Hybridity under scrutiny: How European standardization shakes the foundations of EU constitutional and internal market law

Hybridity Under Scrutiny: How European Standardization Shakes the Foundations of EU Constitutional and Internal Market Law

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1 INTRODUCTION

1.1 The origins of the new approach as a form of co-regulation

The reliance on private governance regimes is a global phenomenon in modern regulation. The participation of private parties, such as the social partners or the standardization bodies, as (co) decision-makers, is prevalent in the EU, too. Private rulemaking occupies a central place in EU administrative governance in sectors such as financial markets, food regulation, consumer protection, product safety, data protection and environmental policy.

The 2001 Commission's White Paper on Governance[1] officially promoted the use of non-legislative instruments for regulatory purposes in the EU. This initiative was followed by the Better Regulation Program of 2002,[2] setting the objective of better and less law-making. The 2003 Inter-Institutional Agreement on Better Law-Making (IIA) concluded the agenda of endorsing non-legislative instruments of regulation.[3] The IIA recommended employing alternative regulatory mechanisms such as self-regulation and co-regulation. Particularly, it reminded the EU legislator to legislate only in necessary cases in accordance with the principles of

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1 European Commission, *European Governance A White Paper*, COM (2001) 528 Final.

2 Commission Action Plan, *Simplifying and Improving the Regulatory Environment*, COM (2002) 278 Final.

3 European Parliament, Council and the Commission, *Inter-Institutional Agreement on Better Law-Making* (2003) OJ C 321/01; this document addressed the aspects of co-regulation and self-regulation as alternative mechanisms to law-making. Recently, the Inter-institutional Agreement on Better Law-Making from 2016 replaced the 2003 IIA. The new Inter-Institutional Agreement exclusively focuses on delegated and implementing acts.

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proportionality and subsidiarity.[4] Moreover, the IIA prescribed substantive and procedural grounds for using self and co-regulatory mechanisms and subjected them to the Commission's review.[5] The importance of co-regulation has been confirmed by the Commission's new Better Regulation package issued on 19 May 2015, which encourages the use of 'both regulatory and well-designed non-regulatory means'.[6]

The IIA defined co-regulation as 'the mechanism whereby a Community legislative act entrusts the attainment of the objectives defined by the legislative authority to parties which are recognised in the field'.[7] In other words, co-regulation is a mechanism that brings together private and public parties at the different stages of decision-making so as to regulate different interests.[8]

Following this definition, the system of European standardization in the EU's product regulation sector and now services[9] as well, has clear features of co-regulation.[10]

The core of this regulatory technique consists in its combination of public and private elements, whereby private regulators – the European Standards Organizations (ESOs) – are called upon by the Commission to write Harmonized European Standards (HESs) that embody technical specifications of essential health and safety requirements for products contained in Directives. The latter strategy is known as New Approach to Technical Standardization and Harmonization and was launched in 1985, long before the EU officially shifted towards the wide use of self and co-regulation in the governance process.[11]After the Commission publishes the reference to a HES in the *Official Journal*, the latter acquires presumption of

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4 Inter-Institutional Agreement, *supra* n. 3, para. 16.

5 *Ibid*., paras 18–20.

6 Commission Communication of 19 May 2015 on *Better Regulation for Better Results – An EU Agenda*, COM (2015) 215 final, s. 3.1.

7 *Ibid*., para. 18.

8 P. Verbruggen, *Does Co-regulation Strengthen EU's Legitimacy?*, 15(4) Eur. L. Rev. 425 (2009).

9 The European Parliament and the Council Regulation (EU) 1025/2012 of 25 Oct. 2012 on European standardization amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (2012) OJ L 316/12, Art. 1.

10 C. H. H. Hofmann, G. C. Rowe & A. H. Türk, *Administrative Law and Policy of the European Union* 588 ff. (Oxford University Press 2011); *see also* European Economic and Social Committee, *The Current State of Co-regulation and Self-Regulation in the Single Market*, Pamphlet Series (2004): here employment of standardization for the legislation is described as an example of co-regulation; Opinion of the European Economic and Social Committee, *Self-regulation and Co-regulation in the Community Legislative Framework* INT/754 (2015); *see also* Linda Senden in this special issue.

