effects.[159]

[154] For an explanation, see ibid 527–8; Schepel (n 40), 202–7: where Schepel employs even stronger adjetives 'the result is sobering and depressing: in this way, the pertinent and interesting questions raised by the facts in *Fra.bo* all remain unanswered and even beyond scrutiny'.

[155] For a perceptive analysis, Mataija (n 85), 247–51.

[156] Schepel (n 6) 247, 276. See, among other (still binding) provisions, the New Approach resolution 1985, stating that 'these technical specifications are not mandatory and maintain their status of voluntary standards' and recitals 1, 2, and 11 of the European Standardisation Regulation 2012, stating that 'The primary objective of standardisation is the definition of voluntary technical or quality specifications with which current or future products, production processes or services may comply'.

[157] On the particular context and socio-political significance of the *Fra.bo* case, signalling the epic story of an SME struggling against the Golliath's of the German market, see <https://www.frabo.com/eng/frabo/the-frabo-case>.

[158] For a similar account, Hettne (n 56), 411–12.

[159] See, for example, Case C-249/81 *Commission v Ireland* [1982] ECLI : EU : C:1982:402; Case C-222/82 *Apple and Pear Development Council v K.J. Lewis Ltd and others* [1983] ECLI : EU : C:1983:370; Case C-29/82 *F. Van Luipen en Zn BV* [1983] ECLI : EU : C:1983:25; Case C-45/87

B. *James Elliot*

The second and even more significant in-road into the functionalist architecture informing the New Approach seemingly came from the *James Elliot* judgment by the ECJ.[160] In its most cited section, this ECJ judgment established that HTSs 'form part of EU law' (para. 40) and, as such, the court had jurisdiction under Article 267 TFEU to give a preliminary ruling regarding their interpretation (para. 47). Although the case involved at least five questions posed by the Irish Supreme Court—and the question of jurisdiction was only a sub-part of the first question—from the outset AG Campos Sanchez-Bordona focused entirely on the novelty and significance of the question about whether the ECJ had jurisdiction over HTSs.[161] The ECJ's judgment in the affirmative thus caused a foreseeable degree of furore in EU law and legal thinking: being received with exclamation marks,[162] 'catchy' neologisms,[163] and mythological allegories.[164]

In asserting its jurisdiction over HTSs, the *James Elliot* judgment has been widely read as a 'ground-breaking outcome'[165] that unequivocally consolidates the path towards a (whether or not desirable) 'juridification' of HTSs in the EU

Commission v Ireland [1988] ECLI : EU : C:1988:435, paras. 20, 22; and Case C-325/00 *Commission v Germany* [2002] ECLI : EU : C:2002:633. See also, more recently, Case C-470/03, *AGM-COS.MET Srl v Suomen valtio and Tarmo Lehtinen* [2007] ECLI : EU : C:2007:213, paras 65–66. The central legal provision in this respect is article 1.1 (f) of the Information Directive 2015, which defines several hypotheses of 'de facto technical regulations' in connection to different modalities of co-regulation. For a discussion of these cases, Mataija (n 85), 229–31, 245–7.

[160] Case C-613/14 *James Elliott* [2016] EU : C:2016:821.

[161] AG Campos Sanchez-Bordona opened his legal opinion with the following synthesis: 'This case brings directly before the Court of Justice, for the first time, the issue of whether the Court has jurisdiction to give a preliminary ruling on the interpretation of a harmonised technical standard adopted by the CEN and subsequently converted into a national technical standard, in addition to various questions of interpretation concerning the subject-matter of the harmonised standard and the issue of whether that standard may be relied upon in proceedings between private parties' Case C-613/14 *James Elliott* [2016] EU : C:2016:821, Opinion of AG Campos Sanchez-Bordona, para. 3 (see also, para. 35).

[162] M Medzmariashvili, 'A Harmonised European (Technical) Standard-Provision of EU Law! (Judgment in C-613/14 James Elliott Construction)' (*European Law Blog*, 24 January 2017) <https://europeanlawblog.eu/2017/01/24/a-harmonised-european-technical-standard-provision-of-eu-law-judgment-in-c-61314-james-elliott-construction/> accessed 5 June 2020; K P Purnhagen, 'Voluntary "New Approach" technical standards are subject to judicial scrutiny by the CJEU!—the remarkable CJEU judgment "Elliott" on private standards' (2017) 8 *European Journal of Risk Regulation*, 586.

[163] Hettne (n 56); van Waeyenberge and Restrepo (n 56).

[164] B S Gherardinni, 'Harmonised European Standards and the EU Court of Justice: Beware Not to Open Pandora's Box' (*European Law Blog*, 27 May 2016) <https://europeanlawblog.eu/2016/05/27/harmonised-european-standards-and-the-eu-court-of-justice-beware-not-to-open-pandoras-box/> accessed 12 June 2020; P van Cleynenbreugel and I Demoulin, 'The EP's "European Standards" Resolution in the Wake of James Elliott Construction: Carving Ever More Holes in Pandora's Box?' (*European Law Blog*, 25 September 2017) <https://europeanlawblog.eu/2017/09/25/the-eps-european-standards-resolution-in-the-wake-of-james-elliott-construction-carving-ever-more-holes-in-pandoras-box/> accessed 11 June 2020.

[165] Volpato (n 55), 592.

legal order[166]—and thereby the 'end of the New Approach'.[167] In fact, as stated in the introduction, this is how the judgment has been also interpreted in official Commission documents,[168] and also of the European Parliament—to the extent that the latter thought it necessary to even issue a counteractive interpretation (disappointingly, with no better argument than) appealing to the formalistic veil or legalistic fiction that had long informed the perceived legitimacy of the New Approach.[169]

In the following, I outline my disagreement with this generalized reading of *James Elliot*. Instead of innovating upon or liquidating the New Approach, I argue that the ECJ's judgment in *James Elliot* is significant because in many ways it reaffirms the idea of a private administrative law as the structure informing the New Approach. It does so not only by signalling the peculiar status HTSs hold in the EU legal order, but also by acknowledging the important 'police powers' that HTS processes exercise in purporting to effectively reconcile the values of free trade and social protection within the internal market through techno-political debate and policy making. To grasp the significance of the *James Elliot* judgment, however, I argue that one needs to extend one's view beyond the mere question of jurisdiction that has dominated discussion among EU legal practitioners and scholarship (and which, in fact, was only a sub-question referred by the Irish Supreme Court). Instead, by situating the decision in the broader context provided by the circumstances of the case, *James Elliot* can be read as a judgment

[166] Colombo and Eliantonio (n 55); Senden (n 13); Medzmariashvili (n 54); Tovo (n 54); Simoncini (n 58), 118.

