Regulating European Standardisation through Law

The Interplay between Harmonised European Standards and EU Law

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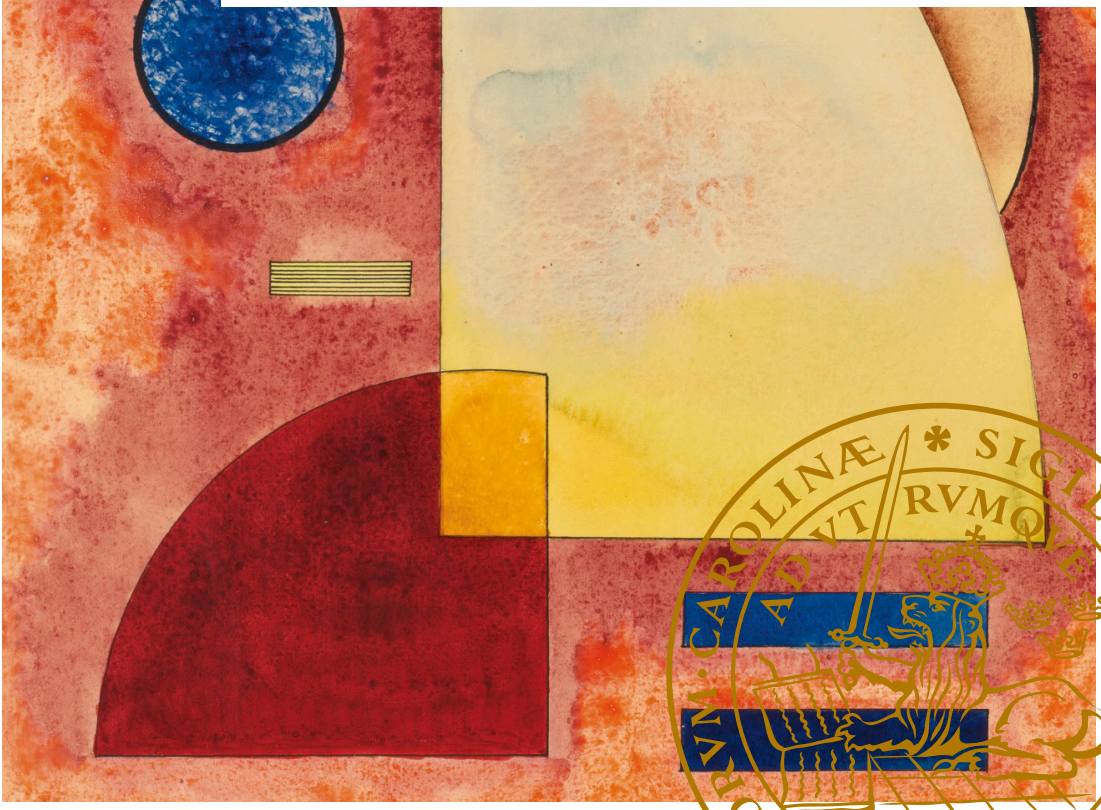

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The Interplay between Harmonised European Standards and EU Law

Megi Medzmariashvili

LUND
UNIVERSITY

DOCTORAL DISSERTATION

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Abstract

Standardisation is one of the oldest human activities. Industrial revolution and electro-technical advancements have further increased the importance of standardisation. Nowadays standards regulate our daily life not only through the products and services we use, but also directly as laws. In the EU, Harmonised European Standards (HESs) are used in legislation—occupying the law's domain—but at the same time, the HESs are not produced through the same manner as laws—i.e. by democratically elected individuals.

This thesis investigates the legal status of these technical rules under EU law and whether and how EU law can regulate and hold European standardisation accountable by means of judicial review.

In answering these questions, I admit that there are different visions of how the HESs used in EU legislation can be seen, which influences how we regulate and hold accountable European standardisation. Notwithstanding these differences, one thing is clear: if we accept that the HESs play an important role in regulating health, safety, and the environment, and at the same time are not produced by democratically elected individuals, then the least the law can do is to regulate and ensure the legal accountability to perfect the standardisation process, to make it more accountable and 'public-regarding.'

In exploring these issues, I propose conceiving of the EU law as a 'gentle civiliser' for the standardisation process. In particular, I argue that the EU economic law could be a backdoor through which constitutional principles of good governance reach and regulate the European standardisation system. To do so, the judicial review of the European standardisation system at the EU level should be a process oriented as to trigger a more inclusive, open, and transparent standardisation process; in other words, judicial review should be a catalyst for a 'public-regarding' standardisation.

Key words: EU Law, European Standardisation, Harmonised European Standard, Internal Market, Judicial Review of European Standardisation

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Cover photo by Wassily Kandinsky, *Intermingling* (1928)

I have chosen this painting as a beautiful depiction of the relation between law and standards that this thesis argues to be *Intermingling* and not rivalry.

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To Luara and Tengo (in memoriam)

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List of Abbreviations

TFEU	Treaty on the Functioning of the European Union (TFEU)
TEU	Treaty on European Union
CJEU	Court of Justice of the European Union
ECJ	European Court of Justice
GC	General Court
ISO	International Organisation for Standardisation
IEC	International Electrotechnical Commission
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardisation
ETSI	European Telecommunications Standards Institute
ESO	European Standards Organisation
HES	Harmonised European Standard (HES)
ECOS	European Environmental Citizens Organisation for Standardisation
ANEC	European Association for the Coordination of Consumer Representation in Standardisation

1. Law, Governance and European Standardisation

1.1. Introduction

> 'Come, let us build ourselves a city, with a tower that reaches to the heavens, so that we may make a name for ourselves; otherwise, we will be scattered over the face of the whole earth.' But the Lord came down to see the city and the tower the people were building … and said, 'If as one people speaking the same language, they have begun to do this, then nothing they plan to do will be impossible for them. Come, let us go down and confuse their language so they will not understand each other.'[1]

Imagine the world without standards. Just as the absence of a common language brought defeat to the Tower of Babel, so the absence of standards would make life extremely difficult and the world hard to imagine. A standard, akin to a language 'in the form of a technical specification'[2], not only enables knowledge exchange and product and technological interoperability; more importantly, standards make life safe.

The 1904 Great Baltimore Fire provides a striking example of the vital role of standards. The fire lasted 30 hours, destroyed 1500 buildings and had devastating effects. One of the main reasons why the fire lasted so long was

[1] 'Genesis', *BibleGateway* [website], Genesis 11:1-9, New International Version <https://www.biblegateway.com/passage/?search=Genesis+11:1-9> accessed 30 November 2016.

[2] S.A. Bøgh (ed.), *A World Built on Standards: A Textbook for Higher Education* (Danish Standards Foundation 2015), 13; P.J. Slot, *Technical and Administrative Obstacles to Trade in the EEC* (Sijthoff 1975), 17.

the lack of national standards in firefighting equipment—thus, Baltimore's fire hydrants could not accommodate the hoses of firefighters from nearby cities.[3]

The need for standards was recognised early in the history of human civilisation.[4] The first standards were the result of humans' attempts to harmonise their activities in response to environmental changes. The creation of a calendar is one of the earliest examples of standardisation.[5] Over 20,000 years ago our ancestors in Europe kept track of days by scratching lines in caves and cutting out holes in sticks and bones.[6] The development of farming and agriculture required more precise ways of predicting seasonal changes. In response to this, Sumerians living in the Tigris-Euphrates Valley created 'a calendar very similar to the one we use today'[7], dividing the year into 30-day months.[8]

The making of standards is an 'age-old process', not confined to any particular region. At the end of the eighteenth century, the standards setting gained momentum and took place in 'the specific political, economic and scientific European context of the day'.[9] Today, standards play an important role in the context of European market integration, while European standardisation forms part of the European Union's trade policy.

Standardisation, in the European Commission's (Commission) words, is 'a powerful and strategic tool for improving the efficiency of European

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3 C. Shapiro, 'Setting Compatibility Standards: Cooperation or Collusion?' in R. Dreyfus, D. Zimmerman and H. First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (Oxford University Press 2001), 81.

4 'Through History with Standards', *American National Standards Institute* [website], <www.ansi.org/consumer_affairs/history_standards.aspx?menuid > accessed 15 November 2018.

5 Ibid; As opposed to a standard that is a technical rule, standardisation is the process of making standards and complying with them. In a narrow understanding, standardisation is a process of developing standards. A broad meaning of standardisation includes also the conformity assessment and the certification stages. For more on this see section 1.3.2. of this chapter.

6 'Through History with Standards' (n 5).

7 Ibid.

8 Ibid.

9 R. Wenzlhuemer, 'The History of Standardisation in Europe', *Institute of European History* (IEG) [website], 12 March 2010, Introduction <http://ieg-ego.eu/en/threads/transnational-movements-and-organisations/internationalism/roland-wenzlhuemer-the-history-of-standardisation-in-europe> accessed 28 October 2018.

policies.'[10] This is because standards influence many areas of public concern, inter alia: a) European standards contribute to the removal of trade barriers among Member States by replacing divergent national technical requirements;[11] b) standards enhance innovation through the dissemination of new technologies;[12] c) standards enable the protection of public health and the environment by setting rules on how products should be made, used, maintained and disposed of.[13]

Since the 1980s, the EU has utilised these benefits and deployed European standards to harmonise technical requirements for goods and, indeed, now services too.[14] By way of the New Approach strategy, the harmonisation burden is divided between the EU legislator and European Standards Organisations (ESOs).[15] Under this strategy the EU legislator lays down general principles—so-called 'essential requirements'—concerning health, safety and the environment, while the more detailed technical rules in the form of Harmonised European Standards (HESs) are developed by the ESOs so as to implement the essential requirements. The term 'new' was inserted into the name of this regulatory mechanism to signify something distinct from detailed legislative harmonisation, i.e. from the so-called 'old' regulatory strategy. The New Approach differs from the 'old strategy' insofar as it uses privately made

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10 The Commission, 'European Standards' [website] <https://ec.europa.eu/growth/single-market/european-standards_en> accessed 15 November 2018.

11 The Commission, 'Benefits of Standards' [website] <https://ec.europa.eu/growth/single-market/european-standards/policy/benefits_en> accessed 15 November 2018.

12 Ibid; Report of the Expert Panel for the Review of the European Standardisation System, 'Standardisation for a Competitive and Innovative Europe: a Vision for 2020', February 2010, <http://www.anec.eu/attachments/Definitive%20EXPRESS%20report.pdf> accessed 15 November 2018.

13 'Benefits of Standards' (n 11).

14 Council Resolution (85/C 136/01) of 7 May 1985 on a New Approach to Technical Harmonisation and Standards [1985] C 136/1; The European Parliament and the Council Regulation (EU) 1025/2012 of 25 October 2012 on European standardisation amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council [2012] OJ L 316/12, Article 1.

15 See about the operation of the New Approach strategy, for instance J. Pelkmans, 'The New Approach to Technical Harmonization and Standardisation' (1987) 25 (3) *Journal of Common Market Studies* 249.

technical standards instead of legislation to implement product and service requirements uniformly throughout the internal market.

The use of private rules such as standards in place of traditional or 'command and control'[16] types of regulation is characteristic of the era of new governance. The privatisation and liberalisation movement of the 1980s and the 1990s entailed a shift in regulation, prompting an increased reliance on private rule-making and regulation.[17] Nowadays, private regulators play a significant role in shaping and implementing EU policies in different sectors, such as the General Product Safety Directive[18], Audiovisual Media Services Directive[19], European codes of conduct for various professions[20], etc.

The EU's New Approach strategy is an illustrative example of the tendency to resort to private bodies for public purposes. Indeed, it fits into the broader landscape of new governance. The latter denotes 'a shift away from the monopoly of traditional politico-legal institutions and implies…the involvement of actors other than classically governmental actors…'[21] The use

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16 The phrase 'command and control' displays derogatory intent and carries connotations of state intervention in private life. This phrase is used to describe a regulation which involves setting of rules and standards by public authorities dictating a certain type of action. See: M. Lee, *EU Environmental Law: Challenges, Change and Decision-Making* (Hart Publishing 2005), 183.

17 The use of private regulation is manifested, for instance, in the fields of product and food safety, see: F. Cafaggi, 'Product Safety, Private Standard Setting and Information Networks' (2008) EUI Working Papers 2008/17 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1303419&download=yes> accessed 10 January 2019. See also: C.M. Bruner, 'States, Markets, and Gatekeepers: Public-Private Regulatory Regimes in an Area of Economic Globalization' (2008) 30 (1) *Michigan Journal of International Law* 125.

18 The European Parliament and the Council Directive 2001/95/EC of 3 December 2001 on general product safety [2002] OJ L11/4; Article 3(3) of this directive states that 'the conformity of a product to the general safety requirements shall be assessed by taking into account': a) national standards transposing European ones; b) Member State standards where the products are marketed; c) product safety codes of good practice; d) the state of the art and technology.

19 The European Parliament and the Council Directive 2010/13/EU on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services [2010] OJ L95/1; Article 9(2) of this directive encourages the media service providers to develop 'codes of conduct regarding inappropriate audiovisual commercial communications.'

20 P. Delimatsis, '"Thou Shall Not… (Dis) Trust": Codes of Conduct and Harmonization of Professional Standards in the EU' (2010) 47 (4) *Common Market Law Review* 1049.

21 G. de Burca and J. Scott, 'New Governance, Law and Constitutionalism' in G. de Burca and J. Scott (eds), *Law and New Governance in the EU and US* (Hart Publishing 2006), 3.

of private rules and private regulation in general, instead of classical governmental regulation, is motivated by several advantages: First and foremost, private regulation generally enjoys a high level of expertise. It is believed that industrial players in technical sectors maintain up-to-date knowledge and are better equipped to tackle technical and complex issues of the current market.[22] In addition, private regulation is usually less hierarchical and therefore more flexible.

Notwithstanding these benefits, private regulation also has its limitations. For instance, the actions of private regulators are less transparent to the public and they are not subject to the same mechanisms of control and accountability as governmental actors.[23] Similarly, the beneficial use of HESs in EU legislation and policies is accompanied by legitimacy and accountability concerns. They are aggravated by the fact that HESs carry legal effects, assume authority to regulate public health, safety and environment, and at the same time seem to be beyond the reach of law and judicial scrutiny.[24]

As the EU's reliance on privately produced European standards increases, the unresolved legal issues surrounding standardisation—inter alia, EU's legal basis of the relationship between the Commission and the ESOs, the legal status of HESs and justiciability of them—require more attention. These are reasons for conducting the present research, which examines the legal position of European standardisation in EU governance and analyses whether EU law is able to regulate and judicially review the European standardisation system.[25] It is important to stress that in this thesis the phrase 'European standardisation'

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[22] M. Mataija, *Private Regulation and the Internal Market: Sports, Legal Services and Standards Setting in EU Economic Law* (Oxford University Press 2016), 12.