11 Council Resolution (85/C 136/01) of 7 May 1985 on a New Approach to Technical Harmonization and Standards, C 136/1 (1985). This resolution includes Annex I-Conclusions on Standardization approved by the Council on 16 July 1984 and Annex II-The Guidelines on the New Approach to Technical Harmonization and Standardization (So-called Model Directive).

conformity, meaning that an economic operator using an HES is presumed to be in compliance with the mandatory essential requirements.

The employment of standards for regulatory purposes is a story of success accelerating the harmonization process and is today a key factor in the EU's trade policy, since it contributes to the removal of the technical barriers to trade, supports innovation by stimulating dissemination of new technologies, and enhances competition.[12] The technical requirements set via the standards aim to deliver safe products on the market and by doing so protect health and the environment.[13] Next to decision-makers, market players too benefit from standardization, since standards as mediums of information sharing enable transfer of technologies and by doing so facilitate innovation. The involvement of private parties in EU administrative governance has overall the clear advantage of delivering policies which are based on the expertise of the regulatees.

It is also for these reasons that the use of the HESs was extended beyond the areas of the New Approach. In 2010, the Commission reported that the 'number of mandates supporting legislation outside the New Approach has significantly increased'.[14] In order to address new developments, and provide a consolidated legal framework for European standardization and the New Approach, a number of regulations were adopted in 2008 and 2012.[15]

However, the updated legal framework on European standardization kept the basic principles of the New Approach intact. Regulation 1025/2012 reiterates that standards, including the HESs, are voluntary private rules, distinct from legal requirements. At the same time, the above-mentioned Regulation is silent about the legal status of the HESs, about the question of whether they are part of EU law or not, and does not give any legal qualification to the cooperation established between the Commission and the ESOs.

While the official legal instruments seem to try to keep European standardization far from the reach of law, the current developments at the judicial level tell us a different story. Some cases concerning standardization, and in particular the HESs, have reached the CJEU in the last years.

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12 Report of the expert panel for the review of the European Standardization System, *Standardisation for a Competitive and Innovative Europe: A Vision for 2020*, Feb. 2010, EXP 383 final.

13 J. Pelkmans, *The New Approach to Technical Harmonization and Standardisation*, XXV(3) J. Common Mkt. Stud. 249–269 (Mar. 1987).

14 *Report from the Commission to the European Parliament, the Council and European Economic and Social Committee*, the Operation of Directive 98/34/EC in 2009 and 2010 COM (2011) 853 final.

15 Regulation 764/2008 of 9 July 2008 Laying down Procedures Relating to the Application of Certain National Technical Rules to Products Lawfully Marketed in *Another Member State*, OJ L 218; Regulation 765/2008 of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, OJ L 218; Decision 768/2008 of 9 July 2008 on a *Common Framework for the Marketing of Products*, OJ L 218; and Regulation 1025/2012 of 25 Oct. 2012 on European Standardization, OJ L 316.

Although these cases are a just handful, they carry important implications for the system of European standardization. For instance, *Fra.bo*[16] established that even formally private standards can fall under the scope of free movement rules,[17] whereas the process of setting the HESs could be subject to EU competition rules as demonstrated by the *EMC* case.[18] And finally, the recent *James Elliot* case[19] establishes the Court's jurisdiction over the HESs in the preliminary ruling procedure and officially regards the harmonized standards as part of EU law.

Notwithstanding the competing narratives at the legislative and judicial levels about European standardization, and the obscurity about the legal aspects thereof, as will be shown below, the mechanism of implementation of EU law through co-regulation and in particular, the European standardization process, surprisingly, has not been subject to an extensive legal research thus far. This lack of research is problematic, because of the far-reaching economic implications of the use of standards in the process of European integration and the need, for European action, to comply with basic principles of democracy and the rule of law.