[167] This is how Harm Schepel entitled his presentation discussing the *James Elliot* judgment at a seminar on 'International Trade, International Standardisation and Private Law' held on 3–4 November 2016 at University of Helsinki. The following paragraphs should be read as a response to that interpretation.

[168] See Commission, 'Better Regulation Toolbox: Tool 18—The choice of policy instruments' (2017) <https://ec.europa.eu/info/sites/info/files/file_import/better-regulation-toolbox-18_en_0.pdf> explaining that 'Where indirectly referenced technical standards, even when voluntary, confer a legal effect, such technical standards fall under Article 267 of TFEU meaning that the Court of Justice of the European Union shall have jurisdiction to give preliminary rulings concerning the validity and interpretation of such standards' (with a footnote reference to the *James Elliot* judgment sustaining this legal proposition).

[169] In its resolution of 4 July 2017 on European standards for the twenty-first century [2018] 2016/2274(INI) OJ C334/2, the European Parliament: 'notes that standards are a voluntary, market-driven tool providing technical requirements and guidance the use of which facilitates compliance of goods and services with European legislation and supports European policies when they are developed in an accountable, transparent and inclusive way; [and] stresses, however, that *standards cannot be seen as EU law,* since legislation and policies regarding the level of consumer, health, safety, environment and data protection and the level of social inclusion are determined by the legislator' (emphasis added). This legalistic fiction is still pervasive also in other policy documents: see, for example, Commission, 'Commission Notice—The "Blue Guide" on the implementation of EU products rules 2016' (2016) OJ C 272/1, p. 10. It has been long documented why appealing to this fiction is a bad strategy to defend the legislative technique to technical harmonization informing the New Approach, as it represses the problem rather than confronting it (and with good reasons) upfront: see mainly Schepel (n 6), 227–34, and 246–58.

that strengthens (rather than undermines) the New Approach and the model of a private administrative law informing it.

C. *James Elliot* in context

As a point of departure, it is relevant to focus on the facts of the case and what was established in the previous judicial proceedings before the Irish courts. This is important because it indicates why a substantive judgment by the ECJ was not only necessary for the outcome of the case at stake before the Irish courts, but also relevant to clarify, prospectively, whether and to what extent the New Approach interacts with national laws of contract in European law. The case concerned an action for contractual liability brought by James Elliot Construction against Irish Asphalt, its supplier of a particular type of aggregate to be used to build the internal floors of a Youth Facility in Dublin (specified in the contract as 'Clause 804 hardcore'). Once the facility was delivered, and after cracks appeared on the floor and ceilings that rendered the building unusable, James Elliot Construction had to perform remedial work costing €1.5 million. As it was found that 'the damage in question was caused by the presence of pyrite in the Clause 804 aggregate supplied by Irish Asphalt', James Elliot Construction sought legal compensation from Irish Asphalt. Moreover, during the judicial proceedings it was proven that this product 'did not meet Irish standard I.S. EN 13242:2002 transposing European standard EN 13242:2002, in particular as regards its sulphur content'. Therefore, the Irish High Court held Irish Asphalt liable for breaching its contractual duty to provide goods of a 'merchantable quality' and 'fit for purpose' according to Article 14.2 of the Irish Sale of Goods Act 1980, in a decision later confirmed on appeal by the Irish Supreme Court.[170]

Having proved that the damage was caused by the blatant infringement of a norm applicable to the contract, the case appeared to be a relatively simple one and Irish Asphalt had to be held liable—as both the Irish High Court and Supreme Court held. However, Irish Asphalt had much to gain if it gave the case an EU law twist. As the infringed norm was a transposition of a HTSs implementing the Construction Products Directive 1989 enacted under the New Approach framework, it could be argued that the 'merchantable quality' of the product should be held to be proven (or at least sheltered) by the 'presumption of conformity' that was specifically established by Article 6.1 of the referred Directive—a presumption that could only be rebutted at the moment and through the means of proof established in that particular statutory framework. Moreover, on this line of reasoning, as the implied term to provide goods of

[170] The Supreme Court disagreed that the 'fitness for purpose' implied term had been breached, but accepted the breach of the 'merchantable quality' term—I thank Rónán Condon for this clarification. Further details about the facts of the case can be found in Case C-613/14 *James Elliott* [2016] EU : C:2016:821, paras 23–29; and the Opinion of AG Campos Sanchez-Bordona, paras 25–29.

'merchantable quality' established by Article 14.2 of the Irish Sale of Goods Act 1980 would impose further obligations to manufacturers of construction products than those established by the referred Directive and its HTSs, and these requirements had not been subject to the notification proceedings established by Article 8.1 of the Information Directive 1998, such a legal provision would be contrary to EU law and therefore legally inapplicable according to settled ECJ case law.[171] In this sense, by re-framing the case in EU law terms, both the alleged regulatory infringement and the very contractual duty established in national law that was deemed as breached by Irish Asphalt could be legally circumvented. Therefore, and in what would be an epic come back, a blatantly lost case for Irish Asphalt could therefore suddenly be transformed into a winning one.

In this sense, forensically, there was much at stake when these aspects of EU law were brought into the legal reasoning of the case. To a significant extent, the case's result depended upon on the resolution of a number of interpretative questions concerning the scope of the New Approach and the meaning and reach of HTSs in the EU legal order. This conviction prompted the Irish Supreme Court to stay the proceedings and refer these legal issues to the ECJ for a preliminary ruling.[172] From a normative perspective, moreover, these interpretative questions were also important to clarify, not only for the result of the *James Elliot* case, but also to provide prospective guidance on how HTS processes interact with the national law of contracts in order to ensure a predictable and consistent application of the New Approach throughout the EU. Logically, though, a prior step for the ECJ to provide an authoritative answer to these legal questions was to establish its jurisdiction over the case. This was in fact the very first question asked by the referring Court, and it has been the question where much of the doctrinal

[171] In support of this argument, reference is made in the proceedings to the judgments by the ECJ in Case C-194/94 *CIA Security International* [1994] EU : C:1996:172, and Case C-443/98 *Unilever* [1998] EU : C:2000:496.