[23] See for instance J. Black, 'Constitutionalising Self-Regulation' (1996) 59 *Modern Law Review* 24; Also, J. Wouters, A. Marx, and N. Hachez, 'Private Standards, Global Governance and Transatlantic Cooperation: The Case of Global Food Safety Governance', Leuven Centre for Global Governance Studies Working Paper <https://ghum.kuleuven.be/ggs/research/biosafety_biodiversity/publications/wouters-marx-hachez_final.pdf> accessed 15 January 2019.

[24] J. Freemen, 'Private Parties, Public Functions and the New Administrative Law' (2000) 52 (3) *Administrative Law Review* 813. Here it is suggested that the legal concerns are heightened when private regulators are used for public purposes.

[25] I use the term 'European standardisation system' to cover a whole regulatory strategy under which the Commission requests the development of an HES, which is then drafted by one of the ESOs, and later the Commission publishes the references to this HES in the official journal and by doing so attaches it to the relevant EU harmonisation directive. In other words, it denotes the strategy enabling the use of European standardisation in support of EU policy and legislation.

refers only to the part of standardisation used in support of EU legislation and policies.

In light of the above, this thesis aims to investigate and analyse the EU legal framework applicable to the European standardisation system and proposes to discuss the legal accountability thereof by means of judicial review. In doing so, I position the European standardisation system within EU governance and ask the following overarching research question: Does EU law apply to, regulate and ensure legal accountability of the co-regulation via European standardisation, and if so, how?[26]

The two aspects of this research objective are dealt with together in the following manner. First, I investigate how substantive EU law, i.e. constitutional and economic laws,[27] regulates the European standardisation system and reveal the legal framework applicable thereto. Secondly, I analyse whether and how EU law can ensure legal accountability of the co-regulation via European standardisation. In this thesis, I understand legal accountability as overseeing the European standardisation system through EU law and by means of judicial review at the EU level.[28] These two parts of the research aim are interlinked. In investigating the EU legal framework applicable to the European standardisation system, I map the different perspectives taken by EU constitutional and economic laws in regulating it, as well as reflecting on ensuring legal accountability of the European standardisation system through judicial review in the light of those perspectives.

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[26] In this thesis the terms 'European Standardisation System' and 'Co-regulation via European standardisation' will be used interchangeably and denote the same, i.e. regulatory strategy enabling the use of the HESs in EU legislation and policy. Whereas European standardisation will refer to only the Commission-mandated standardisation activities.

[27] Under EU constitutional law fall treaty provisions concerning the separation of powers among institutions, governing the delegation of rule-making power, establishing the hierarchy of legal acts and provisions concerning the judicial review. The EU economic law is understood as consisting of the competition law and free movement provisions. Also, the CJEU case law regarding those treaty provisions form part of EU constitutional and economic laws.

[28] Judicial review at the EU level encompasses direct and indirect actions before the CJEU in accordance to Articles 263 and 267 TFEU.

1.2. Setting the Scene: European Standardisation in Support of EU Legislation and Policies—A Case of Co-regulation

In this section, I briefly explain the EU's move towards using non-legislative instruments such as self- and co-regulation mechanisms. Next, I consider the use of HESs in EU policies and legislation as a case of co-regulation, briefly describe the main aspects of this strategy and in doing so provide the background to this research.

The story of creation of the EU's internal market consists of efforts to eliminate physical, fiscal and technical barriers. Technical barriers were the most pervasive and disruptive obstacles to the free movement of goods. The countless national technical standards and regulations created technical barriers to trade and hindered the proper functioning of the single market for goods.[29] Legislative harmonisation against these technical barriers was found to be largely ineffective, as adoption of the legislation with detailed technical specifications for every product was an extremely protracted process,[30] often fraught with political wrangling and contention.

In the wake of the ill-starred product-to-product detailed legislative harmonisation, the EU moved towards a new strategy, freeing the political process from the responsibility of adopting detailed technical specifications and transferring it to the expert-based ESOs. The New Approach, launched in 1985, focused on the harmonisation of technical requirements by means of adopting harmonised standards in the field of products.[31]

Under this strategy, the Directives lay down binding essential requirements for products in respect of health, safety and environment.[32] Then the Commission

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[29] See: M. Egan, *Constructing a European Market: Standards, Regulation and Governance* (Oxford University Press 2001), 51.

[30] The process of tackling the technical barriers through the positive and negative integrations and the adoption of the New Approach strategy is explained in detail in Chapter 3.

[31] Council Resolution on a New Approach to Technical Harmonisation and Standards (n 14). This resolution includes Annex I: Conclusions on Standardisation approved by the Council on 16 July 1984, and Annex II: The Guidelines on the New Approach to Technical Harmonization and Standardisation (so-called Model Directive). The New Approach strategy is explained thoroughly in Chapter 3.

[32] These are also the maximum requirements the Member States may impose on products. See in this regard, Case C-112/97 *Commission v Italy* ECLI:EU:C:1999:168.

issues a mandate and requests one of the ESOs[33] to develop detailed rules for the implementation of the essential requirements in the form of an HES. Subsequently, the Commission publishes the reference to the HES in the official journal. Only at this stage does the HES acquire presumption of conformity, meaning that an economic operator following the HES is presumed to be in compliance with the mandatory essential requirements.

The employment of standards for legislative purposes not only helped to remove technical barriers and expedite the harmonisation process, but also shifted the standard-setting process from the Member States to the EU level and in this way also promoted European standardisation.[34] Soon, the use of HESs extended beyond the areas of the New Approach.[35] At present, not just standards but private rule-making in general occupies a central place in EU administrative governance, especially in the areas of food regulation, consumer protection, data protection and environmental policy.[36]

The involvement of private actors in the process of developing and implementing EU policies and legislation started to acquire a clearer framework with the Commission's White Paper on Governance[37], followed by the Better Regulation Program of 2002, which share the objective of better regulation through non-legal instruments.[38] The use of non-legal instruments—inter alia, standards and industry codes as 'alternatives' to legislation—was endorsed by the 2003 Interinstitutional Agreement (IIA) on Better Law-

[33] The institutional structure of the European Standards Organisations (ESOs) is discussed in detail in Chapter 2.

[34] The European New Approach was suggested as a blueprint for standard-setting in the world. See: A. Casella, 'Product Standards and International Trade: Harmonisation through Private Coalition?' (2001) 54 *Kyklos* 243.

[35] The Commission has mandated the adoption of technical standards in various fields ranging from bunk beds to traffic management systems. For further information on the use of standards in different fields see: Commission reports on the operation of Directive 83/189/EEC in 1992, 1993 and 1994, COM (1996) 286 final; Commission Report on Operation of Directive 98/34/EC from 1995 to 1998, COM (2000) 429 final; and Commission Report on the Operation of Directive 98/34/EC from 1999 to 2001, COM (2003) 200 final.

[36] M. Eliantonio and M. Medzmariashvili, 'Hybridity under Scrutiny: How European Standardization Shakes the Foundations of EU Constitutional and Internal Market Law' (2017) 44 (4) *Legal Issues of Economic Integration* 323, at 332–5.

[37] European Commission, 'European Governance: A White Paper', COM (2001) 428 final.

[38] Commission Action Plan, 'Simplifying and Improving the Regulatory Environment' (Communications) COM (2002) 278 Final.

Making.[39] The IIA recommended the use of alternative regulatory mechanisms, such as self- and co-regulation, and legislating only when necessary in line with the principles of proportionality and subsidiarity.[40] Resorting to European standards for the development and implementation of EU legislation and policies is a case of co-regulation and in this manner forms part of the EU's agenda of better regulation.

The co-regulation is defined in the IIA 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.'[41] In other words, the co-regulation is a method of regulation that brings together private and public parties at different stages of the decision-making process in regulating specific objectives and interests.[42] It follows that the regulatory strategy under which the EU employs private regulation, i.e. standardisation to harmonise product requirement, bears the clear features of co-regulation,[43] and

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39 European Parliament, Council and the Commission, Interinstitutional 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 lawmaking. Interinstitutional Agreements are, according to Craig, 'Constitutional glue' through which the major players decide and resolve high-level issues. Therefore, accepting non-legislative acts for governance in the EU through inter-institutional agreement stresses the importance of these non-legislative acts. In 2016, the Interinstitutional Agreement on Better Law-Making was adopted, which focuses exclusively on legal instruments—legislative, delegated and implementing acts. Unlike the previous IIA, the current one does not mention alternative methods of regulation, but aims to improve the legislative process, as well as the process of adopting the delegated and implementing acts, i.e. making it transparent and more inclusive. See: European Parliament, Council and the Commission, Interinstitutional Agreement on Better Law-Making [2016] OJ L 123/1.

40 Ibid, para 16. Also, IIA urged to use regulatory mechanisms only when the treaty does not specifically require the use of legal instruments. It is worth mentioning that the IIA prescribed substantive and procedural grounds for using self and co-regulatory mechanisms and subjected it to the Commission's review. Simultaneously, it prohibited, albeit vaguely, the use of alternative mechanisms when 'fundamental rights and important political options are at stake' or 'where the rules must be applied in a uniform fashion in all Member States'; see Interinstitutional Agreement from 2003 (n 39), paras 17, 18, 20.

41 Ibid, para 18.

42 P. Verbruggen, 'Does Co-regulation Strengthen EU's Legitimacy?' (2009) 15 (4) *European Law Review* 425.

43 C.H.H. Hofmann, G.C. Rowe, and A.H. Türk, *Administrative Law and Policy of the European Union* (Oxford University Press 2011), 588ff. See also: European Economic and Social Committee, 'The Current State of Co-regulation and Self-Regulation in the Single Market' (2005) EESC Pamphlet Series <http://old.eesc.europa.eu/resources/docs/2018_cahier_en_smo_def.pdf> accessed 10 September 2018. Here the employment of standardisation for the legislation is described as

therefore is referred to in this thesis as the co-regulation via European standardisation.

The agenda of using non-legal instruments in the form of self- and co-regulation in order to implement EU policy goals and legislation was reinforced again in 2015 by the Commission with the new Better Regulation package.[44] Encouraging the use of non-legal instruments, i.e. private rules, is motivated by the idea that they can provide clear benefits.[45] The most commonly articulated and accepted advantage of private regulation is the accumulation of expertise.[46] The involvement of industry players in regulation provides up-to-date knowledge and enables the highly technical challenges of each sector to be addressed. Secondly, private regulation that is the result of a wide group of stakeholders' deliberations, as suggested stands a better chance of securing voluntary compliance.[47] In addition, private regulation is understood to yield a greater degree of flexibility, which is missing in the institutionalised and hierarchical modes of regulation.[48] All these benefits of private regulation are also attributes of European Standardisation, hence they motivate the resorting to standardisation instead of detailed legislative harmonisation.

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an example of co-regulation. See also: Opinion of the European Economic and Social Committee, on Self-regulation and co-regulation in the Community legislative framework [2015] INT/754. However, one could argue that legislative use of the HESs is not a clear case of co-regulation, because these standards are not adopted by the legislator but remain as private voluntary rules.

44 Commission Communication of 19 May 2015 on Better Regulation for Better Results: An EU Agenda COM (2015) 215 final. On 19 May 2015, the Commission published the Better Regulation Package that aims to promote and deliver the commitment to better regulation; For more details about the Better Regulation Package see: <https://ec.europa.eu/info/law/law-making-process/better-regulation-why-and-how_en#documents> accessed 23 May 2016.

45 For a detailed overview of the self- and co-regulation mechanisms in the EU context see: L.A.J. Senden et al, 'Mapping Self- and Co-regulation Approaches in the EU Context' (2005) Explorative Study for the European Commission, DG Connect, Utrecht University <https://dspace.library.uu.nl/handle/1874/327305> accessed 10 May 2017.

46 See for instance: F. Cafaggi, 'Rethinking Private Regulation in the European Regulatory Space' (2006) EUI Working Paper 2006/13 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=910870> accessed 10 April 2017; Also, I. Ayres and J. Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford University Press 1992).

47 R. Baldwin and M. Cave, *Understanding Regulation: Theory, Strategy and Practice* (Oxford University Press 2010), 127.

48 Mataija, *Private Regulation and the Internal Market* (n 22), 12.

However, the use of non-legal instruments in general and HESs in particular encounters two sets of legal conundrums. First, HESs, like most privately developed rules, lack democratic legitimacy, as they are developed by non-elected private bodies and thus are beyond electoral control, which heightens the need for legal accountability. Secondly, due to their private nature these HESs seem to escape legal accountability in the form of judicial review. It is important to note that these legal concerns are not unique to European standards but are relevant to new forms of governance more generally. In section 1.4, I briefly explain the relation between law and new governance, as it gives a sense of the wider context of the 'law's problem'[49] with using standards in legislation and policy documents. Also, by revisiting legal concerns relating to new governance, I suggest that the portrayal of the (arguably) antagonistic relation between law and new governance in general, and law and standards in particular, be recast. Hence, I propose to investigate the potential of EU law in regulating and perfecting the European standardisation process, rather than regarding the law as a possible rival to the flexibility and effectiveness of standardisation.

1.3. Research Aim and Objectives

The aim of this study is to explore and analyse the legal framework of the European standardisation system and investigate the potential of judicial review to render the European standardisation process accountable. To do so, first, I position the co-regulation via European standardisation within the EU governance system and discuss the application of EU constitutional and economic laws thereto. Moreover, I assess whether EU law can regulate and judicially control the European standardisation system, that is to say, provide the mechanism of legal accountability.

These research objectives are of crucial practical significance. As mentioned above, use of European standardisation in EU legislation and policy is prevalent, but what happens if an HES, relating to toys, for example, allows

[49] The phrase borrowed from the article by C. Joerges, H. Schepel, and E. Vos, 'The Law's Problem with the Involvement of Non-Governmental Actors in Europe's Legislative Process: The Case of Standardisation under the "New Approach"' (1999) EUI Working Paper Law 99/9 <http://cadmus.eui.eu/bitstream/handle/1814/154/law99_9.pdf?sequence=1&isAllowed=y> accessed 10 April 2014.

toxic materials in the toys' paint, contrary to the mandate? Or what if a cement standard is adopted on the basis of a discriminatory procedure that excludes other competitors from the market, or a new national standard is contradictory to an HES, favouring domestic producers? Answering these questions requires a general consideration on the issue of what part of EU law applies to and regulates the European standardisation system.

The research aim is pursued in two steps. First, in order to situate the European standardisation system within EU governance and analyse the EU legal framework applicable thereto, I make use of EU constitutional and economic laws. These are substantial parts of the EU's legal ambit. Hence, the question of regulating and holding the European standardisation system accountable is analysed by way of the EU constitutional and economic law frameworks. To do so, I place European standardisation within the above-mentioned EU law frameworks and investigate how these parts of EU law apply to and regulate the European standardisation system. In answering the research question, I first study how European standardisation is viewed under EU constitutional and economic laws and then map the various perspectives that these parts of EU law offer in terms of regulation, control and accountability of the European standardisation system.