1.2 The process of European standardization: an area neglected by legal scholars

It would be untrue to claim that standardization is not at all explored in the academic circles. The role and benefits of standardization for the EU market were addressed by Sweet and Wayne. They conclude that standardization played a crucial part to increase the pace of integration and quicken the achievement of a single market.[20] Majone gives a more detailed account of the reasons for resorting to the European standardization in the process of EU governance. According to him, the poor credibility of intergovernmental arrangements and the highly technical nature of regulatory policy-making were among the motivations behind employing the HESs and ESOs for regulatory purposes.[21]

It is noticeable that, on the one hand, the scholars are engaged with standards as a tool and policy instrument for new modes of governance and regulation.[22] On the

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16 Case C-171/11, *Fra.bo*, ECLI:EU:C:2012:453.

17 *See* Jorgen Hettne in this special issue.

18 Case C-367/10 P *EMC*, ECLI:EU:C:2011:203; *see* on this point Björn Lundqvist in this special issue.

19 Case C-613/14, *James Elliott Construction Limited v. Irish Asphalt Limited*, ECLI:EU:C:2016:821; *See* the discussion about this case in Linda Senden, Mariolina Eliantonio & Megi Medzmariashvili in this special issue.

20 A. Stone Sweet & S. Wayne, *Integration, Supranational Governance, and the Institutionalization of the European Polity* in *European Integration and Supranational Governance* (A. Stone Sweet & S. Wayne eds, Oxford University Press 1998).

21 *See* G. Majone, *The Rise of the Regulatory State in Europe*, 17(3) W. Eur. Pol. 77–101 (1994).

22 *See* K. Abbott & D. Snidal, *International Standards and International Governance*, 8(3) J. Eur. Pub. Pol'y 345 (2001); S. Bartolini, *New Modes of European Governance: An Introduction*, in *New Modes of Governance in*

other hand, standardization has formed part of the research about the legitimacy of using rules of private origin in the public domain.[23]

However, standards are not a popular topic among lawyers. Moreover, according to Schepel, 'standardisation is a much-neglected area of social science research, attracting much less attention than it deserves'.[24] The standardization if explored in the legal scholarship is usually addressed through the lens of a particular legal discipline, most commonly in the context of private law and regulation[25] and competition law.[26] For instance, the recent book by Mataija, *Private Regulation and the Internal Market: Sports, Legal Services and Standards Setting in EU Economic Law*,[27] investigates the relation between the EU economic law and private regulation in certain sectors, inter alia, in the standards setting process, and then focuses on the interplay between private regulation and internal market. The standardization sector is used as an example to explore this issue. Also, as mentioned, standardization is commonly a subject of legal research in the fields of EU competition and intellectual property law.[28] However, standardization is rarely the subject of holistic legal research.

Schepel's contribution *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets*, remains a major book, perhaps even the only one

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Europe: Governing in the Shadow of Hierarchy 1–18 (A. Héritier & M. Rhodes eds, Palgrave Macmillan UK 2011); R. Bellamy, D. Castiglione, A. Follesdal et al., *Evaluating Trustworthiness, Representation and Political Accountability*, in *New Modes of Governance* 135–162 (Héritier & Rhodes eds, Palgrave Macmillan UK 2011).