[172] As the AG Campos Sanchez-Bordona explains: 'the Supreme Court did not rule on the aspects of the case relating to the application of EU law, for it was uncertain about the legal nature of European technical standards and whether they could be relied on in contractual relationships between private parties, about the interpretation of EN 13242:2002, and about the obligation of prior notification laid down in the Irish provisions on the sale of goods' It is relevant to note that only the Irish government questioned the admissibility of a preliminary ruling based on the view that the dispute 'concerns a purely internal commercial situation or relationship (breach of a contract between two Irish undertakings), restricted to Ireland' with 'no applicable EU legal provisions whose validity or interpretation is open to doubt'. However, the AG 'like the [Irish] Supreme Court' disagreed, because 'the outcome of the case depends on the interpretation of EN 13242:2002, adopted pursuant to Directives 89/106 and 98/34 and implemented by the Irish technical standard I.S. EN 13242:2002' Therefore, in view of the AG 'the Supreme Court has jurisdiction to adjudicate on whether there has been a breach of contract, but its finding may be conditional upon the interpretation of EU law, a situation in which the Court of Justice considers that it has jurisdiction to give a preliminary ruling on questions submitted to it by national courts'. See Case C-613/14 *James Elliott* [2016] EU : C:2016:821, Opinion of AG Campos Sanchez-Bordona, paras 30, 33–34.

analysis of the *James Elliot* judgment has focused.[173] It is thus important to dwell on this question and examine the reasoning given by the ECJ, which answered the question in the affirmative.

D. The legal reasoning of *James Elliot*

The legal provision at stake was Article 267 (b) TFEU, which establishes that the ECJ 'shall have jurisdiction to give preliminary rulings concerning: the validity and interpretation of acts of the institutions, bodies, offices or agencies of the Union'. In his legal opinion, AG Campos Sanchez-Bordona argued that the ECJ had jurisdiction in this particular case because HTSs should be considered as 'acts of the institutions, bodies, offices or agencies of the Union' (para. 40). In this way, the AG contradicted the position taken not only by James Elliot Construction, but also by the Irish Government and the Irish Supreme Court which had argued that HTSs cannot be regarded as 'acts of the institutions, bodies, offices or agencies of the Union' due to their 'private' and 'voluntary' character (para. 39). AG Campos Sanchez-Bordona mainly formulated three arguments in support of his legal proposition. First, that if the ECJ had jurisdiction to interpret the Construction Products Directive 1989 through preliminary rulings, logically it should also have jurisdiction over every act that supplements it (paras 42–45). Second, that HTSs cannot be assimilated to merely private modes of technical standardization because EU institutions exercise 'significant control' during their process of enactment. This 'significant control' includes the issuance of a standardization mandate, the publication of references to HTSs in the Official Journal of the European Union, and the power/duty to review the content of HTSs before or after publication—all of which differentiates HTSs from 'purely private' modes of technical standardization (paras 46–54).[174]

The third and final argument that AG Campos Sanchez-Bordona articulated is that although CEN is a private body, its terms of organization and operation in the issuance of HTSs are 'subject to action by the European Union'. These actions are manifest in the General Guidelines of Operation that have been subscribed between the Commission and CEN, the financial support that the EU regularly provides to ESOs for these standard-setting activities in pursuit of EU law and policies, and the legal effects that EU Law attributes to HTSs

[173] Literally, the referring court asked—question 1 (a): 'Where the terms of a private contract oblige a party to supply a product produced in accordance with a national standard, itself adopted in implementation of a European standard made pursuant to a mandate issued by the European Commission under the provisions of the Construction Products Directive (89/106/EEC) of 21 December 1988, is the interpretation of the said Standard a matter upon which a preliminary ruling may be sought from the Court of Justice of the European Union pursuant to Article 267 TFEU?'.

[174] The AG draws upon the judgment by the ECJ in Case C-185/08 *Latchways and Eurosafe Solutions* [2010] EU : C:2010:619 in support of this argument, a *contrario sensu*, where the ECJ held that it did not have jurisdiction to interpret EN 795 issued by CEN outside HTSs processes because of its lack of connection with EU Law (para. 49).

(paras 56–63). Through these arguments, AG Campos Sanchez-Bordona revitalized a whole delegation frame and nomenclature to represent HTSs under the EU legal order, by characterizing the private regulatory authority exercised by ESOs through HTSs as an instance of 'controlled delegation in favour of a private standardisation body' (para. 55). Therefore, AG Campos Sanchez-Bordona's legal opinion purports to advance a full-scale 'juridification' by 'agencification' of HTS processes in the EU by concluding that these processes must be assimilated in their nature and place to those of EU administrative agencies within the EU legal order as 'acts of the institutions, bodies, offices or agencies of the Union' subject to the ECJ's jurisdiction under 267 TFEU.[175]

However, the ECJ elaborated a different account of HTSs to the one advanced by AG Campos Sanchez-Bordona. Basically, the ECJ established that as HTSs are issued by 'an organisation governed by private law' (para. 43) they cannot be conceived as 'acts of the institutions, bodies, offices or agencies of the Union' (para. 34). Yet, even if private measures, HTSs are to be regarded as 'measures implementing or applying an act of EU Law' (para. 34) due to their special connection to those New Approach directives that they are meant to specify (para. 43). Hence, HTSs form 'part of EU law' and, therefore, are subject to its interpretative jurisdiction through preliminary ruling under 267 TFEU (paras 40 and 47).

The ECJ made, in particular, four arguments to sustain this account of HTSs and thereby its jurisdiction over them. First, that HTSs give 'concrete form on a technical level to the essential requirements' that are legislatively defined by an EU directive (para. 36). Second, that HTSs are issued pursuant to a mandate (para. 44) and through a process that is monitored by the Commission (para. 45). Third, that references to HTSs have to be published in the Official Journal of the European Union (para. 37). Finally, that despite being voluntary or non-binding (para. 42), HTSs produce legal effects after such a publication, thus generating a 'presumption of conformity' that enables certified products to freely circulate and be commercialized in the internal market and forbidding member states from 'impos[ing] additional requirements on such products for their effective use on the market … within their territory' (paras 38–39, 41, and 46). For these reasons, the ECJ established its jurisdiction to give a preliminary ruling over the interpretation of HTSs.