Of course, using exclusively EU constitutional and economic law frameworks as the lenses for the current investigation should be seen as a delimitation of this thesis. The research is also constrained by the subject of investigation, which concerns the part of European standardisation used in support of EU legislation and policies. Here it is important to explain what is meant by EU constitutional and economic laws and the sources I draw on in this regard. This research is based on doctrinal pieces and the official EU documents. The normative framework of this thesis consists of two branches of EU law, i.e. EU constitutional and economic laws composed of relevant treaty Articles and case law.[50] More precisely, the EU constitutional law in this thesis encompasses treaty provisions concerning the separation of powers among institutions, governing the delegation of rule-making powers, establishing the hierarchy of legal acts and provisions concerning the judicial review. The EU

[50] The case law consists of reported judicial decisions from the CJEU handed down in an annulment or a reference proceedings. The Court's judgments are used as authoritative interpretations of the relevant legal provisions. It also includes the Opinions of Advocate Generals with the caveat that they are not binding.

economic law is understood as consisting of the competition law and free movement provisions.[51]

The second step in this research is that of addressing the issue of legal accountability of the European standardisation system. I discuss the legal accountability of co-regulation via European standardisation by means of judicial review. I side with scholars regarding judicial review as one of the main mechanisms of legal accountability.[52] However, new governance regimes are usually beyond the reach of judicial review and at first sight the two do not coexist in harmony.[53] Thus, I conceptualise and discuss the role of the Courts in the forms of new governance in general and in the process of European standardisation in particular. Next, I explore whether the co-regulation via European standardisation can be judicially reviewed at the EU level. Amid the uncertainty concerning the legal status of European standards and while ESOs are largely perceived as private bodies, judicial review of the European standardisation system is questionable. Finally, I contemplate the scope of judicial review in the light of the Court's limited ability to deal with technical complexities of standardisation.

Before dwelling on the application of the different parts of EU law to the European standardisation system, I begin by explaining the reasons for resorting to the New Approach strategy. Next, I outline the operating principles of this strategy. To do so, I investigate the EU internal market legislation

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[51] In this thesis EU economic law is limited to and encompasses only Articles 34–36 TFEU concerning the free movement of goods and Articles 101 and 102 forming part of EU competition law.

[52] See among others: J.L. Mashaw, 'Judicial Review of Administrative Action: Reflections on Balancing Political, Managerial and Legal Accountability' (2005) *Revista Direito GV* 153; P.L. Strauss, *An Introduction to Administrative Justice in the United States* (1989), cited in footnote 31 in C. Tobler, 'The Standards of Judicial Review of Administrative Agencies in the US and EU: Accountability and Reasonable Agency Action' (1999) 22 (1) *Boston College International and Comparative Law Review* 213; C. Harlow and R. Rawlings, 'Promoting Accountability in Multilevel Governance: A Network Approach' (2007) 13 (4) *European Law Journal* 542, at 547. It should be stressed that, as Craig explains, judicial review is just 'one method of securing accountability'. See P. Craig, 'Accountability and Judicial Review in the UK and EU: Central Precepts', in N. Bamforth and P. Leyland, *Accountability in the Contemporary Constitution* (Oxford Scholarship Online 2014).

[53] See detailed discussion of this in Chapter 7 of this thesis.

relevant to European standardisation[54] and the Commission's guidance documents thereon.[55]

By investigating the 'official documents' concerning the New Approach, I argue that this strategy was designed to function on the basis of the formal separation between directives and technical standards. In order to 'insulate' European standardisation from law, the HESs were relegated to the status of voluntary guidelines.[56] As such, I name this view the 'Official View', which in short aspired to maintain a 'bright line'[57] between law and standards, as well as between public and private spheres of law.[58]

In the light of current developments at the legislative[59] and judicial levels[60] concerning the co-regulation via European standardisation, I question the

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[54] These are: Regulation (EU) 1025/2012 on European Standardisation (n 14); The European Parliament and the Council Decision No 768/2008/EC on a Common Framework for the Marketing of Products [2008] L218/82; The European Parliament and the Council Regulation (EC) 765/2008 Setting out the Requirements for Accreditation and Market Surveillance Relating to the Marketing of Products and Repealing Regulation (EEC) No 339/93 [2008] L218/30.

[55] It encompasses the Commission's guidance notices, communications and staff working papers related mainly to the functioning of the co-regulation via European standardisation within the new legislative framework. The latter documents do not carry a biding interpretative authority and the content of them does not preclude the other interpretations from the ECJ, who has an ultimate responsibility and jurisdiction to interpret the EU law. However, these documents help us to understand the complex system for the operation of the new legislative framework and present important value in the absence of the judicial decisions. Moreover, they are used in this thesis to present the 'official theory' on the functioning of the co-regulation via European standardisation, with the caveat that they are not legally binding.

[56] H. Schepel, 'Private Regulators in Law' in J. Pauwelyn, R. Wessel, and J. Wouters (eds), *Informal International Lawmaking* (Oxford University Press 2012), 359.

[57] The term used by Schepel, 'Private Regulators in Law' (Ibid).

[58] It is important to note that the terms 'public' and 'private' in this thesis do not carry any theoretical connotations. The public sphere is regarded to consist of law, public rules and public authorities. In other words, it includes the EU institutions, EU law, i.e. legislative and non-legislative acts. Whereas the private sphere encompasses private actors and non-binding rules adopted by private bodies. On this see for instance: M. Taggart (ed.), 'The Province of Administrative Law Determined' in *Province of Administrative Law* (Hart Publishing 1997). According to the author, the main difference between public and private is that the private sphere is dominated by self-regarding behaviour and the public by public-regarding behaviour.

[59] The Adoption of Regulation 1025/2012 on European Standardisation (n 14) represents a big change concerning European standardisation that is made at legislative level.

[60] To mention first and foremost the Case C-613/14 *James Elliott Construction Limited v Irish Asphalt Limited* ECLI:EU:C:2016:821; Case C-171/11, *Fra.bo*; ECLI:EU:C:2012:453. The

above-described 'Official View.' Specifically, I argue that the adoption of EU Regulation on European standardisation[61] is a formal step in the juridification of the standardisation system and moving it into the EU legal ambit. Next, the recent *James Elliott* case,[62] which declared the HES to be part of EU law, signals that the EU judiciary has a different perspective on the legal status of HESs and does not regard them as merely private, voluntary rules, as claimed by the 'Official View' for many years.

I continue to question the 'Official View' on the use of European standardisation in the light of EU constitutional law framework. In particular, I examine co-regulation via European standardisation through the lens of EU constitutional law. In EU constitutional and administrative law scholarship,[63] the European standardisation process tends to be seen as delegated rule-making. I argue that the 'Delegation View' is based on the assumption that HESs regulate important aspects of health and safety, and that by providing the presumption of conformity, HESs become de facto mandatory for business operators. The lens of EU constitutional law not only regards the use of European standardisation as a case of delegation, but in its turn sets the requirements for the lawful delegation of rule-making powers. Hence, at this stage, I analyse whether the European standardisation system satisfies the constitutional requirements of lawful delegation of rule-making powers.

The two aforementioned perspectives on the use of European standardisation in EU policies and legislation provide different legal frameworks thereon by placing it ex-ante in either the public or the private sphere. That is, the 'Official View' regards European standardisation as purely a private and voluntary activity, leaving it entirely in the realm of private law and does not seem to require the public accountability of this system. Although at the time of

latter case could be an indirect indication of judicial developments concerning European standardisation.

61 Regulation 1025/2012 on European Standardisation (n 14).

62 Case C-613/14 *James Elliott* (n 60).

63 See for instance: R.V. Gestel and H.W. Micklitz, 'European Integration through Standardization: How Judicial Review is Breaking Down the Club House of Private Standardization Bodies' (2013) 50 (1) *Common Market Law Review* 145, at 151 and 177; C.H.H. Hofmann, G.C. Rowe, and A.H. Türk, 'Rule-Making by Private Parties', in C.H.H. Hofmann, G.C. Rowe, and A.H. Türk, *Administrative Law and Policy of the European Union* (Oxford University Press 2011). For a contradicting view see: Joerges et al, 'The Law's Problem' (n 49). For a general conceptualisation of delegation to private parties see: C.M. Donnelly, *Delegation of Governmental Power to Private Parties: A Comparative Perspective* (Oxford University Press 2007).

creating the New Approach, such a view could have been beneficial for the effective functioning of that strategy, with the increased reliance of HESs on EU legislation and policies, greater juridification became necessary. In response to this, the lens of constitutional law helps us to focus on the public and mandatory effects of these standards and sees HESs as products of delegated rule-making in view of the hierarchy of EU legal acts. Consequently, EU constitutional law offers a public law framework for the regulation of European standardisation and the need for legal accountability of the standardisation process is a key element for the system's overall legitimacy.

In the light of these two perspectives, I argue that co-regulation via European standardisation cannot strictly be placed ex-ante within either the 'public' or the 'private' sphere. Rather it is a complex system consisting of public and private elements. The hybrid public-private nature of the European standardisation system is manifested in the following manner. The private standard bodies are in charge of setting standards that are then given legal significance by the EU legislator and the Commission. Although the 'influence' of EU institutions is strong in this context, HESs maintain, at least formally, private and non-binding status, as EU institutions neither adopt the HESs nor grant binding legal status. The recent *James Elliott* case[64] signals a recognition of the hybrid nature of HESs. Here, the Court explicitly said that the voluntary nature of HESs 'cannot call into question the existence of the legal effects of a harmonised standard',[65] concluding that HESs are not the products of purely private activity, but instead form part of EU law.[66]

As Cafaggi has noted, private regulation in the context of complex regulatory regimes is 'partly grounded on private autonomy, partly on delegation by public power'.[67] Similarly, I argue that the European standardisation system is a hybrid of public-private cooperation, and HESs exist on a continuum running between public and private spheres.[68]

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64 Case C-613/14 *James Elliott* (n 60).

65 Ibid, para 39.

66 See also the similar argument in M. Gnes, 'Do Administrative Law Principles Apply to European Standardization: Agencification or Privatization' (2017) 44 (4) *Legal Issues of Economic Integration* 367–80; Eliantonio and Medzmariashvili, 'Hybridity under Scrutiny' (n 36).

67 Cafaggi, 'Rethinking Private Regulation in the European Regulatory Space' (n 46), 3.

68 See: P. Glenn, 'Transnational Legal Thought: Plato, Europe and Beyond', in M. Maduro, K. Tuori, and S. Sankri (eds), *Transnational Law: Rethinking European Law and Legal Thinking* (Cambridge University Press 2014), 76, as well as F. Cafaggi, 'Private Regulation in European Private Law', in A. Hartkamp, M. Hesselink, E. Hondiua et al (eds), *Towards a*

In examining the European standardisation system through the lens of EU economic law, I consider the application of free movement and competition law provisions thereto and ask how these provisions regulate such a hybrid co-regulatory strategy. I argue that because of its hybrid public-private nature, the European standardisation system is a potential subject of both free movement and competition laws. The EU economic law dealing with European standardisation would adopt a functional approach, that is, instead of focusing on the abstract legal nature of HESs, it would explore the effects of these standards on the internal market and competition.

The EU economic law perspective on the European standardisation system is rather fluid in contrast to the 'Official View' and constitutional law perspective. It does not adopt ex-ante a wholly public or private legal framework in approaching standardisation, but instead deals with it on a case-by-case basis, and hence provides a 'Hybrid (flexible) Framework' for regulating and perfecting the standardisation process.

By undertaking the above-described approach, this thesis strives to make the following four points. First, the regulatory use of European standardisation is not beyond the reach of law, as the 'Official View' had hoped. The current changes at the legislative and judicial level bring European standardisation within the ambit of EU law, emphasise the need to unfold the legal framework applicable thereto and require seeking the ways of holding this co-regulatory strategy legally accountable. Second, unpacking the legal framework of the European standardisation system is a complex exercise since there are different perspectives on European standardisation used in EU legislation and policy, entailing different legal scopes. Notwithstanding these different perspectives, both EU constitutional and economic laws share the need for the legal accountability of the co-regulation via European standardisation, even if they diverge in respect of how and the extent to which it should be achieved.

Third, in view of the flexibility offered by this hybrid co-regulatory strategy, judicial review as a mechanism of legal accountability should be limited to holding the public part of this strategy, i.e. the Commission, fully legally accountable for the HESs. In reviewing the private part of this co-regulatory strategy, i.e. the European standardisation process within the ESOs, the judicial review has to focus on the process of standard-setting and its adherence to the procedural principles of good governance. Finally, positioning the European

European Civil Code (Kluwer Law International 1998). Though these sources mainly discuss standards as a continuum running between non-law and law, it equally applies to our discussion too.

standardisation system within the sphere of EU governance, unravelling the legal ambit thereof and setting out the possible ways of holding the co-regulatory strategy legally accountable, serves to complement the overall legitimacy of the European standardisation system.

1.3.1. Research Method

As stated above, the overarching research question is whether and how EU law applies to, regulates and ensures legal accountability of the European standardisation used for legislative purposes. The nature of the question posed leads to the application of the traditional doctrinal legal method, or so-called 'legal dogmatics'.[69] At the outset, I explain the legal dogmatics method, in particular its key characteristics and the potential results that can be obtained by applying the legal doctrinal approach. Finally, in light of these considerations, I set out the reasons for using the legal dogmatics method in order to answer the current research question.

'Any jurist has some idea of what legal doctrine is about', but it is not easy to explain it.[70] One of the main features of legal doctrine is the internal perspective, as noted by Holmes.[71] This means that the legal system is not only the subject of investigation, but also the normative framework for the investigation. The two other distinctive features of legal doctrine are: a) viewing the law as a system; and b) systematising a present law.[72]

The dogmatics is employed as a research method mainly with the aim of describing the current status of law, as well as prescribing practical legal solutions.[73] In mapping possible applications of the different parts of EU law to the European standardisation system, I rely on legal dogmatics as a research

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69 On the theory of legal doctrine see: A. Peczenik, 'A Theory of Legal Doctrine' (2001) 14 *Ratio Juris* 75, 75.

70 J.M. Smits, 'What is Legal Doctrine? On the Aims and Methods of Legal-Dogmatic Research' (2015) Maastricht European Private Law Institute Working Paper 2015/06 <https://www.researchgate.net/publication/282704825_What_is_Legal_Doctrine_On_the_Aims_and_Methods_of_Legal-Dogmatic_Research> accessed 23 May 2017.

71 'The business of the jurist is to make known the content of the law; that is, to work upon it from within (…)'; O.W. Holmes, *The Common Law*, cited in Smits, 'What is Legal Doctrine?' (Ibid).

72 See on this matter: Smits, 'What is Legal Doctrine? (n 70).

73 Ibid.

method.[74] Using legal dogmatics entails, first, taking an internal approach, i.e. putting the phenomenon of the co-regulation via European standardisation inside the particular field of EU law. Then, the current standing of a particular part of EU law based on EU treaties, applicable legislation and case law is described. On the basis of this descriptive analysis, I consider the possible application of the relevant field of EU law to the case of European standardisation. In other words, the relevant part of EU law is used as a normative framework in which the European standardisation system is analysed.