23 *See* M. Rhodes & J. Visser, *Seeking Commitment, Effectiveness and Legitimacy: New Modes of Socio-Economic Governance in Europe*, in *New Modes of Governance in Europe: Governing in the Shadow of Hierarchy* 104–134 (A. Héritier & M. Rhodes eds, Palgrave Macmillan 2011); R. Werle & J. E. Iversin, *Promoting Legitimacy in Technical Standardization*, 2 Sci., Tech. & Innovation Stud. 19 (2006); T. M. Greven, *The Informalization of Transnational Governance: A Threat to Democratic Government*, in *Complex Sovereignty: Reconstructing Political Authority in the Twenty-First Century* 261–284 (E. Grande & L. W. Pauly eds, University of Toronto Press 2005); A. Héritier, *The Accommodation of Diversity in European Policy-Making and Its Outcomes: Regulatory Policy as a Patchwork*, 3(2) J. Eur. Pub. Pol'y 149 (1996); A. Héritier, *New Modes of Governance in Europe: Policy-Making Without Legislating?* No. 81 HIS Political Science Series 33 (2002); C. Joerges & E. Vos, *Structures of Transnational Governance and Their Legitimacy*, in *Compliance and Enforcement of European Community Law* 71–94 (J. A. E. Vervaele ed., Kluwer Law International 1999); D. Schiek, *Private Rule-Making and European Governance-Issues of Legitimacy*, 32 Eur. L. Rev. 443 (2007).

24 H. Schepel, *The Constitution of Private Governance: The Product Standards in the Regulation of Integrating Markets* (Hart Publishing 2005).

25 *See* for instance the recent book by B. Van Leeuwen, *European Standardisation of Services and Its Impact on Private Law: Paradoxes of Convergence* (Hart Publishing 2017).

26 *See* for instance: B. Lundqvist, *Standardization Under EU Competition Rules and US Antitrust Laws: The Rise and Limits of Self-Regulation* (Edward Elgar 2014); D. Spulber, *Innovation Economics: The Interplay Among Technology Standards, Competitive Conduct, and Economic Performance*, 9(4) Competition L. & Econ. 777 (2013); R. Schellingerhout, *Standard-Setting from a Competition Law Perspective*, Competition Pol'y Newsl. 1 (Nov. 2011); J. Pierce, *The Antitrust Dilemma. Balancing Market Power, Innovation and Standardisation* (Lund University 2016).

27 M. Mataija, *Private Regulation and the Internal Market: Sports, Legal Services and Standards Setting in EU Economic Law* (Oxford University Press 2016).

28 *See* for instance: Lundqvist, *supra* n. 26.

so far, dealing exclusively with standardization in the context of law and governance. However, the scope of the latter 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. 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.

1.3 The aim of this special issue

This gap in academic research is problematic since the process of European standardization, while playing an important role in the context of European integration and delivering undeniable benefits to the European economy, faces several legal challenges. Namely, the delegation of rulemaking power to the private standard-setting bodies is problematic from the perspective of the EU constitutional doctrine of the delegation of powers. Also, the limited judicial reach to European standardization exacerbates legal concerns. These two sets of legal challenges expressed in respect to private rulemaking are based on the delegation of broad discretionary powers to regulatory agencies,[29] and secondly, on the need to find the adequate mechanisms of control and accountability for such private rulemaking.[30] Furthermore, the apparent advantages of the standardization for marker players pose at the same time also challenges beyond their constitutional framework. Namely, standard-setting processes could be subject to abuse for market share gain.[31] In addition, creating a level playing field and developing interoperability standards requires transfer of intellectual property and the regulation thereof.

In the light of the lack of legal research focusing specifically on the co-regulation via standardization, the increased legislative use of European standardization and the juridification process taking place at the EU level, this special issue intends to fill the void left. To do so, the special issue presents several different perspectives with the aim to examine the wide range of concerns raised by the phenomenon of private-

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29 C. Scott, *Regulatory Governance and the Challenge of Constitutionalism*, 2010/07 EUI Working Papers RSCAS (2010).