[175] See, in particular, Opinion of the AG Campos Sanchez-Bordona, para. 40 categorically holding that 'harmonised technical standards, like those in the present case, … should be regarded as "acts of the institutions, bodies, offices or agencies of the Union" for the purposes of Article 267 TFEU'. Similarly, see Colombo and Eliantonio (n 55): concluding that 'it is hard to deny that the standardisation process represents a case of uncontrolled delegation'; and M Hiemstra and L Senden, 'Private regulation in the internal market: Assessing European technical standardisation through a citizen's eye' in M de Cock Buning and L Senden (eds), *Private Regulation and Enforcement in the EU: Finding the Right Balance from a Citizen's Perspective* (Bloomsbury Publishing, 2020), 78–81: 'from an EU law perspective, whilst European standardisation is not formally part of the hierarchy of norms as described, one can understand the Commission's mandate as framed in the Regulation as some form of subdelegation to ESOs'.

E. *James Elliot* and the scope of the ECJ's jurisdiction

With this synthesis of the reasoning of *James Elliot* in mind, two aspects of the ECJ's legal reasoning are worth underlining for my overall argument. The first aspect is the scope given by the ECJ to its jurisdiction over HTSs. Although 267 (b) TFEU gives the ECJ full jurisdiction to issue preliminary rulings regarding questions about 'the validity and interpretation of acts of the institutions, bodies, offices or agencies of the Union', the *James Elliot* judgment demonstrates that the ECJ's jurisdiction over HTSs is not as complete or plenary. In other words, due to the particular nature of HTSs—as acts that cannot be ascribed to EU 'institutions bodies, offices or agencies', but that nevertheless 'implement or apply an act of EU law', the ECJ established that it only has 'jurisdiction to interpret [these] acts' (para. 34). While the judgment does not exclude that this jurisdictional authority may also become extended to questions of validity of HTSs, and some legal commentators have readily assumed that *James Elliot* already entails these plenary jurisdictional powers over HTSs,[176] or it should render these plenary jurisdictional powers by the ECJ over HTSs,[177] in my view there are good reasons to hold that it neither entails nor justifies such an extension.

First, since *Cremonini and Vrankovich*, the ECJ has consistently held that the 'safeguard procedure' (or their equivalents under Articles 10 and 11 of the new European Standardisation Regulation 2012) is the only means through which HTSs can cease to produce legal effects.[178] Although this line of case law concerns additional measures of conformity assessments imposed by Member States, it is plausible that this rule can also apply to EU bodies and consequently to the ECJ itself. Therefore, according to this case law, any issues regarding the validity or merits of HTSs would have to be channelled through these specific procedures or the overall political process that has been established for these purposes by the European Standardisation Regulation 2012 and complementary legal framework.[179] Second, the two judgments that the ECJ specifically cites in support of

[176] Hettne (n 56), 417; Lundqvist (n 54), 432, 434; and Cleynenbreugel and Demoulin, (n 164). Less categorical, Hiemstra and Senden (n 175); Gnes (n 55); and Medzmariashvili, (n 54). For a refreshing and provocative account within this position, see Tovo (n 54): arguing that HTSs should be conceived as 'atypical implementing acts within the meaning of Article 291 TFEU imputable to the Commission' and thereby subject to 'limited judicial review by the ECJ'.

[177] M Eliantonio, 'Private actors, public authorities and the relevance of public law in the process of European standardization' (2018) 24 *European Public Law*, 473.

[178] See fn 119 and accompanying text.

[179] With respect to mechanisms of review of HTSs processes, and beyond what has already been established at a formal level by legislation, early on it was highlighted that the important role that the so called technical board have had in practice in these respects in 'handling appeals by participants dissatisfied with outcomes in their various technical committees', Egan (n 29), 143, 165. Consistent with this view, the European Parliament has recently called upon the establishment of a specialized tribunal within HTSs processes as a 'transparent and accessible appeal mechanisms build[s] trust in the ESOs and in the standard-setting processes'. European Parliament resolution of 4 July 2017 on European standards for the twenty-first century [2018] 2016/2274(INI) OJ C334/2, para. 69.

such a legal proposition also restrain the role of the court to an interpretative jurisdiction over acts that cannot be attributed to 'institutions, bodies, offices or agencies of the Union'.[180]

Finally, this constrained jurisdictional reach is consistent not only with preventing a dysfunctional judicialization of techno-political conflicts in HTS processes under the New Approach regime. It is also consistent with the genuine and significant contribution that judicial institutions can really make to technical standardization norms and processes from their distinctive institutional place. The distinction between 'discourses of justification' and judicial 'discourses of application' influentially elaborated by Klaus Günther is useful to illuminate this point.[181] Due to their particular institutional set-up and terms of operations through legalistic procedures, courts are not really well equipped with the technical knowledge and operational capacities to duly address issues of validity in the formulation of HTS as abstract and general rules (which are hence better resolved through techno-political 'discourses of justifications'). Yet, their very same institutional design and position gives courts a privileged connection to hermeneutic problems or questions regarding how HTSs must be interpreted or applied in particular cases or situations (to be resolved through legal 'discourses of application'). In fact, this is precisely the account that the ECJ itself articulated in *James Elliot* about its own jurisdictional powers over HTSs, by stressing that such an interpretative jurisdiction is strictly connected to safeguarding the values of legal certainty and formal legal equality by warranting a clear, consistent, and predictable application of the New Approach to technical harmonization throughout its territory.[182]

[180] See, Case C-192/89 *Sevince* [1990] EU : C:1990:322, para. 10: 'Since the Court has jurisdiction to give preliminary rulings on the Agreement, in so far as it is an act adopted by one of the institutions of the Community (see judgment in Case 181/73 Haegeman [1974] ECR 449), it also has jurisdiction to give rulings *on the interpretation* of the decisions adopted by the authority established by the Agreement and entrusted with responsibility for its implementation'; and Case C-188/91 *Deutsche Shell* [1993] EU : C:1993:24, para. 18: 'It is settled case-law that the fact that a measure of Community law has no binding effect does not preclude the Court from ruling *on its interpretation* in proceedings for a preliminary ruling under Article 177—see also, Case C-113/75 *Giordano Frecassetti v Amministrazione delle Finanze dello Stato* (1976) ECR 983; Case C-90/76 *Van Ameyde v UCI* [1977] ECR 1091; and Case C-322/88 *Grimaldi v Fonds des Maladies Professionnelles* (1989) ECR 4407, para. 9 stating that 'although the recommendations of the Joint Committee cannot confer upon individuals rights which they may enforce before national courts, the latter are nevertheless obliged to take them into consideration in order to resolve disputes submitted to them, especially when, as in this case, they are of relevance in interpreting the provisions of the Convention' (emphases added).