This thesis is a mix of descriptive and prescriptive analyses. After exploring a current stand of certain parts of EU law, I contemplate their application to new fields—in this case European standardisation. In so doing, this thesis explicates the legal framework that (would) govern the co-regulation via European standardisation, unfolds the different perspectives on it and reflects on whether EU law is able to regulate and ensure legal accountability of the European standardisation system.

Although the tasks undertaken in this thesis include elements of both description and prescription, I do not draw any clear line to indicate where exactly description ends, and prescription begins. Generally speaking, the legal dogmatics method includes both descriptive and normative assessments and, following Peczenik, the distinction between de lege lata and de lege ferenda is not clear-cut.[75] To fulfil the aims of the present research project requires a combination of positive and normative analyses,[76] which are inherent to the legal dogmatics method.

1.3.2. Terms and Delimitations

I now turn to the task of defining and delimiting the central terms of this thesis. In the history of humankind, standards were already present in ancient times. Nowadays, there is an abundance of standards and their categorisation varies. In addition, the word 'standard' has different connotations in everyday

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[74] Analysing and mapping the possible application of the law is one of the several pursuits of the legal dogmatics method.

[75] Peczenik, 'A Theory of Legal Doctrine' (n 69), 79.

[76] See the discussion on the intertwinement of descriptive and normative parts in the legal research and on the distinction between description, prescription and meta-description and meta-prescription in E.L. Rubin, 'Legal Scholarship', in D. Patterson (ed.), *A Companion to Philosophy of Law and Legal Theory* (2nd edn, Wiley-Blackwell 2010), 548–59.

language. Thus, to avoid confusion, this section draws some lines and defines a technical standard, the kind to be discussed in the present work.[77]

Generally speaking, technical standards fall into two categories: de jure and de facto standard.[78] A de jure standard is a written document giving technical specifications for goods, services or processes, resulting from a consensus, and whose application is voluntary.[79] A de facto standard results from a unilateral act and emerges through the mediation of market processes: 'the dynamics in which purchasers on a market take up particular products finally lead to one or more lasting standards being selected from among diverse possible alternative technologies.'[80] The de facto standard can be produced by a company, group of companies, or by non-formal organisations such as fora and consortia,[81] which is quite common in the Information Communications Technology (ICT) sector.

The de jure standards are adopted in the setting of formal standard-setting organisations such as the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI) at the European level.

Regulation 1025/2012 on European standardisation includes only the formal de jure standards in the definition of technical standards.[82] Article 2(1) of that Regulation provides the definition of a standard.[83] From this not so elaborate description, the following elements can be noted: a) standards are technical specifications; b) they are based on scientific and technical data; c) they are

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77 As Busch rightly points out, any research on standardisation is complicated by competing and different meanings of the term. See: L. Busch, *Standards: Recipes for Reality* (MIT Press 2011), 17. Therefore, in the section above, I explain the meaning of the term 'standard'.

78 O. Borraz, 'Governing Standards: The Rise of Standardisation Processes in France and in the EU' (2007) 20 (1) *Governance* 57.

79 Ibid.

80 B. Lelong and A. Mallard, 'Reseaux: Dossier sur la fabrication des Normes' [2000], cited in Borraz, 'Governing Standards: The Rise of Standardisation Processes in France and in the EU' (n 78).

81 Bøgh (ed.), *The World Built on Standards* (n 2).

82 It should be pointed out that Regulation 1025/2012 (n 14) lays down the procedure that enables referencing of the ICT technical specifications adopted by non-formal standard-setting organisations in public procurement.

83 Regulation 1025/2012 (n 14), Article 2(1).

adopted by a recognised standardisation body; and d) their application remains voluntary.

The present research is constrained by these European, de jure standards, which are set by one of the aforementioned standard-setting organisations (excluding ETSI). The notion of a technical standard in this thesis is consistent with the definition given by Article 2(1) of the Regulation.[84] For further delimitation, it must be stressed that this thesis focuses on European Standards adopted following a Commission's mandate. Standards that are mandated by the Commission and used for public purposes are called Harmonised European Standards. The latter is 'a European Standard adopted on the basis of the request made by the Commission for the application of Union harmonisation legislation.'[85]

It is important to note that this thesis does not explore the technical details of certain sets of standards. Since such degree of technical detail is beyond the scope of this research, and exceeds this author's expertise, it is left for specialists in the pertinent fields.

One has to be clear that, in a narrow sense, standardisation means only the process of standards developing, which in turn includes different stages of decision-making. However, standardisation is rather a broad process and also involves conformity assessment and certification stages that are exercised by public, private or a mixture of these two entities. This thesis does not include conformity assessment and certification processes and is limited to the standardisation in its narrow understanding.

The term 'accountability' also requires clarification.[86] Accountability is an extremely elusive concept and the word can mean many different things.[87]

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84 Ibid.

85 Regulation 1025/2012 (n 14), Article 2.

86 See: J. Mashaw, 'Accountability and Institutional Design: Some Thoughts on the Grammar of Governance', in M.W. Dowdle, *Public Accountability: Designs, Dilemmas and Experiences* (Cambridge University Press 2006), 115–24. This piece unpacks the concept of accountability and suggests approaching it by addressing six important points such as: 'who is accountable to whom, what are they accountable for, what process of accountability to be assured; by what standards accountability should be judged; and the potential effects of breaching those standards.'

87 See for instance the following works on the different faces of accountability: R. Behn, *Rethinking Democratic Accountability* (Brookings Institution Press 2001); M. Dubnik, 'Accountability and the Promises of Performance: In Search of the Mechanisms' (2005) 28 (3) *Public Performance and Management Review* 376; V. Mehde, 'Responsibility and Accountability in the European Commission' (2003) 40 *Common Market Law Review* 423.

Moreover, the concept of accountability is sometimes confused with responsibility. While it is true that accountability and responsibility are related concepts, they are nevertheless distinct.[88] Responsibility entails an obligation to do something or to refrain from doing something and it can belong to both the public and the private realm, while accountability implies giving a public account for certain types of responsibility.[89] Hence, accountability belongs to the 'realm of public justification'.[90]

There is continual disagreement over the concept and the nature of accountability.[91] Notably, accountability is a common concept in political discourse.[92] It is thus important to state that accountability is understood here only in the legal sense.[93] Generally, accountability has two aspects: as a virtue and as a mechanism.[94] Accountability as a positive quality of organisations and officials is a virtue.[95] In this sense, accountability is a contested concept since a general consensus on the standards of accountability is lacking.[96] Standards of accountability vary and depend on public organisations, political systems, and perspectives. In this thesis, accountability as a virtue is not addressed.

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88 J. Braithwaite, 'Accountability and Responsibility through Restorative Justice', in M.W. Dowdle (ed.), *Public Accountability: Designs, Dilemmas and Experiences* (Cambridge University Press 2006), 44.

89 One could be accountable for certain types of responsibility. For instance, one could be responsible for watering the plants at home, but one is not publicly accountable for not doing it. See discussion of this in Braithwaite, 'Accountability and Responsibility through Restorative Justice' (Ibid), 44–9.

90 Ibid.

91 Dowdle, *Public Accountability: Designs, Dilemmas and Experiences* (n 86), 1–26.

92 See the Commission's white paper on Governance (2001, 2003). Here the word 'accountability' is used as a synonym for 'clarity', 'transparency', 'responsibility', and is also equated with the concepts of 'involvement' and 'deliberation'.

93 This thesis uses accountability—namely legal accountability—in its very concise meaning. Also, it is not the aim of this section, or of this thesis as a whole, to provide an overview of the rich academic material on the concept of accountability.

94 This understanding is borrowed from M. Bovens, 'Analysing and Assessing Accountability: A Conceptual Framework' (2007) 13 (4) *European Law Journal* 447; and M. Bovens, 'Two Concepts of Accountability: Accountability as a Virtue and Accountability as a Mechanism' (2010) 33 *West European Politics* 946.

95 D. Curtin and L. Senden, 'Public Accountability of Transnational Private Regulation: Chimera or Reality?' (2011) 38 (1) *Journal of Law and Society* 163.

96 W.B. Gallie, 'Essentially Contested Concepts' (1955) 56 *Aristotelian Society* 167; Also, Bovens, 'Two Concepts of Accountability' (n 94), 949.

Accountability as a mechanism implies the arrangements of holding a subject responsible before a forum.[97] In other words, according to Bovens, 'accountability is a relationship between an actor and a forum, in which the actor has an obligation to explain and to justify his or her conduct, the forum can pose questions and pass judgement, and the actor may face consequences.'[98] Bovens' understanding of legal accountability equates to a judicial review.[99] 'This is certainly a view of legal accountability with which the European judiciary and EU lawyers would empathize.'[100] Similarly, in this thesis, the concept of legal accountability encompasses the mechanism of regulating the co-regulation via European standardisation through EU law and reviewing it judicially. In other words, it is confined mainly to the possibility of reviewing technical standards and the standardisation process by the CJEU and assessing the extent of such review. The increased reliance on standardisation in EU legislation and policy,[101] coupled with the fact that standards concerning vital aspects of public life such as health, safety and environment are developed in a private setting, indisputably demands third-party oversight, which in this thesis primarily takes the form of the Court.

1.4. Broader Picture of this Research: Interplay between Law and New Governance

Having explained the research objectives and approach, I now turn to elucidating the broader theme to which this thesis belongs, i.e. the relationship between law and new governance. In addition, I highlight that this research does not provide far-reaching findings in respect of this wider theme.

To start with, the term 'new governance' needs to be clarified, as it is a rather vague concept.[102] Some of the main features of new governance are, as

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97 Bovens, 'Two Concepts of Accountability' (n 94).

98 Ibid.

99 J. King, 'The Instrumental Value of Legal Accountability', in N. Bamforth and P. Leyland, *Accountability in the Contemporary Constitution* (Oxford University Press 2013).

100 C. Harlow, 'Accountability through Law', in C. Harlow, *Accountability in the European Union* (Oxford University Press 2002).

101 The Regulation 1025/2012 (n 14); The latter Regulation allows the use of Harmonised European Standards not only in the sector of goods, but in the services sector too.

102 P.F. Kjaer, *Between Governing and Governance: On the Emergence, Function and Form of Europe's Post-National Constellatio*n (Bloomsbury 2010), 2.

suggested, 'the shift away from the command and control type of regulation'[103] and heterarchical, instead of hierarchical, policy and rule-making.[104] In other words, the new governance denotes the move away from the traditional way of governance through states and public authorities and reflects the trend of using private regulation.

It follows then that the use of private regulators and private rules through the mechanisms of self- and co-regulation are examples of this shift to new forms of governance. In the same manner, the new strategy that outsourced the technical harmonisation to private ESOs and enabled the use of HESs in legislation and policy documents, clearly belongs to and signals a more significant move, i.e. a shift to new forms governance.

The European landscape has proven to be 'fertile terrain for the elaboration of a "new governance" approach to European integration that is keen to illuminate the limits of a traditional approach to European law-making and law-enforcement…[as well as] to uncover alternative experiments in European Governance.'[105] When a new form of governance emerged in the EU, this was portrayed as a non-hierarchical structure detached from traditional EU institutions. Scott and Trubek argue that what characterises these new forms of governance is a relocation of norm-making beyond the institutional frame of the EU, which remains to some extent connected to the inter-institutional decision-making process, through the so-called Community Method.[106] This

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[103] E. Korkea-Aho, 'What is New about New Governance? Making Sense of the Institutional Conditions and Constitutional Implication of New Modes of Governance' (2009) 32 *Retfærd Årgang NR*. 1/124 <http://retfaerd.org/wp-content/uploads/2014/06/Retfaerd_124_2009_2.pdf> accessed 15 May 2016.

[104] D. Schiek, 'Private Rule-Making and European Governance: Issues of Legitimacy' (2007) 32 (4) *European Law Review* 443; see also A.M. Banks, 'The Growing Impact of Non-State Actors on the International and European Legal System' (2003) 5 (4) *International Law Forum du droit international* 293; Burca and Scott, 'New Governance, Law and Constitutionalism' (n 21); Kjaer, *Between Governing and Governance* (n 102), 2. According to Kjaer, the most common feature of governance recognised in the research community is a heterarchical as opposed to hierarchical structure.

[105] K.A. Armstrong, 'New Governance and the European Union: An Empirical and Conceptual Critique', in G. de Burca, C. Kilpatrici, and J. Scott (eds), *Critical Legal Perspective on Global Governance: Liber Amicorum David M Trubek* (Bloomsbury 2013), 250; on the mapping of the relationship between the new governance and the law see: M. Dawson, 'Three Waves of New Governance in the European Union' (2011) 36 (2) *European Law Review* 208.

[106] See: J. Scott and D.M. Trubek, 'Mind the Gap: Law and New Approaches to Governance in the European Union' (2002) 8 (1) *European Law Journal* 1.

detachment from the institutional framework prompted many to view this process as the new governance, or regulatory governance.[107]

It is common to distinguish new governance from law and see it as non-binding and non-hierarchical.[108] In light of this portrayal, new governance is often seen as something external or even antagonistic to law.[109] This is because, according to the basic tenets of representative democracy, the norms having a legislative nature should be legitimised through the legislative process.[110] Consequently, as Schepel suggests, the law has a problem with granting legal validity to private/(new) governance since the latter lacks democratic legitimacy,[111] existing as it does outside the constitution and independently of constitutional and political institutions.

The topic of the legitimacy of new governance has given rise to an abundance of scholarly debates.[112] Usually, the argument for and against the legitimacy of new governance using private rule-making revolves around the dichotomy of expert-based or democratic decision-making. However, for some, these are not

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[107] In this thesis, the terms 'new governance' and 'regulatory governance' are used interchangeably and denote the move from government to governance structure, i.e. the involvement of private parties in the process of governance.

[108] Dawson argues against such a negative definition of governance. He claims that while new governance is not opposed to law, at the same time, it does not imply 'naïve complementarity'; See: M. Dawson, *New Governance and Transformation of European Law: Coordinating EU Social Law and Policy* (Cambridge University Press 2011), chapters 2 and 3.

[109] Ibid, 72.

[110] P. Craig, *EU Administrative Law* (Oxford University Press 2006), 143.

[111] H. Schepel, *The Constitution of Private Governance: The Product Standards in the Regulation of Integrating Markets* (Hart Publishing 2005), 2.