30 Case C-270/12, UK v. Council and EP ECLI:EU:C:2014:18.

31 *See* for instance, the Commission's decisions in *Rambus* (Commission Decision SG-Greffe (2010) D/275 C (2010) in Case COMP/C-3/38 636, *Rambus*) and *Qualcomm* (Press release Antitrust: Commission Closes Formal Proceedings Against Qualcomm, 24 Nov. 2009, MEMO/09/516) concerning patent wars and abuse of IP rights taking place during the standard setting process; also, Communication from the Commission, *Guidelines on the Applicability of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Co-operation Agreements*, OJ C11 (14 Jan. 2011).

party rulemaking, of which European standardization is a representative example, from the perspectives of different sectors of EU law. In particular, this special issue has a twofold objective. Firstly, it addresses the question of the legitimacy of using EU standardization for regulatory purposes. The question of legitimacy is approached from the perspective of the compliance of the standardization process with the EU constitutional and administrative law constraints, and from the prism of both *ex ante* and *ex post* accountability. Secondly, it discusses the legal challenges, if any, of utilizing the European standardization as a tool for market integration from the perspective of free movement, competition and intellectual property law provisions.

The contributions to this special issue show that the process of EU standardization has not yet found a proper constitutional positioning in the system of European governance. All papers indeed indicate that, while being promoted as an efficient market tool, European standardization presents several legal challenges which render it hard to reconcile with the values the EU aims at protecting. As will be shown in the following section, its hybrid nature is in essence what makes European standardization strong from a market perspective and weak from the perspective of compliance with several aspects of EU law.

2 A HOLISTIC VIEW ON THE PROCESS OF EUROPEAN STANDARDIZATION: A GREY AREA OF LEGALITY OPERATING 'IN THE SHADOW OF HIERARCHY'

2.1 The constitutional positioning of european standardization and its consequences

As mentioned in the introduction, the process of development of HESs represents a peculiar mosaic of private and public elements of regulation: the process is initiated by issuing a request by the Commission – a public authority. The standard-setting process is organized in the committees of the private ESOs, consisting of experts and engineers representing the relevant industry. In the end, an adopted European standard acquires the status of a harmonized standard by virtue of the Commission's publication of a reference in the *official journal*, and from this time, it carries a presumption of conformity with respect to the essential requirements of a relevant New Approach Directive.

This display of both public and private features has been explored and assessed specifically in the contribution by *Gnes*. He notes that the hybrid nature of this process makes it difficult to put European standardization under predefined boxes of either public law-making or private rulemaking; however, if one considers the presumption of conformity which arises from the publication of the reference of

an HES in the *Official Journal* and which Member States are obliged to respect, the process of European standardization cannot be considered as a purely private activity. Departing from the notion of public administration as a 'functional' one, *Gnes* demonstrates that the ESOs ought, in fact, to be qualified as private bodies entrusted with public tasks.

This is first of all due to the special contractual relationship in place between the ESOs and the Commission as these contracts may be awarded only to one or more of the (only) three European standardization organizations, the Commission funds the activities of the ESOs and the assessment of the standards is carried out together by the controller (Commission) and the controlled (ESO). *Senden* regards this process as 'top-down highly conditioned [and] supervised'.[32] Secondly, according to *Gnes* (and this observation is shared by *Hettne* and *Medzmariashvili*), the qualification of the ESOs as private bodies entrusted with public tasks arises from the fact that, while *de jure* compliance with HESs is voluntary for producers, HES usually constitute *de facto* the only possibility for producers and service providers to market their products, because of the high threshold in terms of time and costs associated with the need to prove that their products conform to the essential requirements of the underlying Directive. Finally, *Gnes* notes that HESs do not only fulfil the aim to promote better, faster and cheaper industrial developments, but they also realize public interest objectives related to product safety and environmental protection.

The conclusions of *Gnes* find support in the *James Elliott* case, in which the Court of Justice said, in no unclear terms, that the voluntary nature of HESs 'cannot call into question the existence of the legal effects of a harmonised standard'[33] (in the form of the presumption of conformity) and the HES are not the product of a purely private activity, but a part of EU *law*.

As *Gnes* underlines, tackling the question of the legal nature of the process of European standardization, 'is not only a theoretical question'.[34] What consequences can thus be deemed to descend from the qualification of HESs as the product of activities of private bodies entrusted with public tasks? First of all, that HESs need a place within the framework of EU constitutional law; secondly, that the activities of the ESOs ought to follow certain procedures and to respect some principles of administrative action and especially the principles of access to documents, participation and duty to give reasons; thirdly, that, in order to comply with the rule of law, judicial review needs to be available.