[181] K Günther, *The Sense of Appropriateness: Application Discourses in Morality and Law [1988]* (SUNY Press 1993). For a discussion, see Habermas (n 149), ch. 5.

[182] In the words of the ECJ, 'such a solution being justified by the very objective of Article 267 TFEU, which is to ensure the uniform application, throughout the European Union, of all provisions forming part of the European Union legal system and to ensure that the interpretation thereof does not vary according to the interpretation accorded to them by the various Member States' Case C-613/14 *James Elliott* [2016] EU : C:2016:821, para. 34.

In light of the nature of the queries referred by the Irish Supreme Court concerning their application to the particular situation presented in the *James Elliot* case, the ECJ precisely deployed its interpretative jurisdiction to make a number of valuable clarifications about the content and scope of HTSs in the EU legal order. To present a better account of how these clarifications interrelate, I will put them in logical order rather than in the numerical order in which they were originally asked. In response to the third question referred,[183] the ECJ first clarified that the 'presumption of conformity' granted to certified products according to the New Approach only applies at the border, prohibiting Member States from imposing any additional modes of conformity assessments to these products in order to access national markets. However, the ECJ explained that this presumption does not extend to compliance with any special duties that might arise from contractual relations among merchants (paras 54–61). Second, in response to question 1 (b),[184] the ECJ clarified that referring to an HTS as a parameter to determine the infringement of contractual obligations does not preclude the use of other relevant means or instances of proof in order to determine the infringement of these obligations by contractual parties (paras 48–53). Finally, in response the second question referred,[185] the ECJ clarified that implied contract terms established by national private law cannot be regarded as 'technical regulations' and therefore do not have to be notified according to the Information Directive 1998 (now Information Directive 2015) in order to be effective within contractual relations (paras 63–72). In this way, the ECJ used its interpretative jurisdiction to provide a number of helpful clarifications concerning whether and to what extent HTSs and the overall New Approach scheme in which they are embedded interact with national laws of contracts. *James Elliot* is therefore a good illustration of how the judicial institutions of the EU could best contribute to the sound development of HTS processes.

[183] This question was 'Is a national court hearing a claim for breach of a private contract alleged to arise from a breach of a term as to merchantability or fitness for use (implied by statute in a contract between the parties and not modified or disapplied by them) in respect of a product produced in accordance with EN 13242:2002, obliged to presume that the product is of merchantable quality and fit for its purpose, and if so, may such a presumption only be rebutted by proof of non-compliance with EN 13242:2002 by tests carried out in accordance with the tests and protocols referred to in EN 13242:2002 and carried out at the time of supply of the product?'.

[184] 'If the answer to question 1(a) is yes [ie jurisdiction of the ECJ over HTSs], does EN 13242:2002 require that compliance, or breach of the said standard, be established only by evidence of testing in accordance with the (unmandated) standards adopted by CEN and referred to in EN 13242:2002, and where such tests are carried out at the time of production and/or supply; or may breach of the standard (and accordingly breach of contract) be established by evidence of tests conducted later, if the results of such tests are logically probative of breach of the standard?'.

[185] 'When hearing a private-law claim for breach of contract in respect of a product manufactured pursuant to a European standard issued pursuant to a mandate from the Commission under Directive [89/106], is a national court obliged to disapply the provisions of national law implying terms as to merchantability and fitness for purpose or quality, on the grounds that either the statutory terms or their application create standards which have not been notified in accordance with the provisions of Directive 98/34?'.

F. *James Elliot* and the nature of HTSs

The second aspect of the reasoning of the ECJ in *James Elliot* that is worth stressing concerns the nature of HTSs in EU law. The judgment is quite sinuous in these respects. First, the ECJ acknowledged that HTSs are 'private' (para. 43) and 'voluntary' (para. 42) and, as such, they cannot be assimilated to 'acts of the institutions, bodies, offices or agencies of the Union' (para. 34). However, at the same time, the ECJ held that HTSs can neither be assimilated to mere private acts issued by individuals or organizations in exercise of their subjective rights. Due to the special connection that HTSs have with New Approach directives and procedures, the Court held, HTSs are to be regarded as acts 'implementing or applying an act of EU Law' (para. 34) and thereby as 'part of EU Law' (para. 40). According to the ECJ, in other words, HTSs have a peculiar nature and place in the EU legal order that cannot be assimilated to that of public authorities nor to those of private individuals or organizations. Therefore, in *James Elliot*, the ECJ thus officially establishes that there is something unique—and almost extravagant—about HTSs in the EU legal order.

As, in the very same words of AG Campos Sanchez-Bordona, 'the Court has not had occasion [before] to rule directly on this issue' (para. 35), this is the main novelty and significance of the *James Elliot* judgment for the EU legal order. For the first time, the ECJ formally acknowledged the peculiar nature and place of HTSs in EU law as neither corresponding to a public command nor to mere private action. HTSs cannot be regarded as mere private action because they entail regulatory authority that is purportedly exercised in the public interest. In turn, HTSs cannot be regarded as 'acts of the institutions, bodies, offices or agencies of the Union' because they neither hold their equivalent status nor prerogatives. In this sense, it can be inferred that according to the ECJ the regulatory powers exercised by ESOs through HTSs are neither public nor private action, but something different and diverse: private regulation. This distinctive nature and place of private regulation in the EU legal order is what the ECJ has given official legal recognition in *James Elliot*.

The peculiar nature and place of HTSs underpin the enduring enigma of technical standardization in EU law and legal thought. This *différence* has indeed generated much puzzlement and intrigue among EU law and EU legal thinking.[186] While some have drawn upon the placeholder category of 'hybridity' to try to make sense of it,[187] others have simply acknowledged their perplexity when

[186] Hiemstra and Senden (n 175), 81: 'cryptic'; Volpato (n 55), 601: 'conundrum'; and Cleynenbreugel and Demoulin (n 164): referring to the *James Elliot* as causing a 'a serious crisis of faith'.