[112] See: M. Rhodes and J. Visser, 'Seeking Commitment, Effectiveness and Legitimacy: New Modes of Socio-Economic Governance in Europe', in A. Héritier and M. Rhodes (eds), *New Modes of Governance in Europe: Governing in the Shadow of Hierarchy* (Palgrave Macmillan 2011); R. Werle and J.E. Iversin, 'Promoting Legitimacy in Technical Standardization' (2006) 2 *Science, Technology & Innovation Studies* 19; T.M. Greven, 'The Informalization of Transnational Governance: A Threat to Democratic Government', in E. Grande and L.W. Pauly (eds), C*omplex Sovereignty: Reconstructing Political Authority in the Twenty-First Century* (University of Toronto Press 2005); A. Héritier, 'The Accommodation of Diversity in European Policy-Making and its Outcomes: Regulatory Policy as a Patchwork' (1996) 3 (2) *Journal of European Public Policy* 149; A. Héritier, 'New Modes of Governance in Europe: Policy-Making Without Legislating?' (2002) No. 81 HIS Political Science Series 33 <https://www.ihs.ac.at/publications/pol/pw_81.pdf> accessed 3 March 2017; C. Joerges and E. Vos, 'Structures of Transnational Governance and Their Legitimacy', in J.A.E. Vervaele (ed.), *Compliance and Enforcement of European Community Law* (Kluwer Law International 1999).

competing paradigms and could potentially coexist in harmony.[113] This presupposes a notion of rule-making as rooted in the scientific and technical reasonableness of rules, while 'reasonableness' is thought to constitute a kind of 'democratic rationality'.[114]

In the constitutional law scholarship, private/new governance faces narrow and broad constitutionalist critiques.[115] The former questions the delegation of broad discretionary powers to the regulatory agencies.[116] Broader constitutionalist critique looks beyond the formal delegation of powers to non-state actors[117] and is concerned with finding the adequate mechanisms of control and accountability.[118] The similar constitutionalist critiques follow the New Approach strategy. This is because the latter strategy belongs to and represents the new governance landscape, as explained above.

The employment of European standardisation for legislative and policy purposes faces the legal concerns that at the broader level could be conceived as an 'uneasy' relationship between law and new governance. However, it is important to stress that the aim of the present research is not to discuss the 'law's problem' with new forms of governance,[119] or to address the constitutional challenges of the regulatory governance[120] as such, at the general level. Nor do I enter into the discussion of whether public bodies can and should delegate their powers to private parties at all. Rather, I accept the benefits of private regulation and admit that the use of standardisation for legislative and policy purposes will remain with us, as is evident from the over thirty-year history of the New Approach. As such, I suggest, instead of juxtaposing law and standards, to explore the potential of law—in this case EU

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[113] Borraz, 'Governing Standards: The Rise of Standardisation Processes in France and in the EU' (n 78).

[114] Ibid. For the democratic legitimacy of standardisation, see: C. Ruwet, 'Towards a Democratization of Standards Development? Internal Dynamics of ISO in the Context of Globalization' (2011) 5 (2) *New Global Studies* 1.

[115] C. Scott, 'Regulatory Governance and the Challenge of Constitutionalism', in D. Oliver, T. Prosser, and R. Rawlings, *The Regulatory State: Constitutional Implications* (Oxford Scholarship Online 2011) .

[116] Ibid.

[117] G.P. Calliess and P. Zumbansen, *Rough Consensus and Running Code: A Theory of Transnational Private Law* (Bloomsbury 2010), chapter 2.

[118] Scott, 'Regulatory Governance and the Challenge of Constitutionalism' (n 115).

[119] G. de Burca, 'The Constitutional Challenge of New Governance in the European Union' (2003) 28 (6) *European Law Review* 814.

[120] Scott, 'Regulatory Governance and the Challenge of Constitutionalism' (n 115).

law—to regulate and make the European standardisation system more accountable. In other words, my aim is to acquire a better understanding of the legal ambit of the European standardisation system.

1.4.1. Present Research amidst the Uneasy Relation between Law and Standards

The resort to private regulators for governing purposes is problematic for law and legal theory.[121] In the same vein, the law has a problem with using the European standardisation in support of EU legislation and policy. The contestation in scholarship concerns whether the law can recognise private rules in general, and standards in particular, as laws.

According to Jaffe, the classical Austinian understanding of the concept of law—a command of the sovereign—places the limit on regarding private regulations as laws[122] since private rules are developed not by public authorities but by private actors that do not have legal validity by virtue of delegation or recognition from the state. However, with the emergence of private governance, some theorists view private rule-making as producing rules similar to law.[123] Teubner and Fischer-Lescano belong to the group of scholars who view private rules as laws even beyond delegation or state recognition. They suggest that these private regimes assume legal validity from the fact that they create laws responding to the 'demand…which cannot…be satisfied by national or international institutions.'[124]

Besides accepting or denying the legal validity of the private regulation, there exists an uneasy relationship between law and private/(new) governance.[125] The tension between law and private rule-making in general, and standardisation in particular, translates into a set of dichotomies: expert vs. democratic legitimacy; law vs. non-law; and effectiveness vs. the rule of law.

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[121] See for instance: C. Scott, F. Cafaggi, and L. Senden, 'The Conceptual and Constitutional Challenge of Transnational Private Regulation' (2011) 38 (1) *Journal of Law and Society* 1.

[122] L.L Jaffe, 'Law-Making by Private Groups' (1937) 5 (2) *Harvard Law Review* 201, at 207.

[123] G. Teubner, 'Global Private Regimes: Neo-Spontaneous Law and Dual Constitution of Autonomous Sectors in World Society?', in K.-H. Ladeur (ed.), *Public Governance in the Age of Globalization* (Routledge 2004).

[124] A. Fischer-Lescano and G. Teubner, 'Regime-Collisions: The Vain Search for Legal Unity in the Fragmentation of Global Law' (2003) 25 *Michigan Journal of International Law* 999, at 1010.

[125] See also the discussion in section 1.4.

It is problematic to perceive the relationship between law and standards in this way for a range of reasons. First, such a view either accepts or rejects the use of private standards bodies for public purposes because it either prefers expert legitimacy over democratic legitimacy or vice versa. It assumes that expert knowledge and democracy are different, although fixed and rival fields.[126] This results in the view that standard-setting should be subject to one realm or the other. Second, the dichotomy between law and non-law requires that standards are equated to laws or relegated to the level of guidelines. Third, the effectiveness vs. judicial review dichotomy entails an invigoration of strict judicial control or the sacrificing of it on 'the altar of effectiveness.'[127] Within these dichotomies there is a general trend of juxtaposing standards with the law and identifying similarities.

Generally, '…a vast amount of "private" activity [especially standardisation] affects the choices available to the people at large just as effectively as a governmental rule'.[128] Hence, some scholars propose that European standards bear some similarities with the law and should be perceived as 'quasi' legal acts on the basis that these technical rules are de facto mandatory.[129] Snyder has argued that 'there is something we should call law, which carries much of the effect of legislation or case law, but is privately made.'[130] After identifying the similarities in function, the next question concerns whether these standards are produced in a similar manner to law, and if not, one would conclude that these rules lack democratic legitimacy. The 'normative imperative seems obvious: these private structures need somehow to be juridified and so

[126] E. Fisher, *Risk Regulation and Administrative Constitutionalism* (Bloomsbury 2007), 16.

[127] M. Eliantonio, 'Judicial Accountability in the Standardization Process: Sacrificing the Rule of Law on the Altar of Effectiveness' (presented at the conference on Regulatory Governance in Tilburg, 2016).

[128] R.G. Dixon, 'Standards Development in the Private Sector: Thoughts on Interest Representation and Procedural Fairness', cited in Busch, *Standards: Recipes for Reality* (n 77), 17.

[129] Gestel and Micklitz, 'European Integration through Standardization (n 63). For instance, Splinder suggests that private European standards have a quasi-legal character; G. Splinder, 'Market Process, Standardisation and Tort Law' (1998) 4 (3) *European Law Journal* 316, at 329.

[130] D.V. Snyder, 'Private Lawmaking' (2003) 64 *Ohio State Law Journal* 371, at 373. More careful theorists distinguish between law and other social norms, see for instance: G.-P. Callies and M. Renner, 'Between Law and Social Norms: The Evolution of Global Governance' (2009) 22 *Ratio Juris* 260.

rendered, if not democratic, if not public, then at least "public-regarding"[131]."[132] The default solution then, according to the relevant scholarship, is either to extend public law values to private regulatory systems,[133] or, as Teubner offers, to 'transform private law into the constitutional law of the diverse private governance regimes.'[134] Fischer-Lescano and Teubner adopt a rather moderate approach and argue that bringing private regimes under the hierarchical order of the state-centred law is a task destined for failure.[135] Consequently, they suggest that law can act as a 'gentle civilizer of social systems'[136] and control the excess of private regulation.[137] This means that the role of the law should be one of a 'controller' of private regulation, making it accountable.

In contrast to the above, this thesis does not enter into the theoretical dispute about the legal nature of standards, as to whether these technical rules are law, social norms or something in-between. The starting point of this research is that irrespective of where one stands in this debate, the reality is that European standardisation is a useful and effective mechanism to break down technical barriers and, thus, achieve internal market goals. The detailed legislative harmonisation of technical requirements concerning products did not yield the envisaged results mostly because the EU legislator is technically 'incompetent' to adopt technical specifications; it is meaningless then to require that the legislator adopt standards through constitutional channels.[138] That said, this should not mean that the law cannot shape or regulate the private European standardisation at all. Quite the contrary, the question to be asked then is

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[131] The term was coined by J.L. Mashow, 'Constitutional Deregulation: Notes Toward a Public, Public Law' (1980) 54 *Tulane Law Review* 849.

[132] H. Schepel, 'Constituting Private Government Regimes: Standards Bodies in American Law', in C. Joergens et al (eds), *Transnational Governance and Constitutionalism* (Bloomsbury 2004).

[133] A.C. Aman, 'The Limits of Globalisation and the Future of Administrative Law: From Government to Governance' (2001) 8 *Indiana Journal of Global Legal Studies* 379, at 385; See also J. Freeman, 'Private Parties, Public Function and the New Administrative Law' (2000) 52 *Administrative Law Journal* 813.

[134] G. Teubner, 'After Privatisation? The Many Autonomies of Private Law' (1985) 51 *Current Legal Problems* 393, at 394.

[135] Fischer-Lescano and Teubner, 'Regime-Collisions: The Vain Search for Legal Unity in the Fragmentation of Global Law' (n 124); Mataija*, Private Regulation and the Internal Market* (n 22), 7.

[136] Fischer-Lescano and Teubner, 'Regime-Collisions: The Vain Search for Legal Unity in the Fragmentation of Global Law' (n 124).

[137] Mataija, *Private Regulation and the Internal Market* (n 22), 7.

[138] See the discussion of this in Chapter 3 of this thesis.

whether and how the EU law can regulate European standardisation. This question, to some extent, overlaps with the above-mentioned discussions, but it also has a pragmatic and narrow standpoint. It is mainly concerned with exploring the potential of law, particularly EU law, to deal with private regulation, i.e. European standardisation.

The question of whether and how the EU law regulates the European standardisation system is important to ask, especially since the use of European standardisation has increased exponentially. At the same time, there is a clear lack of legal accountability of the European standardisation process. By exploring the set research questions, this thesis argues that while EU constitutional and economic law provisions were not designed to address primarily private regulation, the European standardisation system can still be scrutinised and hence regulated by EU law—even if this possibility is not always apparent or satisfactory. Highlighting and suggesting the different methods by which to 'discipline' standardisation through law and to perfect the standardisation process through the judiciary can ensure the system's legal accountability and contribute to its overall legitimacy.

1.5. Existing Literature and the Contribution of this Thesis

There is no shortage of literature exploring the role and benefits of European technical standards as flexible instruments of supranational governance at the EU level.[139] To summarise the literature on standardisation, on the one hand scholars have engaged with standards as tools and policy instruments for new modes of governance and regulation.[140] They explain that poor credibility of intergovernmental arrangements and the highly technical nature of regulatory policymaking were one of the key reasons for employing HESs in support of

[139] Some of the literature overview given in this section might coincide with the text of the article by M. Eliantonio and M. Medzmariashvili, 'Hybridity under Scrutiny' (n 36).

[140] See: K. Abbott and D. Snidal, 'International Standards and International Governance', (2001) 8 (3) *Journal of European Public Policy* 345; S. Bartolini, 'New Modes of European Governance: An Introduction', in A. Héritier and M. Rhodes (eds), *New Modes of Governance in Europe: Governing in the Shadow of Hierarchy* (Palgrave Macmillan 2011), 1–18; R. Bellamy, D. Castiglione, A. Follesdal et al, 'Evaluating Trustworthiness, Representation and Political Accountability', in A. Héritier and M. Rhodes (eds), *New Modes of Governance* (Palgrave Macmillan 2011), 135–62.

EU legislation and policies.[141] In this context, there is an agreement that the use of HESs in EU Directives increased the pace of integration and hastened the achievement of a single market.[142] On the other hand, though, the legitimacy of using standards in legislation has been questioned and standardisation has featured in research focusing on the legitimacy of using rules of private origin in the public domain.[143]

However, standards and standardisation are not popular topics among lawyers. According to Schepel, 'standardisation is a much-neglected area of social science research, attracting much less attention than it deserves.'[144] The same is true of European standardisation, which is largely unexplored in the EU legal scholarship. Standardisation is seldom the sole topic of research in the legal discipline and is investigated mostly in the context of private law and regulation.[145] Most commonly, standardisation is investigated within a particular legal discipline—usually competition and/or intellectual property law.[146] However, there is no comprehensive analysis of different legal aspects surrounding European standardisation.

Schepel's book, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets*, remains a major contribution; indeed, it is the only one so far to deal exclusively with standardisation in the context of law and governance. In that book, standardisation is not investigated under a particular legal discipline and includes standardisation in various jurisdictions: the EU; the US; and Mexico. Only two chapters discuss

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[141] See: G. Majone, 'The Rise of the Regulatory State in Europe' (1994) 17 (3) *West European Politics* 77.

[142] A.S. Sweet and S. Wayne, 'Integration, Supranational Governance, and the Institutionalization of the European Polity', in A.S. Sweet and S. Wayne, *European Integration and Supranational Governance* (Oxford University Press 1998).

[143] See: M. Rhodes and J. Visser, 'Seeking Commitment, Effectiveness and Legitimacy: New Modes of Socio-Economic Governance in Europe', in A. Héritier and M. Rhodes (eds), *New Modes of Governance* (Palgrave Macmillan 2011).

[144] Schepel, *Constitution of Private Governance* (n 111), 2.

[145] 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); See also Mataija, *Private Regulation and the Internal Market* (n 22). The latter book explores the relation between the EU economic law and private regulation in certain sectors, inter alia, in the standard-setting. However, the focus of the book is not on standardisation as such, but on private regulation, and the interplay between the internal market and private regulation is examined in the context of Sports, Legal Services and Standard-Setting.

[146] See for instance: B. Lundqvist, *Standardization under EU Competition Rules and US Antitrust Laws: The Rise and Limits of Self-Regulation* (Edward Elgar 2014).

standardisation in Europe, including six Member States, as well as standardisation at the EU level. The book certainly has an extremely broad scope and seeks to construct the field of 'standards law'.[147]

Unlike Schepel's work, this thesis focuses solely on the Commission-mandated European standards, which are used for the regulation of the goods sector. By doing so, this work hones in on a specific part of European standardisation—namely, that used for legislative purposes. This affords the opportunity to make a meaningful contribution to enhancing our understanding of the part of European standardisation that raises the most legal concerns.