The first concern is addressed in the papers of *Senden* and *Medzmariashvili*. In particular, they explore the question of whether HESs should be considered a

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32 L. Senden in this special issue, at 5.
33 Case C-613/14, *James Elliott Construction Limited v. Irish Asphalt Limited*, para. 39.
34 M. Gnes in this special issue, at 3.

product of implementation or of delegation and, in the latter case, whether the requirements for lawful delegation are met. The legal and jurisprudential framework, which needs to be used as to make this assessment, consists of Articles 290 and 291 TFEU (on delegated and implementing acts, respectively) and the *Meroni*[35] and *ESMA*[36] cases which limit the Commission's power to delegate its powers.

In particular, as *Senden* shows, the *ESMA* case can provide a legitimacy underpinning to the process of European standardization, because the Court argued that the Treaties provide a system of 'open' delegation which may go beyond the system provided in Articles 290 and 291 TFEU. While a system of delegation from the Commission to the ESOs is not in itself in a violation of the Treaties, the requirements set in the CJEU's case law need to be respected. In this context, the analysis of *Medzmariashvili* shows that, while dubious from the perspective of compliance with the *Meroni* requirements for delegation, the process of European standardization can be more optimistically assessed for compliance with the *ESMA* requirements.

As is well known, *Meroni* established, inter alia, that the Commission may not delegate powers involving a wide margin of discretion to private actors and that delegation is lawful on the condition that judicial supervision is available. Concerning the first condition, *Medzmariashvili* shows that the process of standard-setting ought to be seen as involving discretionary powers, as the HESs are not merely technical rules but entail political judgments too. However, this strict requirement can be seen as having been softened by the more recent *ESMA* case, which allows the delegation of discretionary powers, provided that they are subject to judicial control. *Senden* and *Medzmariashvili* both, therefore, conclude that the core of the solution as to the lawfulness of the delegation to ESOs revolves around the question of the existence of an adequate set of control mechanisms.

The amenability of the process of European standardization to judicial control is not only a necessary precondition for the lawfulness of the delegation of powers to the ESOs, but also, as indicated above, a necessary corollary to the qualification of the process as an activity carried out by private bodies exercising public functions. Whether the system of judicial control functions adequately is a topic that, especially in light of the recent *James Elliott* case, has been addressed in several contributions to this special issue and specifically tackled in *Eliantonio*'s paper.

In *James Elliott*, the Court of Justice established its jurisdiction to rule on the interpretation of HES under Article 267 TFEU, because of their nature of 'measures implementing or applying an act of EU law'.[37] From this perspective, it certainly cannot be denied that *James Elliott* can be seen as a further step in the process of

35 Case 9/56, *Meroni*, ECLI:EU:C:1958:7.
36 Reference to *ESMA*.
37 Case C-613/14, *James Elliott Construction Limited v. Irish Asphalt Limited*, para. 34.

'juridification'[38] of European standardization and as a strengthening of judicial control of the process. Whether *James Elliott* can be taken to mean that a full system of judicial control of the European standardization process is currently in place is however not straightforward.

In *James Elliott*, HESs have been denied the status of acts of 'institutions, bodies, offices and agencies of the Union', which would make them reviewable in an annulment action under Article 263 TFEU. An alternative route could be to bring an action against the Commission's Communication which publishes the reference to the HES. While *Medzmariashvili* sees this as a viable option to achieve an – albeit 'embryonic'[39] – legality review of HES, *Eliantonio* doubts its chances of success in light of the *de facto* hybrid nature of this measure. The Communication is formally a Commission act, but in substance refers to a measure, the HES, which is adopted by a private organization. *Eliantonio* further argues that, even if HESs were reviewable in annulment actions, non-privileged applicants, such as consumers or environmental organizations, would have a hard time meeting the standing requirements of individual and direct concern contained in Article 263(4) TFEU.