[187] Eliantonio and Medzmariashvili (n 17). See, more generally, P Zumbansen, 'Law and Legal pluralism: Hybridity in transnational governance' in P Jurcys, P F Kjaer, and R Yatsunami (eds), Regulatory Hybridization in the Transnational Sphere (Martinus Nijhoff Publishers 2013).

confronted with the phenomenon.[188] Through the reconstruction of how the EU has been reconfiguring the terms of private regulatory authority exercised by ESOs through HTSs, this paper demonstrates why this peculiarity of HTSs is neither new nor unique to technical standards in the EU legal order. My claim is that this reconfiguration can be consistently aligned with the approach taken by the EU to other modes of private regulatory authority within and beyond the internal market. Drawing upon examples from the fields of trade law, financial law, data protection law in e-communications, as well as social and environmental sustainability law through supply chains, I contend that this approach can be productively conceptualized from a doctrinal perspective through the idea of a private administrative law that the EU has been incrementally creating in several fields of private regulation, albeit still in embryonic and largely inchoate ways.[189]

This section has shown how the *James Elliot* judgment reinforces rather than undermines the model of private administrative law of technical standardization that has been devised by the EU through the New Approach. Given the seminal role that *James Elliot* has had in giving formal recognition to this model in EU legal reasoning, I conclude this section suggesting that historiographically *James Elliot* may well become to the development of private administrative law in Europe during the twenty-first century what the *Arrêt Blanco* has symbolically been for the institutionalization of administrative law as a distinctive legal field and rationality in France during the early twentieth century. I warn that this may be a pyrrhic victory for the New Approach however, if the ECJ uses *James Elliot* in the future to justify its jurisdiction over questions of the validity of HTSs by subjecting HTS processes to judicial review under free movement discipline. Throughout this section, my argument has been that the interpretative jurisdiction over HTSs acknowledged by the ECJ in *James Elliot* does not necessarily entail nor justify such an extended reach of its jurisdiction—and one can find ample case law in this line as well. Yet, and to the extent that the ECJ decides to innovate in this respect in the future by extending its jurisdiction over questions of validity of HTSs under free movement law, this would signify an 'agencification' of ESOs and therefore the ultimate 'juridification' of HTS processes by subjecting these techno-political dynamics to judicial review. In this sense, this move would thus indeed represent the 'end of the New Approach'.

[188] Simoncini (n 58), 117: after analysing the *James Elliot* judgment, holding that 'no single legal regime can capture this model of governance, as no such regime is currently provided under the current framework of EU law'.

[189] For a substantiation of this legal proposition, see R Vallejo, The Idea of a Private Administrative Law (PhD, European University Institute 2021).

V. Conclusions: the private administrative law of technical standardization in flux

By way of conclusion, I return full circle to Hemenway's famous remark quoted at the beginning in the epigraph: '... ironically, standards have not been completely standardized' (1975). Ironies are figures of speech to denote outcomes that are somehow incongruous from what was generally expected. In signalling this circumstance as ironical, Hemenway meant to represent the array of inconsistent and sometimes even contradictory methods used in different realms of knowledge to define standards by 1975. For Hemenway it is thus a remarkable irony that 'standards (in their definition) have not been completely standardized'. As noted in the introduction to Section II, the 'world of standards' is certainly much vaster than the microcosm of HTSs, and therefore prone to incongruities. Yet, even in the microcosm of HTSs, my view is that Hemenway's irony still holds true. To conclude my study of HTSs, I thus turn Hemenway's observation into a question: can technical standards ever be standardized?

As this study on HTSs has shown, the EU has been incrementally reconfiguring the terms of private regulatory authority exercised through HTSs in ways akin (but not entirely equivalent) to those applicable to EU administrative agencies. HTS processes have become gradually transformed through EU legal means into a regulatory space where different societal representatives converge with EU political authorities to construct and contest the set of public interests at stake in each of the standardization mandates. Alongside this gradual institutional reconfiguration, a private administrative law of technical standards started to emerge in ways that have been largely consolidated by EU legal and political authorities through the European Standardisation Regulation 2012 and *James Elliot* (2016). This insight reasserts the constitutive properties of law and legal institutions, and suggests how EU law has come to shape HTSs processes as modalities of 'private police powers'.[190]

Does this entail that HTS processes have finally become standardized? My interpretation of the institutional transformation brought about by these processes is far from apologetic. The current configuration of HTS processes may be severely criticized as not fulfilling their immanent normative parameters in several planes. First, despite all the commitments to principles of transparency and participation that have been established in HTS processes at a formal level, an enduring challenge is to make them a reality (especially in cases of certain diffuse interests). This challenge has been duly acknowledged by EU political and policy

[190] On the notion of 'private police powers', see Vallejo (n 18), 336–7; and, more generally, M D Dubber and M Valverde, 'Introduction: Perspectives on the power and science of police' in M D Dubber and M Valverde (eds), *The New Police Science: The Police Power in Domestic and International Governance* (Stanford University Press, 2006).

officials,[191] as well as in recent scholarly assessments.[192] Second, ensuring the accessibility to HTSs that are still largely protected by copyright is also an enduring criticism, the forcefulness of which has actually increased in recent years. Despite greater access to technical standards through FRAND duties or other modes of licensing, the argument that copyright is neither necessary nor justified has intensified with technical standardization now harshly labelled as modes of 'regulation by commodity'.[193]

Finally, the effectiveness of technical standardization processes has also become a matter of significant concern. This has been the case especially after tragic situations such as the so-called 'PIP scandal' in which many women were affected throughout the world. This scandal involved breast implants that, despite having been certified under the Medical Devices Directive 1993, proved defective, causing serious physical and moral damage to their victims. On this basis, sustained concerns have been raised about whether the whole institutional design of the New Approach is prone to regulatory failures at the levels of monitoring and enforcement.[194]

Noticeably, the regulatory effectiveness of technical standards remained beyond the scope of Schepel's monograph and has not been addressed in the

[191] See, for example, Commission, 'Standardisation Package 2016: European standards for the 21st Century' COM (2016) 358 final, p. 3 fn. 4; Commission, 'Report from the Commission to the European Parliament and the Council on the implementation of the Regulation (EU) No 1025/2012 from 2013 to 2015' SWD (2016) 126 final, pp. 4–5; and European Parliament resolution of 4 July 2017 on European standards for the twenty-first century [2018] 2016/2274(INI) OJ C334/2, paras 16, 45, 60, 66, and 74.

[192] See, for example, M Kallestrup, 'Stakeholder participation in European Standardization: A mapping and an assessment of three categories of regulation' (2017) 44 *Legal Issues of Economic Integration*, 381; Hettne (n 56), 414–16; Colombo and Eliantonio (n 55), 336–7; Cauffman and Gérardy (n 137); and B van Leeuwen, 'The impact of the legitimacy of European Standards on their application in private law: A case study on professional standards in the medical sector' in M Eliantonio and C Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique A Cross-disciplinary and Multi-level Analysis* (Edward Elgar, 2020).