It is important to stress that the EU legal scholarship has yet to produce a book with a comprehensive analysis of legal issues surrounding the European standardisation used for regulation. This thesis attempts to fill this void by providing an extensive piece of research into the legal ambit of European standardisation. More precisely, the present work undertakes a detailed investigation of legal aspects of the European standardisation process by exploring it in light of different parts of EU law. By doing so, the thesis also helps to explicate the much-debated though unresolved issue of the legal accountability of the European standardisation system.

As discussed above, European standardisation appears in the works concerning the relation between law and new governance. In that context, standards are approached through the dichotomies of expert vs. democratic legitimacy, law vs. non-law, and effectiveness vs. rule of law. Characteristic of such an approach is that standards and law are seen as rivals. The present work adopts a different approach insofar as it regards EU law as 'a gentle civiliser' for the betterment of the standardisation process. Such an approach is a valuable contribution in itself. In other words, this thesis does not continue the general trend of projecting standards and law as competing systems. Rather here I explore the employment of HESs in support of EU legislation as a flexible and beneficial regulatory technique and consider the limits of law in regulating the standardisation process. More precisely, this research delineates the interplay between law and standards, by projecting EU law not as a rival but as the mechanism through which European standardisation becomes more open, transparent and equipped to deliver well-reasoned standards.

In a broader perspective, this thesis adds to the scholarship on contemporary modes of regulation and lawmaking with the following argument. It is counter-intuitive to either criticise the co-regulation via European standardisation and

[147] Schepel, *Constitution of Private Governance* (n 111), 7.

private rule-making in general for departing from the narrow understanding of constitutional legitimacy, or to play 'the functional effectives as a trump card'[148] to avoid the law reaching these modes of regulation. Rather the law and legal accountability in the form of judicial review ought to be conceived of as a 'gentle civiliser' for private lawmaking in general and for European standardisation in particular.

In sum, the present work comprises a contribution to the existing EU legal scholarship on the European standardisation process, such as it is. Moreover, this thesis offers answers to the potential questions raised in practice about the intersection of law and standards in the EU goods sector. As such, it is also intended for a wider audience, from industry to policymakers.

1.6. Thesis Structure

This manuscript consists of eight chapters, including this introductory chapter and is divided in three parts. Part 1 consists of Chapters 2 and 3 that position European standardisation within the multilevel governance of formal standardisation, as well as puts European standardisation in the context of European market integration. More precisely, In the second chapter, I provide the reader with a map of the world of standardisation. Although this thesis deals exclusively with regional standardisation, i.e. European standardisation, in Chapter 2 I explain the relationship between national, regional and international standardisation. This is done so as to position European standardisation in the three-tiered structure of the standardisation world.

In Chapter 3 I discuss standardisation in the context of European integration, that is, as first being a barrier to trade and then becoming a regulatory tool for market integration. In addition, I explain the reasons for resorting to HESs in harmonising the product requirements, as well as describing central features of the New Approach and outlining the law's problems with it.

Part II consists of Chapters 4, 5, and 6 which map the different perspectives on the understanding of the co-regulation via European standardisation and regulation thereof by EU law. Particularly, in Chapter 4 I explain the operation

[148] Borrowed from J. Corkin, 'Refining Relative Authority: Judicial Branch in the New Separation of Powers', in J. Mendes and I. Venzke (eds), *Allocating Authority: Who Should Do What in European and International Law?* (Hart Publishing 2017). A similar argument is proposed with respect to new modes of lawmaking by J. Corkin therein.

of the co-regulation via European standardisation and present the 'Official View' on it. This is done in order to understand the 'Official View' on the use of the HESs in the EU legislation and policy and to clarify the implications of this for the issue of regulation and accountability thereof through EU law.

In Chapter 5, I examine the legislative use of European standardisation through the lens of EU constitutional law that, as I argue, provides the 'Delegation Framework' for understanding and regulation of the European standardisation system. The EU constitutional law perspective regards the mandated standardisation as delegated rule-making and prescribes the constitutional conditions for the lawfulness of such delegation. In doing so, I envisage the legal framework offered by the EU constitutional law, juxtapose it with the previously described 'Official View' and reflect what EU constitutional law offers in respect of regulation and accountability of the European standardisation system by EU law and through the judiciary.

In Chapter 6 I continue the examination of the legal ambit of the European standardisation system through the lens of EU economic law. In doing so, I argue that following the EU economic law perspective, the mandated European standardisation is a mixed public-private system and falls under the application of the EU free movement and competition law provisions. Consequently, the EU economic law provides the 'Hybrid Framework' for the regulation of the European standardisation system.

Part III of the thesis consists of Chapter 7, which addresses the second part of the thesis objective, i.e. legal accountability of the European standardisation system by means of judicial review. To this end, I discuss both the possibilities and the potential limitations of judicial review of the process of co-regulation via European standardisation.

Finally, in Chapter 8 I conclude the thesis and summarise its main findings.

Part I

Mapping the Standardisation World and Positioning European Standardisation in the Context of European Market Integration

2. A Glimpse of International, European and National Standardisation

2.1. General Overview: Standards

Standards are ubiquitous in our daily life. We encounter hundreds of standards as we go about our day, from dining tables to alarm clocks, from toys to electric gadgets. We coexist with standards and yet seldom notice them. Indeed, we are far more likely to notice the absence of a standard, since this can have detrimental effects.[149] As such, it is difficult to imagine what the world would look like without standards; nothing would fit, and life would be fraught with danger.[150]

Standards fulfil a range of different purposes—such as ensuring safety, providing interoperability, determining size and shape, guaranteeing quality and so on. So, what exactly is a standard? There are various understandings of this word. Moreover, it has divergent connotations in everyday language; it is sometimes used to refer to all types of rules and even laws. In a general sense, the EU defines a standard as a 'technical or quality specification with which current or future products, production processes or services may comply'.[151] The main feature of a standard is that it is a technical specification of a voluntary nature. The latter aspect distinguishes standards from laws and technical regulations. The EU law specifically differentiates between technical standards and technical regulations. Although both are technical specifications,

[149] The Great Baltimore fire is a vivid example of the devastating effects of the absence of a standard (n 3).

[150] Bøgh (ed.), *A World Built on Standards* (n 2), 11.

[151] Regulation (EU) 1025/2012 (n 14), Recital 1.

technical standards are voluntary[152] whereas regulations are mandatory de facto or de jure[153].

The standards can be categorised according to different criteria, such as: the purposes they serve (safety, health protection, quality, interoperability, etc.); the fields they regulate (products, services or the production process); and the bodies that adopt them (firms, fora and consortia, public or private standardisation organisations).

The EU Regulation on European Standardisation under the definition of a standard includes the technical specifications developed by the recognised Standard-Setting Organisations (SSOs).[154] These standards are also called de jure standards since they are developed by the formal SSOs. These formal SSOs can be either international (ISO and IEC), regional (like European ones: CEN, CENELEC and ETSI) or national (for instance French-ANFOR, German-DIN, Swedish-SIS, Danish-DS). The rest of the standards—so-called de facto standards—are produced by a company, group of companies, or in fora and consortia[155] and acquire recognition through continued application.

As explained in the previous chapter, this thesis deals only with European de jure standards that are developed on the basis of a request from the Commission and relate to products, in other words, the Harmonised European Standards (HESs). However, in this chapter, I provide a rather extended view of standardisation and map the world of formal standardisation from international (top) to national (down). This is done in order to position European standardisation in the multilevel system of standardisation governance and to demonstrate that formal standardisation at the European and the International levels display certain similarities in respect of their by-laws, subscribing to the principles of consensus, transparency, inclusiveness and voluntarity. It is also explained how the European standardisation system

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[152] Besides EU Law, WTO law also distinguishes between the technical regulations and standards; See: Agreement on Technical Barriers to Trade, 15 Apr. 1994, Marrakesh Agreement Establishing the World Trade Organization (hereafter WTO Agreement), Annex 1A, Legal Instruments – Results of the Uruguay Round, vol. 31, at 138 (hereafter TBT Agreement), Annex 1 to TBT paras 1–2.

[153] The European Parliament and Council Directive (EU) 2015/1535 of 9 September 2015 laying down a procedure for the provision of information in the field of technical standards and regulations and rule on information society (codification) [2015] OJ L241/1, Article 1(f).

[154] Regulation (EU) 1025/2012 (n 14), Article 2.

[155] Bøgh (ed.), *A World Built on Standards* (n 2).

interacts with and influences standardisation at international and national levels.

Arguably, standards-making increasingly moves from the national to the regional domain, e.g. European and International levels. That said, the national standard bodies remain crucial in communicating national viewpoints, as well as constituting important entry points for Small and Medium-sized Enterprises (SMEs) and societal groups involved in standardisation activities. Detachment of standardisation activities from the states' jurisdictions deepens the legitimacy concerns towards the standards produced at regional-European and international levels. Thus, it is essential that we investigate, pay close attention to and obtain a good understanding of the legal framework for regulation and accountability of the European standardisation system. This thesis meets this need.

The present chapter proceeds as follows. Firstly, I deal with the international standardisation and sketch a general picture, before describing the relationship between International and European standardisation. Secondly, I give an account of the European standardisation process. Given that the latter topic is the main focus of this thesis, a more detailed account of the European standardisation process is presented. In particular, I explain the structure of the European Standards Organisations (ESOs), the process of adopting a standard and the interaction between European and national standardisation. Finally, the chapter concludes by portraying the standardisation governance comprised of three levels—namely, international, regional (European) and national.

2.2. WTO and International Standardisation

De jure standards are prepared in three levels: some of the standards are developed at the national level, others are prepared to be used in the European region. Moreover, a significant number of standards are developed at an international level and are intended to be used globally. International harmonisation of standards is a result of globalisation and increased international trade. On this point, Schepel has noted:

> …the national state generally loses its centrality in the activity of government…and in this general landscape, standards bodies, public nor

> wholly private, nationally based but structurally locked into global frameworks, mediating between market demands and legal requirements[156] seem to flourish.

These standardisation bodies produce rules-standards that are constituent parts of the regulatory governance. The international standards are particularly important since they act as a 'lubricant of international trade'.[157] Due to this, the international regime established by the WTO Agreement on Technical Barriers to Trade (TBT Agreement) encourages the use and development of international standards. In addition, this agreement relies on international standardisation for the purposes of removing technical barriers to trade. The rationale for promoting international standardisation is straightforward: international standards bring the different regulatory requirements of different countries closer and ensure regulatory convergence.[158]

The TBT agreement addresses the technical barriers to trade in three ways: firstly, it urges signatory states to use technical regulations when there is an absolute legitimate need to do so; secondly, it lays down a mutual recognition clause; and finally, it imposes the obligation on signatory states to use international standards. The agreement reads as follows:

> Where technical regulations are required, and international standards exist or their completion is imminent, members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means of the fulfilment of the legitimate objectives pursued, for instance, because of fundamental climatic or geographical factors of fundamental technological problems.[159]

Besides encouraging the states to use international standards, the TBT agreement addresses standardisation through the 'private leg';[160] in particular, the Code of Good Practices (the Code) annexed to the TBT agreement concerns the preparation, adoption and application of standards. The Code is open to standards bodies regardless of whether they are central governmental, local or

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156 Schepel, *The Constitution of Private Governance* (n 111), 11.

157 E. Wijkström and D. McDaniels, 'Improving Regulatory Governance: International Standards and WTO TBT Agreement' (2013) 47 (5) *Journal of World Trade* 1013.

158 Ibid, 1014.

159 TBT Agreement (n 152), Article 2.4.

160 Schepel, *Constitution of Private Governance* (n 111), 180.

private organisations.[161] Standards bodies that accept and comply with the Code shall be acknowledged by signatories of the TBT as complying with the Code. The Code imposes on standards bodies similar obligations as the TBT to signatory states. Namely, standards bodies are required, when an international standard exists, to use it as a basis for their standard, unless it would be 'ineffective or inappropriate'.[162] Moreover, standards bodies should take part in international standardisation and avoid the duplication of work, as well as ensure that standards are not developed with a view of creating unnecessary obstacles to trade. In addition, the Code requires that standards bodies take into account comments that are received at the public inquiry stage of the standardisation process and deliver written explanations when deviating from those comments.[163]

Even though the TBT agreement encourages the use of international standards, it fails to define them.[164] When it comes to defining a standard, according to the TBT, a standard is a

> Document approved by a recognised body, that provides, for common and repeated use, rules guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory.[165]

The international body or system is defined therein as one 'whose membership is open to the relevant bodies of at least all Member States.'[166] Besides the controversy over what constitutes international standards and which standards organisations can be regarded as developers of the international standards, the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU) are usually regarded as international organisations for standardisation.

The ISO's predecessor—the International Federation of National Standardising Associations (ISA)—was founded in 1926. The ISO has existed

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[161] TBT Agreement (n 152), Annex 3: Code of Good Practice for the Preparation, Adoption and Application of Standards, provision B.

[162] Ibid, provision F.

[163] Ibid, provisions L, M, N.

[164] See: Schepel, *Constitution of Private Governance* (n 111), 185.

[165] TBT Agreement (n 152), Annex 1.

[166] Ibid.

in its current guise since 1946. Roughly 160 national standards bodies around the world are members of the ISO.

The standards in the ISO are developed in technical committees, subcommittees, or project committees. These committees consist of experts from industries; they can be joined by the representatives of governmental agencies, non-governmental bodies, consumer associations and so on.[167] Once the need for a standard is established, the next step is to define the technical scope of a future standard and create a new committee or a working group in the case of their absence.

The guiding rule in the ISO is that a standard should be consensus-based. This is a procedural principle geared toward the resolution of significant objections; however, 'consensus does not…imply unanimity'.[168] After national delegations of experts represented in a committee or a working group agree on an official draft of a future standard, it is circulated among the ISO's member bodies for voting and comments which can take up to five months. Later on, the final draft of a future standard is voted on in the committee and upon approval it is again sent to the member bodies of the ISO for a final vote. The final version of a standard is approved as an international standard if a two-thirds majority of the members of the relevant committee is in favour and not more than a quarter of the total number of votes cast are negative.[169]

It is important to note that these international standards are akin to recommendations. It is up to a national standards organisation to adopt (or not) an international standard as a national standard. Even a national standard organisation that voted in favour of an international standard is free to not adopt it. The same is true for states; they can choose whether or not to adopt these international standards as mandatory technical regulations. This voluntary nature of international standards provides a degree of flexibility, meaning that an international standard does not require ratification by each country to become effective. Notwithstanding the 'weak' nature of the international standards, they are influential worldwide. International standards are at the top of the pyramid of the standardisation world and they influence standardisation at the bottom of the structure. For example, 30% of CEN

[167] ISO, <https://www.iso.org/home.html> accessed 30 November 2016.

[168] Lundqvist, *Standardization under EU Competition Rules and US Antitrust Laws* (n 146), 130.

[169] Ibid.

standards are based on the ISO's work. While 75% of European electrotechnical standardisation is based on IEC standards.