It can, in conclusion, be doubted that the system of judicial review foreseen by the Treaties ensures compliance with the rule of law and the *ESMA* requirements for lawful delegation. With regard to this point, *Senden* also notes that 'the Court puts foremost emphasis on the existence of *ex post* judicial control, not paying much attention to *ex ante* checks and balances in the adoption process of HSs'.[40] This observation can also be linked to the above-mentioned need for the European standardization to comply with certain principles of administrative law, in light of its inherently public law nature.

EU legislation does require standardization organizations to follow certain good governance standards, such as transparency, openness, and participation.[41] ESOs are also specifically mandated to broaden the participation of all relevant stakeholders, such as consumer organizations, and environmental and social stakeholders.

The question remains whether these guarantees are sufficient to factually involve all societal interests. *Kallestrup* discusses the input legitimacy requirements of the European standardization process in light of its nature as co-regulation and concludes that the intentions and obligations to ensure stakeholder participation may not have materialized in a sufficient manner. In this context, it would be important to carry out further empirical research to assess the participatory chances of stakeholders in the process.

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38 H. Schepel, The New Approach to the New Approach: The Juridification of Harmonized Standards in EU Law, 20(4) Maastricht J. Eur. & Comp. L. 531 (2013).

39 M. Medzmariashvili in this special issue, at 13.

40 L. Senden in this special issue, at 16.

41 Arts 3, 5–7, 12 of Regulation 1025/2012.

2.2 The dubious nature of the process of european standardization and its implications for free movement, competition and intellectual property law

The hybrid public-private nature of the European standardization process makes not only its constitutional positioning difficult, but has consequences also on whether the free movement and competition rules can constrain such activity and whether the products of this rulemaking can be copyrighted. *Hettne*'s and *Lundqvist*'s papers discuss specifically these concerns.

Different national standards that vary from a Member State to a Member State create obvious technical barriers for the EU's internal market. However, in most of the cases, national standards are voluntary and adopted by private standard bodies, a circumstance that at first sight keeps these rules outside the free movement provisions. Nevertheless, in tackling technical barriers stemming from voluntary national standards, as *Hettne* notes, the Court has paid attention to whether a standard was connected to a state, made compulsory by public authorities as in *Commission v. Ireland*,[42] and constrained the trade in a similar manner as technical regulations.

It is clear that national standards do create barriers for the proper functioning of the internal market and could be the subject of free movement provisions if made compulsory or adopted by public bodies. Even more, the rather recent *Fra.bo* case stretches the application of free movement of goods provisions to private standardization activities. In that case, the Court considered that Article 34 TFEU applies in the context of private standardization and certification activities 'when the *national legislation* works in a way that makes compliance with the national standard *the only option in practice* and thus clearly restricts the marketing of products not certified according to that standard'.[43]

Contrary to national standards, the standards developed at the EU level by the ESOs in harmonized fields in the context of the so-called New Approach are useful tools for achieving the internal market goals. Hence, *Hettne* observes that standards in the EU have a dual face: divergent national standards might create barriers to trade, but standards elevated at the EU level and presented in the form of HESs are trade promoters.

The Court in *James Elliott* was not able to overlook the public aspects of HES and ruled that harmonized standards form part of EU law. But, as *Hettne* stresses, the Court was cautious and:

> wisely did not define a private standardisation body as a 'body of the Union', but rather focused on the legal effects of a harmonised standard. Another approach would have

[42] Case 45/87, *Commission v. Ireland*, EU:C:1988:435.
[43] J. Hettne in this special issue, at 4.