[193] This has been mainly the case in the USA context: see E S Bremer, 'Incorporation by reference in an open-government age' (2013) 36 *Harvard Journal of Law & Public Policy*, 131; N A Mendelson, 'Private control over access to the law: The perplexing federal regulatory use of private standards' (2013) 112 *Michigan Law Review*, 737; and, with references to the New Approach in Europe, P Strauss, 'The troubling conjunction of public and private law' in F Bignami and D Zaring (eds), *Comparative Law and Regulation: Understanding the Global Regulatory Process* (Edward Elgar Publishing, 2016). In the case of Europe, see mainly Gestel and Micklitz (n 11); and, more recently, Lundqvist (n 54). See also, for insistent calls in these respect, European Parliament resolution of 4 July 2017 on European standards for the twenty-first century [2018] 2016/2274(INI) OJ C334/2, paras 79–80.

[194] See, for example, Verbruggen and Leeuwen (n 152); P Rott, 'Certification of medical devices: Lessons from the PIP scandal' in P Rott (ed.), *Certification—Trust, Accountability, Liability* (Springer International Publishing, 2019); C Glinski and P Rott, 'Regulating certification bodies in the field of medical devices: The PIP breast implants litigation and beyond' (2019) 27 *European Review of Private Law*, 403; and R van Gestel and P van Lochem, 'Private standards as a replacement for public lawmaking?' in M Cantero and H-W Micklitz (eds), *The Role of the EU in Transnational Legal Ordering: Standards, Contracts and Codes* (Edward Elgar Publishing, 2020). On this issue, see more broadly (way beyond the New Approach), A Fried (ed.), *Understanding Deviance in a World of Standards* (Oxford University Press, 2020).

ulterior iterations of his argument. Due to its seminal place for the construction of 'standards law' as a contemporary legal field, this omission in Schepel's monograph is evocative of an ingrained paradox informing much of 'pluralist' accounts of private regulatory authority in contemporary political economies. The paradox is that, in all their purported neo-functionalism, these 'pluralist' accounts (alongside their clamorous appeals to 'constitutionalizing private governance') usually end up focusing on questions of para-constitutional forms, rather than on whether HTS processes effectively safeguard the social functions or needs that they are supposed to ensure.[195] In the light of these criticisms and some of their entrenched regulatory failures, I aim to strike a word of caution. The use of (overloaded) vocabularies of constitutionalism to represent HTS processes risks legitimizing (by discursively giving constitutional blessing or status) to what should not be legitimized.

The *Stichting Rookpreventie* case currently being examined by the ECJ's Grand Chamber provides a good illustration of these concerns and, for these reasons, it has the potential to become a landmark judgment for technical standardization processes within and beyond the EU.[196] This case concerns the interpretative relevance that ought to be given to a handful of ISO norms that are referred by Article 4 (1) of the Tobacco Directive 2014. These norms are referred by the Directive as authoritative measurement methodologies to determine whether cigarettes placed on the market comply with the 'maximum emission levels' of tar, nicotine, and carbon monoxide thereby established. The *Stichting Rookpreventie* case is thus not about HTSs in a strict sense, but about the status of 'international standards' in the European legal order. Nevertheless, given the type of issues that have been submitted to the ECJ, *Stichting Rookpreventie* may be an opportunity to redefine the rules of recognition of technical standardization norms in general—and of 'international standards' in particular—throughout the EU.

The *Stichting Rookpreventie* case directly relates to the type of normative challenges pervading technical standardization processes discussed above. One of the issues under discussion is the interpretative relevance that must be attributed to ISO norms that do not fulfil the parameters of publicity or free accessibility established in Article 297 (1) TFEU and the Electronic Publication Regulation 2013. By the time of writing (July 2021), AG Saugmandsgaard had issued an opinion arguing that these parameters are not applicable to ISO norms and that

[195] Compare Schepel (n 6), 414 and 9: concluding the monograph with an enticing appeal of how the theory would entail 'the constitutionalisation of global private governance' while stating from the outset how the monograph 'does not—or only tangentially—deal with certification and conformity assessment. The book focuses on procedure and not substance'. Similarly representing HTSs processes in constitutional terms, albeit from a cosmopolitan foundations rather than a functionalist one, see also Verbruggen and Leeuwen (n 152); and L Senden, 'Towards a more holistic legitimacy approach to technical standardisation in the EU' in M Eliantonio and C Cauffman (eds), *The Legitimacy of Standardisation as a Regulatory Technique A Cross-disciplinary and Multi-level Analysis* (Edward Elgar, 2020).

[196] Case C-160/20, *Stichting Rookpreventie Jeugd and Others* [Case in Progress].

the current conditions of access to ISO norms are consistent with the principles informing these provisions.[197] This opinion thus reaffirms the peculiar nature and place of technical standards in the EU legal order. Yet, throughout his Opinion AG Saugmandsgaard also highlights how several modes of free accessibility regarding ISO norms are already being applied *de facto* with respect to certain disadvantaged groups and the public in general.[198] I take these insights as an indication of how an incipient regime to ensure the publicity of technical standards is already taking shape in practice, which could inspire further developments in this line from the perspective of private administrative law.

The second issue under discussion concerns some stringent questions regarding the regulatory integrity and functionality of the referred ISO norms. The applicants in the case have raised repeated reservations regarding the suitability of these norms to ensure the maximum level of cigarette emissions that are established by Article 3 (1) of the Tobacco Directive 2014 and thereby effectively safeguard the health of European consumers.[199] The applicants also point to some pernicious conflict of interest throughout these ISO standardization processes towards the tobacco industry as an explanation the result. While interest representation is ubiquitous throughout regulatory processes—whether public or private—this does not preclude the possibility that the ECJ retrieves some of its established precedents on conflicts of interest regarding modes of private regulatory authority within the EU.[200] The *Stichting Rookpreventie* case thus represents an instance for the ECJ to reconsider the 'rules of recognition' regarding these matters and thereby to speak in the name of the EU polity, self-actualizing the EU's position on the conditions under which it is prepared to give recognition to international standards in the European legal space (akin, perhaps, to what the

[197] See Opinion of AG Saugmandsgaard Øe of 15 July 2021 at ECLI : EU : C:2021:618.
[198] Opinion of AG Saugmandsgaard Øe, paras 89, 92, and fn 31.
[199] The applicants contrapose for these purposes the measurement method established by the ISO norms with the so called Canadian Intense method used in a specialized study by the Dutch National Institute for Public Health and the Environment. On this basis, the applicants show that according to the latter measurement methodology 99 of the 100 cigarette brands studied that are currently commercialized in Europe contain values that are two to three times higher than the legal limits. This specialized study is available at: <https://www.rivm.nl/sites/default/files/2018-11/Tabel%20resultaten_ratio_kleur_DEF.pdf>, last visited 29 July 2021.