It follows that European standardisation is not isolated from its international counterparts. Quite the contrary, international standards become the basis for many European standards and as a result of the harmonisation of European standardisation in the EU, these international standards enter the domains of national standardisation systems.

2.2.1. Interaction between International and European Standardisation

The relationship between International and European (regional) standardisation is regulated by the agreements concluded among the pertinent standards bodies on these two levels. The Vienna Agreement[170] provides the terms for the cooperation between ISO and CEN, while the relationship between IEC and CENELEC is governed by the Dresden Agreement.[171] The primary aim of these agreements is to avoid duplication of standardisation work and to give priority to standard-setting at the international level.[172]

In meeting this obligation, CEN has developed the policy to use the international works in the form of ISO standards whenever possible;[173] especially so since the WTO gives preference to the ISO standards. An ISO standard can be transposed into a European one in order to meet the different needs and as long as the relevant ISO standard is considered to satisfy those needs.

Within CEN a technical board takes the decision to transpose the ISO standard into a European Standards (EN). Although the justification for transposition of international standards varies from sector to sector, the technical board subjects its decision on transposition of the ISO standard to the following criteria:

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[170] Agreement on Technical Co-operation Between ISO and CEN (Vienna Agreement) signed in 1991.

[171] Agreement between IEC and CENELEC (Dresden Agreement) signed in 1996.

[172] Vienna Agreement (n 170), Article 2.

[173] CEN, *Policy* 1, as published on the website <http://boss.cen.eu/reference%20material/Guidancedoc/Pages/TranspoPolicy.aspx> accessed 30 September 2016.

- need for an EN to support a New Approach Directive and likelihood that the ISO standard is in line with the Essential Requirements and will be accepted as such;
- need and feasibility for an EN for direct reference in public procurement (conditions being that they (the international standards) include provisions for establishing conformity or that technical means exist for establishing the conformity of the products to the standard);
- need for an EN to support European policies other than in New Approach or Public Procurement Directives (and existence of an international standard covering the need);
- need for harmonised European answers to requirements of the European or international market where there is a risk of undue national deviations through direct national transposition of the ISO standard;
- need to review an EN (as a general rule, if not otherwise specified, every five years);
- expressed request or need of the market for the sector in question (global or regional).[174]

What is striking here is that CEN can use an ISO standard even as a response to the Commission's mandate. But CEN is not restricted from modification of an ISO standard in order to meet the essential requirements of a Directive. This is because transposition does not mean verbatim adoption of the ISO standard. CEN has several options to ratify the ISO standard: a) without change; b) with common modification; or c) quoting part of the ISO.[175]

Using already existing ISO standards saves time and resources and avoids duplication, but these are not the only reasons for collaborating with International Standards Organisations. The European standards bodies cooperate with international ones not merely to avoid the duplication of work, but also to promote European standardisation at the international level—in particular, to accelerate the adoption of European standards as international standards and, of course, to aid the national standards bodies in becoming more influential at the international level.[176] Early on, the Commission tried to

[174] Ibid.

[175] Ibid.

[176] Egan, *Constructing a European Market* (n 29), 257.

persuade the international standardisation bodies to address some of the works proposed at the European level. For instance, the Commission suggested that:

> …if international standardisation bodies can respond by accelerating work on projects which are of high priority to Europe, with a view to delivering results within the timetable set by European requirements, European level standardisation can be avoided.[177]

Not surprisingly, most members of International Standards Organisations were not keen to see international standards as secondary to the European standards.[178] In the recently published Commission's communication on European standardisation for the 21st century, the interaction between international and European standardisation was considered:

> …constant: sometimes, European standards are proposed to international standardisation organisations, sometimes, international standards become European ones. This dialogue is important as it makes it easier for companies to go global, notably SMEs.[179]

The interaction between international and European standardisation has a mutually influential purpose.[180] Whether European standardisation is strong enough to influence the international standardisation and deliver a competitive advantage for the European market globally, is debatable, but this is definitely the objective towards which the European standardisation policy strives. On the other hand, many European standards are based on their international counterparts and, in this sense, they are influenced by international standardisation.

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[177] The European Commission, Green Paper on the Development of European Standardization: Action for Faster Technological Integration in Europe, COM (90) 456 final.

[178] Egan, *Constructing a European Market* (n 29), 216.

[179] The European Commission, Communication on European Standards for the 21st Century of 1 June 2016, COM (2016) 358 final.

[180] According to Hofmann, not only do European standards comply with the International standards, but in many cases international standards are based on European standards especially those developed by IEC. See: H.C.H. Hofmann, 'A European Regulatory Union: The Role of Agencies and Standards', in P. Koutrakos and J. Snell (eds), *Research Handbook on the EU's Internal Market* (Elgar Publishing 2016), 16.

2.3. European Standardisation

European standardisation is located at the middle level in the pyramid of the standardisation world. European standards bodies (ESOs) are the 'regional mirrors' of the international standards bodies.[181] The European Committee for Standardisation (CEN) is the ISO's counterpart in Europe; the European Committee for Electrotechnical Standardisation (CENELEC) is the IEC's counterpart in the region; and finally, the European Telecommunications Standards Institute (ETSI)[182] is the regional mirror of the ITU.

European standardisation has gained momentum since the EU started to employ European standards as a tool with which to eliminate technical barriers and harmonise technical requirements.[183] The reliance of EU institutions on the European standardisation has grown over time. Development of European standards has become an important part of European industrial policy, claiming to bring benefits to EU industry, ensuring safer products, higher quality, interoperability, enabling innovation and boosting competitiveness. The EU aims to secure a competitive advantage in the global market by maintaining Europe as 'a global hub for standardisation.'[184] Otherwise, the Commission fears that standards 'would be set somewhere else and Europe would lose opportunities to benefit from first-mover advantage.'[185]

The 'honeymoon' enjoyed by the EU institutions and the European standards bodies began in the 1980s with the aim of eliminating the technical barriers to trade. Nowadays, the partnership is sought to be extended in the fields of services and also aims to exploit the products of non-formal and fast-developing ICT standardisation. To this end, Regulation 1025/2012 stipulates criteria for identifying the consortia-developed ICT standards that can be used in public procurement procedures.[186] These requirements relate to the process according which non-formal ICT standards are produced. Namely, the consortia-developed ICT standards can be used in public procurement if they

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[181] Lundqvist, *Standardization under EU Competition Rules and US Antitrust Laws* (n 146), 128.

[182] These are three European Standard-Setting Organisations officially recognised by Annex I to the Regulation (EU) 1025/2012 (n 14).

[183] The New Approach strategy is discussed in detail in Chapter 3 of this thesis.

[184] Commission, Communication on European Standards (n 179), para 2.

[185] Ibid, para 3.

[186] Regulation (EU) 1025/2012 (n 14), Article 13.

were prepared through an open, balanced, transparent and consensus-based procedure.[187] The rationale behind subjecting non-formal ICT standards to certain procedural criteria, and only then allowing their use in public procurement, is based on the perception that fair procedure leads to the fair standards. The EU public institutions put trust in standards that are produced in non-formal forums only if they conform to the principles of good governance. Similar requirements are not stipulated in the case of de jure European standards because the EU institutions have trust in the formal ESOs and believe that these institutions operate on the basis of the by-laws that conform to similar criteria.

The Europeanisation of standardisation brought momentum to European standards bodies and created a rather centralised system of standardisation. While this section discusses institutional and procedural aspects of European standardisation, it excludes ETSI. This is because the focus of this thesis is on the interaction of the EU institutions and ESOs in regulating the product market that takes place mainly in the context of standardisation activities exercised by CEN and CENELEC.

2.3.1. European Standards Organisations: Example of CEN

CEN is a non-profit organisation (association) with the aim of implementing standardisation throughout Europe and facilitating exchange of goods and services by eliminating technical barriers. CEN was founded in 1961[188] by several national standards bodies and its jurisdiction covers all types of marketable products. The CENELEC's standardisation activities are limited to issuing standards pertaining to electrotechnical products—basically any product powered by electricity. In 1975, these two European standardisation bodies were relocated from Paris to Brussels.[189] Now they are set up as private non-profit bodies under Belgian law.[190] It is important to stress that these ESOs are not bodies or agencies of the EU, although the CEN and CENELEC are

[187] Ibid, Annex II. The latter Annex provides a detailed list of criteria for identifying the consortia-developed ICT standards that can be used in public procurement.

[188] CEN was created in 1961; See: Hofmann et al, 'Rule-Making by Private Parties' (n 63), 9–13.

[189] Hofmann, Rowe, and Türk, *Administrative Law and Policy of the European Union* (n 63), 589ff.

[190] Articles of Association of CENELEC as approved by the General Assembly in 2015/06/05; Articles 1–5.

officially recognised standardisation bodies in the EU according to Annex I to Regulation 1025/2012.

The CEN and CENELEC are 'peak associations' of the national standards bodies (NSBs). They consist of national delegations and 'remain firmly linked to the national standards bodies.'[191] The CEN's members are composed of national standard bodies from 34 European countries; this includes all EU Member States and other countries that are part of the European Single Market.[192] The NSBs recognised in their respective EU countries are granted the status of national members. Along with the national members, the ESOs include affiliate members, which are national standards bodies of 17 neighbouring countries.[193] In addition, CEN consists of associate bodies, as well as other standardisation organisations. The affiliate members, associate bodies, Commission representatives and EFTA secretariat have the status of observers.

In every Member State, there is a national standardisation body connected to CEN and CENELEC that is an entrance point for private parties. By becoming a member of the national delegation to the European counterpart, a private party has the chance to participate in standardisation at the EU level. 'Mirror committees' are found in the NSBs, where all interested parties—such as business operators, consumers, stakeholder organisations—can participate. The national positions concerning the draft of a European standard are formed in these mirror committees and presented later to the technical committee of the pertinent ESO.[194]

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[191] Hofmann, Rowe, and Türk, *Administrative law and Policy of the European Union* (n 63), 594.

[192] See CEN website: <www.cen.eu/you/EuropeanStandardization/Pages/default.aspx> accessed 3 October 2016. The list of members of the CEN consist of: ASI-Austria, NBN-Belgium, BDS-Bulgaria, HZN-Croatia, CYS-Cyprus, UNMZ-Czech Republic, DS-Denmark, EVS-Estonia, SFS-Finland, ISRM-Former Yugoslavian Republic of Macedonia, ANFOR-France, DIN-Germany, NQIS/ELOT-Greece, MSZT-Hungary, IST-Iceland, NSAI-Ireland, UNI-Italy, LVS-Latvia, LST-Lithuania, ILNAS-Luxembourg, MCCAA-Malta, NEN-Netherlands, SN-Norway, PKN-Poland, IPQ-Portugal, ASRO-Romania, ISS-Serbia, UNMS-Slovakia, SIST-Slovenia, UNE-Spain, SIS-Sweden, NV-Switzerland, TSE-Turkey, BSI-United Kingdom.

[193] See: <www.cen.eu/you/EuropeanStandardization/Pages/default.aspx>

[194] Study for the European Commission, Enterprise and Industry Directorate-General, 'Access to Standardisation' (10 March 2009, Final Report).

The CEN and CENELEC have similar organisational structures and are governed by internal regulations. Therefore, key features of the ESOs' organisational structure can be explained using the example of CEN.

The governing bodies of CEN consist of the general assembly, administrative boards and a presidential committee. In addition, CEN operates through other bodies such as the technical board, the technical committees and the CEN Certification Board. Furthermore, the CEN-CENELEC Management Centre (CCMC) coordinates the standardisation functions between the two organisations.

The general assembly is the supreme governing body of CEN. It is formed by and represents the national members. It defines the main policies and strategies of the association. The general assembly meets twice a year in one ordinary and one statutory meeting. It can be called and gathered to meet by the Director General if an extraordinary situation arises. The administrative board manages CEN's businesses.[195] This board has broad power to direct and administer the association's business and to handle administrative matters. Moreover, the administrative board is empowered by the general assembly to manage the technical tasks by delegating them to the technical board.

The technical board is responsible for planning, monitoring and coordinating the standardisation work of its sub-groups and technical committees in close cooperation with CCMC. The technical board also monitors various technical committees.

The technical board consists of one permanent delegate from each Member State, which has to establish necessary contacts at the national level. The standardisation activities are coordinated by the technical board. It is the technical board that designates technical committees, sub-committees, working groups and task forces that engage in writing a standard. All these committees and working groups consist of interested parties nominated by their NSBs. These interested parties are usually the industries concerned. No more than three national delegates per committee are allowed from each country. The national delegations are to convey the national points of view. The national representatives also have the power to accept mandates. Below is a graphic illustration of the CEN's structure as described above.[196]

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[195] See: CEN-CENELEC, 'Internal Regulation, Part 1, Organization and Structure', 2013. Point 4.1; Articles of Association of CENELEC (n 190), Article 16.

[196] The chart below is my own; it was created on the basis of the internal regulations of CEN and CENELEC.

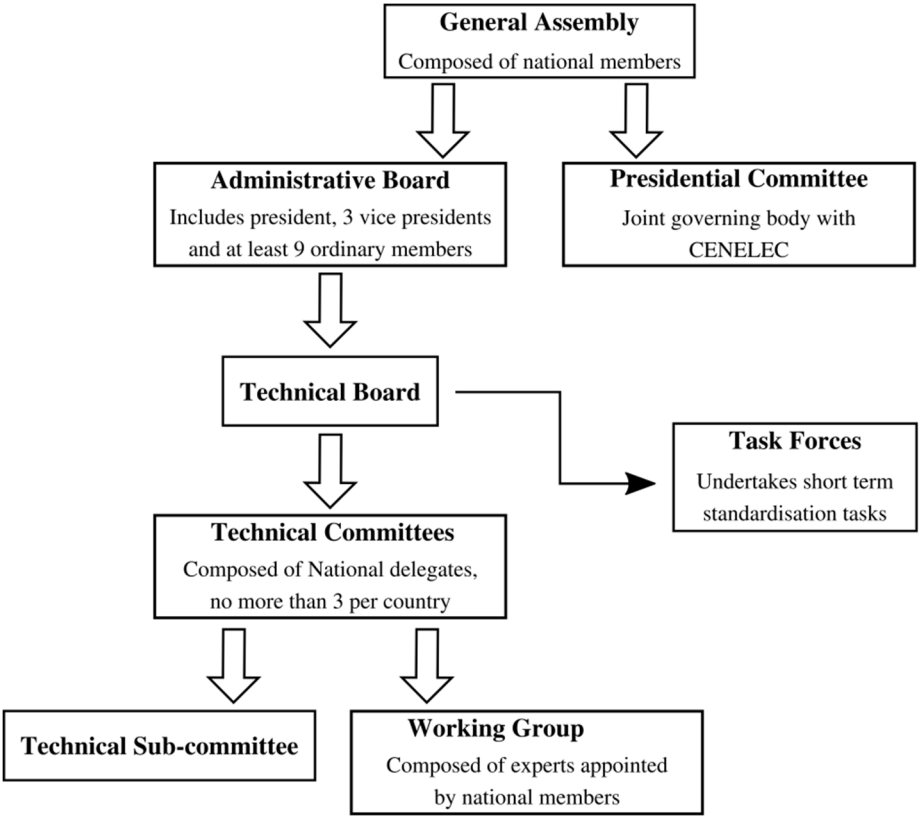

Figure 1
CEN Structure

To sum up, the ESOs are composed of national representatives organised by and for stakeholders.[197] Moreover, they are private bodies established under private law and governed by their statutes. Hence, they are different from the European bodies and agencies. At the same time, the ESOs cooperate with the Commission and provide support with technical harmonisation.