> automatically brought private standardisation bodies within the full realm of EU constitutional law, which seems too inflexible in light of their private nature of standards and their particular function in the development of the Internal Market.[44]

However, the Court's statement that a harmonized standard is 'a necessary implementation measure'[45] faorming part of EU law, still can have strong consequences especially for the copyright protection of standards as noted by *Lundqvist*. 'Free access to technical standards may be a next hot topic'[46] especially after the *James Elliot* case. If, as the Court suggests, harmonized standards do constitute EU law, could the national members of ESOs still claim copyright over these standards and charge fees for access to these rules? According to *Lundqvist* the answer to this question has at heart, again, the question of whether the process of development of harmonized standards belongs to the public or private domain.

However, the Court is not bold, as *Lundqvist* rightly notes, to qualify a harmonized standard as a product of delegated rulemaking, Hence, as *Lundqvist* concludes, it is difficult in the light of *James Elliot* that did not explicitly deal with the issue of copyright, to give an answer to the question of whether standards should be copyrighted or not. From the departure point of European standardization being an activity subject to public law constraints, *Senden*, however, concludes that it is in fact 'highly questionable whether accessibility only upon payment is lawful'.[47]

A final point needs to be made concerning the relationship between European standardization and competition law. It is established by Regulation 1025/2012 that European standardization can be constrained by competition rules if standard-setting bodies qualify as an undertaking or an association of undertakings.[48] Such an approach implies that standardization constitutes private rule-making where competitors cooperate and, hence, is a classical subject of competition rules. In *EMC* even the process of development of a HES has been scrutinized under the competition rules. The Court paid heed to the fact that the members of a committee developing a harmonized standard represent relevant industries and hence 'do not lose their standing as "undertakings" under EU competition law'.[49]Although European standardization initially thus is constrained by competition rules, at the same time, the Commission's Horizontal guidelines[50] create a 'safe harbour' for standardization that complies with certain procedural principles. In other words, the standard-setting organizations could benefit from 'safe harbour' and standards developed would not restrict competition within the meaning of Article 101 TFEU 'if

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44 *Ibid*, at 10.
45 Case C-613/14, *James Elliott Construction*, EU:C:2016:821, para. 43.
46 B. Lundqvist, in this special issue, at 2.
47 L. Senden, in this special issue, at 16.
48 Regulation 1025/2012, recital 13.
49 B. Lundqvist, in this special issue, at 14.
50 Communication from the Commission, *supra* n. 31.

standard-setting is unrestricted and the procedure for adopting the standard in question is transparent, and the standard does not contain any obligation to comply with the standard and access to the standard is provided on fair, reasonable and non-discriminatory terms'.[51] Whether these requirements are fully respected by the European standardization process, especially that of transparency, is a question which ought to be tackled by further empirical research.

3 CONCLUSIONS

According to the European Parliament, it is of 'the utmost importance to draw a clear line between legislation and standardization in order to avoid any misinterpretation with regard to the objectives of the law and the desired level of protection'.[52] While an important exercise, this line is, however, in practice very difficult to draw.

HESs are tightly intertwined with EU law, and, one might argue, more than originally envisaged by the founders of the New Approach. Also, the developments at the legislative level, with the adoption of Regulation 1025/2012, and in case law, with *Fra.bo* and *James Elliott*, seem to move the vector of standardization towards the public sphere. This has implications not only from a constitutional and administrative law perspective, but also raises further questions related to the application of free movement, competition and intellectual property rules. 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.

In the end, European standardization faces an unresolved dilemma, namely how to abide with the pressing need to acknowledge the public law relevance of the process, through the respect of constitutional and administrative law constraints, through effective participation of stakeholders and judicial review, and, at the same time, not lose the benefits of private rulemaking, such as economic efficiency and trade promoting effects. While there does not seem to be an easy fix to this dilemma, it is one which the European legislator cannot avoid in the long run. The risk is otherwise the continued existence of grey areas of legality which will, ultimately, undermine the very trust in the process which is now its main strength.

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51 B. Lundqvist in this special issue, at 13; *Also see* Communication from the Commission, *supra* n. 31, para 280.

52 Report of the European Parliament on the future of European standardisation (2010/2015(INI)), point 15.