As the applicants explain, there is a specific aspect informing this inconsistency. The measurement method established by ISO 3308 determines the levels of cigarette emissions by considering the ventilation holes that have been added by producers to cigarette filters, which significantly dilute the level of emissions with clean air. However, when cigarettes are actually 'consumed as intended' (article 2 n. 21 of the Directive), these ventilation holes are largely closed off by the smoker's lips and fingers. The 'Canadian Intense' method conversely measures the cigarette's emissions during this intended use and accordingly shows that the levels of emission are in fact significantly higher than the ones establised by legislation.
[200] See, for example, Case C-49/07 *MOTOE v Elliniko Dimosio* [2008] ECLI : EU : C:2008:376; and Case C-1/12 *Ordem dos Técnicos Oficiais de Contas v Autoridade da Concorrência* [2013] ECLI : EU : C:2013:127.

Kadi judgment meant for the UN Security Council's terrorist listing resolutions).[201]

Even if the ECJ does not take that leap, the legal framework governing *Stichtin* also contemplates some political avenues to address these types of functional concerns. Article 4 (3) of the Tobacco Directive 2014 entitles the Commission to adapt the measurement methods through delegated acts 'where this is necessary, based on scientific and technical developments' subject to the procedural requirements established in Article 27. Article 4 (4) likewise contemplates the possibility of Member States doing so. These regulatory powers to adopt justified measures to safeguard the health of European or Dutch consumers are consistent with Article 2.4 of the TBT, which entitles signatory states to diverge from international standards when these standards are 'ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued'. Whether or not any of these political avenues are chosen in the end to address these functional concerns, they reaffirm the Habermasian position underpinning the idea of a private administrative law. As these provisions show, legal/political officials of the state (or Member States in the case of the EU) maintain an asymmetrical position to ultimately assert public interests with respect to private regulators to mitigate situations of eventual regulatory drift or special interest capture, which results from their political responsibility to represent all of their citizens.

The *Stichting Rookpreventie* case thus substantiates why grandiloquent appeals to constitutionalism or constitutionalization to represent good governance parameters being internalized by different types of private regulators in national or transnational governance can easily become reifying. For these reasons, my view is that the nature of these institutional transformations instilled in technical standardization processes by the EU are better conceived as these processes having become increasingly 'governmentalized' rather than 'constitutionalized'.[202] This view is reaffirmed by some recent EU legal administrative reforms expressed in the so called Joint Initiative on Standardisation 2016. This initiative has been conceived as a 'collaborative, open, highly inclusive and transparent' programme integrating EU, EFTA, Member State, industry, and societal representatives, under the Commission's coordination, in order to foster 'an efficient, open,

[201] H Lindahl and B Van Roermund, 'Law without a state? On representing the Common Market' in Z Bankowski and A Scott (eds), *The European Union and its Order* (Blackwell, 2000): 'determining what counts as a good market is no "merely" an economic decision; (re-) negotiating the constitutive and regulative rules of the common market instances the process of *political* representation'.

[202] I am referring with this to the notion of 'governmentality' as articualted by Michel Foucault: 'the ensemble formed by the institutions, procedures, analyses, and reflections, the calculations and tactics that allow the exercise of [a] very specific albeit complex form of power . . . which has as its target population, as its principal form of knowledge political economy, and as its essential technical means apparatuses of security'. M Foucault, 'Governmentality [1978]' in J D Faubion (ed.), *The Essential Works of Michel Foucault, 1954–1984: Power*, vol 3 (The New Press, 1997), 219–20; and, later published as part of M Foucault, *Security, Territory, Population: Lectures at the College De France, 1977– 78* (Springer, 2007), 108–9.

transparent, inclusive and agile European Standardisation System' capable of supporting in a timely, inclusive, and responsive way 'market needs and public policies'.[203]

Consistent with this governmentalization of civil society institutions, the idea of a private administrative law does not entail ready-made answers to these or other controversies regarding technical standardization processes.[204] Instead, as an institutional concept, the idea of a private administrative law provides the structure that enables these questions to be raised as meaningful questions in the first place. As signalled by the *PIP* and the *Stichting Rookpreventie* cases highlighted in this concluding section, in the light of the asymmetrical (not hierarchical) position that the EU holds over HTS processes, the idea of a private administrative law thus conveys the grammar upon which socio-political conflict regarding these or other issues in HTS processes are already (dialectically) unfolding. Recalling Hemenway's famous quote, it is for these reasons that the private administrative law of technical standardization can hardly ever become standardized.

[203] See the Commission's, 'Joint Standardisation Initiative under the Single Market Strategy' (2016) <https://ec.europa.eu/growth/content/joint-initiative-standardisation-responding-changing-marketplace_en>; and the Commission's, 'Standardisation Package 2016: European standards for the 21st Century' COM (2016) 358 final, pp. 3, 5–8. Indeed, as Egan had already observed by 2001 to conclude her study on technical standardization at the EU: 'many neoliberal reforms, often touted as a means of "rolling back the state2, contain elements that actually strengthen the state in some ways. In fact, the divorce of markets from states is untenable, and markets are absolutely dependent on public authority. The market-oriented reforms enacted by the European Union are particular striking in this regard since the effort to create 'freer markets' has resulted in 'more rules' and strengthened the authority of the European Union in exercising market governance' Egan (n 29), 261.

[204] In addition to this three-fold set of issues, concerns of a more managerial order have been raised regarding the timeliness, financing, and overall efficiency of HTSs processes. See, for example, Commission, 'Report from the Commission to the European Parliament and the Council on the implementation of the Regulation (EU) No 1025/2012 from 2013 to 2015' SWD (2016) 126 final, pp. 5–6; and European Parliament resolution of 4 July 2017 on European standards for the twenty-first century [2018] 2016/2274(INI) OJ C334/2, paras 16 and 68.