[197] Regulation (EU) 1025/2012 (n 14), Recital 2.

2.3.2. Standard-Setting Process

The process of the development of European standards, including harmonised ones, is mainly governed by the by-laws of the ESOs. However, Regulation 1025/2012 stipulates the main principles for the standard-setting. It requires: a) transparency of standards;[198] b) stakeholder participation, particularly the involvement of SMEs;[199] c) encouragement of participation by consumer groups[200] and public authorities,[201] and support for non-discriminatory and consensus-based standardisation.[202] In a similar vein, Regulation 1025/2012 sets out the criteria for identifying consortia-developed ICT specifications to be used in public procurement procedure.[203]

As for the actual process of development of a European standard, in principle anyone can propose a standard to a national standard body (NSB) or directly to the technical committee of the pertinent ESO. The technical committee then decides on whether to accept the proposal or initiates the procedure for drafting a standard.[204] The technical tasks of standardisation are exercised solely by the ESOs on an independent basis. Once a draft of a European standard has been prepared, it is released, as a 'CEN Enquiry', for public comments. Anyone can comment on a draft standard; the draft is modified according to comments and then submitted for a formal vote. The Commission's representatives attending the technical committee do not have the right to vote.[205] The decision-making policy of the CEN-CENELEC seeks unanimity. However, when a vote is found

198 Ibid, Article 4.

199 Ibid, Article 6.

200 Ibid, Article 5.

201 Ibid, Article 7.

202 Ibid, Recital 2 and Article 15(c).

203 Regulation (EU) 1025/2012 (n 14), Annex II that lays down the principles guiding the identification of consortia-derived ICT specifications, which could be referred in public procurement procedure. These encompass openness, consensus, balance, transparency. They mirror WTO principles enshrined in TBT Agreement (n 152), Annex 3: Code of Good Practice for the preparation, Adoption and Application of Standards, so-called WTO Code of Good Practice.

204 However, if a proposal concerns a new field of standardisation, then the CEN's technical board has to make a decision. See: CEN-CENELEC, 'Internal Regulation', 2018, part 1 et seq.

205 CEN-CENELEC, 'Internal Regulation', 2018, part 2, para 3.2.4.

to be necessary, this will require a simple majority. There are three cases[206] where, in addition to the requirement for a simple majority, the votes cast by the members are accorded different weights.[207]

Generally speaking, there is no direct participation of key industry stakeholders at the EU level. This is because the national delegation principle applies to CEN-CENELEC, meaning that industry experts are nominated by NSBs.[208] These experts can come 'from a wide range of technical backgrounds, often industrial.'[209] The responsibility for ensuring the involvement of SMEs lies at the national level,[210] because European standardisation is, in the first instance, managed at the national level,[211] and CEN-CENELEC consists of national delegations.

In addition, the ESOs are also required to facilitate the involvement of stakeholder organisations.[212] Regulation 1025/2012 officially demands that European standardisation is open to other interested stakeholders. This is important for making standardisation a 'flexible and transparent platform for consensus-building between all participants.'[213]

Participation of the interested stakeholders at the EU level is promoted through the European stakeholder organisations, which receive Union funding. According to Annex III to Regulation 1025/2012, the European stakeholder

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[206] a) Formal approval of EN (European Standard) and HD (harmonisation document), b) Formal approval of TS (Technical Specification), c) Any initiation of a new work item to become an EN or TS within a CEN Technical Committee (except amendment or revision).

[207] The CEN-CENELEC, 'Internal Regulations', 2018, 'Part 2: Common Rules for Standardization Work', paras 6.1 and 6.2, also Annex D: Weighted votes are allocated to national members in accordance with Annex D. 'A proposal shall be adopted if a simple majority of votes cast is in favour and if 71% or more of the weighted votes cast are in favour. If the proposal is not adopted in this way, the votes of the members of the EEA countries shall be counted separately. The proposal is then adopted if it receives at least 71% of weighted votes in favour'.

[208] This is not the case for ETSI, here enterprises or representatives of industrial organisations can have direct membership.

[209] Commission describing the organisational structure of CEN in Case COMP/F-2/38.401 EN 1971-1 Standards-*EMC/European Cement Producers*, 2005, para 26.

[210] Regulation (EU) 1025/2012 (n 14), Article 6. The latter Article requires national standards bodies to encourage the involvement of SMEs.

[211] COMP/F-2/38.401 EN 1971-1 Standards-*EMC/European Cement Producers* (n 209) 2005, para 26.

[212] Regulation 1025/2012 (EU) (n 14), Article 5.

[213] Ibid, Recital 9.

organisations eligible for Union financing are the organisations representing consumers, SMEs and environmental and social interests. It is worth noting that these interested groups do not have voting rights. Although Regulation 1025/2012 moves toward a more inclusive standard-setting process and the ESOs should reflect this in their by-laws, the standardisation still remains more of an engineer-driven practice. The standard-setting process rests on collaboration between the members of the ESOs. In other words, these organisations are 'result driven rather than created to protect various minority or societal interests, such as consumer protection'.[214] However, increasing reliance on standards in EU legislation and policy documents requires stronger incorporation of broader societal interests in the process of standardisation. To this end, the ESOs' by-laws need to ensure that different interest groups are heard.

Interested stakeholders, at their own expense, develop the standards in the ESOs; however, when the Commission mandates the preparation of an HES, it is the EU that incurs the costs. Specifically,

> where a request for funding is made, the Commission shall inform the relevant European standardisation organisations, within two months following the receipt of the acceptance…of a mandate…about the award of a grant for drafting a European standard or a European standardisation deliverable.[215]

Beyond receiving financial support from the EU, ESOs receive membership fees from national standards bodies. The latter bodies, in their turn, benefit from selling the national standards transposing the European standards.

2.3.3. Interaction between European and National Standardisation

The system of standardisation and the institutional features of national standards bodies in Europe varies from country to country. In some states, NSBs are the governmental agencies, in other states, standards organisations are private law bodies, meaning that standardisation activities are either all centralised in one institution or spread across different sectoral bodies. With the Europeanisation of standardisation, NSBs have been converging into

[214] Lundqvist, *Standardization under EU Competition Rules and US Antitrust Laws* (n 146), 145.

[215] Regulation 1025/2012 (EU) (n 14), Article 10(4); The financial arrangements between the Commission and the ESOs are given in Article 17 of Regulation 1025/2012.

centralised, 'private non-profit associations enjoying public recognition and monopoly of power, elaborating and promulgating standards according to a rather homogenous set of procedures built on the core principles of consensus, openness, and transparency.'[216]

The regulatory framework laid down by the New Approach strengthened harmonisation efforts of European standardisation and, nowadays, it is facilitated, in addition, by Regulation 1025/2012. The European standards adopted by the ESOs are expected to be transposed as national standards by the NSBs. The NSBs are under the obligation to

> …not object to a subject for standardisation in their work programme being considered at European level in accordance with the rules laid down by the European standardisation organisations and may not undertake any action which could prejudice a decision in this regard.[217]

Moreover, the HESs have primacy over the national standards. According to Regulation 1025/2012, the NSBs are obliged to withdraw conflicting national standards, to freeze national standardisation activities when a similar standard is under way at the EU level, and to refrain from publishing new or revised versions of the national standards that contradict an HES.[218]

The primacy and harmonisation effects of the HESs were one of the arguments put forward by AG Sanchez-Bordona in the *James Elliott* case, advising the ECJ to give a preliminary ruling on the interpretation of an HES. He reasoned that:

> If the Court of Justice has, as is obvious, jurisdiction to give a preliminary ruling on the interpretation of Directive 89/106, it must also have an identical right to answer questions referred for a preliminary ruling in relation to the harmonised technical standards supplementing that directive. Otherwise, the harmonisation of construction products would be rendered ineffective, for the harmonised technical standards (in this case, EN 13242:2002) could be given diverging interpretations in the various Member States.[219]

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[216] Schepel, *Constitution of Private Governance* (n 111), 101.

[217] Regulation 1025/2012 (EU) (n 14), Article 3(5).

[218] Ibid, Article 3(6).

[219] Case C-613/14 *James Elliott* (n 60); Opinion of AG Campos Sánchez-Bordona in *James Elliott* ECLI:EU:C:2016:63, para 44.

Additionally, the European and national standardisation bodies cooperate closely and exchange information on the planned standardisation work so as to avoid the clash between European and national standards and ensure transparency. Regulation on European standardisation requires that both the national and European standards bodies publish their standardisation work programme online and notify the other standardisation bodies and the Commission.[220] The national standards bodies are explicitly required to notify a draft of a national standard to the rest of the standardisation bodies. In case of a negative response, the consultation with the ESOs and the Commission is necessary.[221]

With the adoption of Regulation 1025/2012, the role of European standardisation in the building of the internal market has been re-established. The centralised system of European standardisation has also been strengthened. Following these developments, the European standards enjoy primacy over the conflicting national standards.

2.4. Three-tiered System of Governance in Standards

This chapter presented a general picture of multilevel governance in the formal standardisation system. It focused on the de jure standardisation and discussed its institutional and procedural features at the international, European and national level. In particular, this chapter took a top-down approach, from the international to national standardisation; of course, the picture could have been presented the other way around. The rationale behind portraying the pyramid of the standardisation world from top to bottom was based on the fact that national standards bodies nowadays are less engaged with standard-setting at the national level. Rather, their function is to communicate national viewpoints, concerns and preferences at the European or global level.

This chapter also clarified that with the increasing importance of standards, more attention is paid to the process of developing them. It was shown that all formal standards bodies subscribe and develop by-laws that promote open, transparent and consensus-based standardisation. Adherence to these principles guarantees the wide acceptance of standards and paves the way for these to be used by public authorities as a regulatory tool. Compliance with the

[220] Regulation 1025/2012 (EU) (n 14), Article 3.

[221] Ibid, Article 4(3).

procedural principles during the European standard-setting process, as will be seen in the coming chapters, is vital for the legitimacy of such standardisation. What is more, these procedural principles could serve as a yardstick for judicial review of the European standardisation system.

The next chapter focuses on standardisation at a regional level and deals exclusively with European standardisation, since the latter is the main topic of this research. It presents the standardisation, firstly thought of as a barrier to trade and then becoming the regulatory tool for European market integration.

3. European Standardisation and the Internal Market

3.1. Standards as a Barrier to and an Instrument for European Market Integration

At this point of this thesis, the focus is exclusively on European standardisation. More precisely, I put technical standards in the context of European market integration, and by so doing explain the aims, benefits and legal concerns of using European standardisation in EU legislation and policies. I argue that although the benefits of Harmonised European Standards (HESs) for the internal market are clearly identifiable, the EU legal framework for the regulation and accountability of the European standardisation system is still puzzling.

The technical standards in the internal market are Janus-faced. On the one hand, standards that originate at the national level differ substantially across Member States, creating technical barriers to trade. On the other hand, technical standards adopted at the EU level and represented as HESs are important means of removing technical barriers.[222] This chapter reveals the dual face of technical standards in the context of market integration and sets out reasons for embodying standards in EU law in the following manner. Firstly, a standard as a barrier to market integration is addressed. This is done by revisiting the positive and negative integration strategies and underlining the limits of such strategies. Secondly, the HESs are presented as tools for the harmonisation of various technical requirements. The use of HESs for market integration occurred through the New Approach strategy. As such, the latter strategy is described herein. The New Approach sets the framework for the

[222] Egan states: 'paradoxically, technical standards have been perceived as both a barrier to trade and a means towards constructing a fully-fledged common market within the EC'; See: M. Egan, 'Associative Regulation in the European Community: The Case of Technical Standards' (1991) <http://aei.pitt.edu/7113/> accessed 18 May 2017; J. Pelkmans, 'Completing the Internal Market for Industrial Products' <https://publications.europa.eu/en/publication-detail/-/publication/0fa57d19-f6b9-442f-9c8d-329658d15eb6> accessed 18 May 2017.

public-private co-regulation via European standardisation and incorporates standards in EU law.

The EU sui generis polity has endeavoured to maximise the degree of market integration ever since the Treaty of Rome was signed.[223] The realisation of the internal market[224] is based on the free movement of goods, services and establishment, as well as free movement of workers and capital.[225] Notably, the rules on free movement of goods play a central role in the establishment of the internal market. However, without eliminating technical barriers to trade it is impossible to secure the free movement of goods. Hence, the removal of technical barriers to trade was and remains an essential factor for the success of the internal market.

Technical barriers include different types of measure, such as technical regulations and standards. The latter is a pervasive form of technical barrier and fundamental obstacle to free trade between States. This is because technical standards often vary from one Member State to another, generating situations in which, for instance, a product made in conformity with German law does not comply with the requirements of Swedish law. In this manner, the technical barriers to trade—stemming from differences in standards—'affect business operations directly, in terms of design, production, sales and marketing strategies.'[226] As a result, the EU market has remained highly fragmented. Every technical specification in force in each Member State has been a potential barrier to trade.[227] Therefore, it is not surprising that companies have ranked the removal of technical barriers to trade as the most crucial step for the accomplishment of the single market.[228]

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[223] Article 2 of the EEC Treaty stated: 'The Community shall have as its task, by establishing a common market and progressively approximating the economic policies of member states, to promote throughout the community a harmonious development of economic activities, a continuous and balanced expansion, an increase in stability, an accelerated raising of the standard of living and closer relations between the states belonging to it'.

[224] The terms 'internal market', 'common market' and 'single market' will be used interchangeably throughout the thesis.

[225] The internal market, inter alia, includes the so-called 'four freedoms'. On the story of European integration, see: A. Moravcsik, *The Choice for Europe: Social Purpose and State Power from Messina to Maastricht* (Cornell University Press 1998), 86–158.

[226] Egan, *Constructing a European Market* (n 29), 51.

[227] The European Commission, Staff Working Paper of 16 December 1996: The 1996 Single Market Review, Background Information for the Report to the Council and European Parliament, SEC (96) 2378, 1996, para 18.

[228] Egan, *Constructing a European Market* (n 29), 40.

In response, the EU has employed positive and negative integration strategies to tackle these technical barriers. The former were exercised through legislative harmonisation, while the latter proceeded via judicial activism. However, these strategies were limited in addressing technical standards, because standards—voluntary private rules—would usually escape the court's jurisdiction.[229] In addition, agreeing on highly technical aspects through political bargaining proved to be a difficult path.

To overcome this conundrum, the EU has adopted the so-called 'Information Directive'.[230] This Directive aimed at preventing the emergence of new technical barriers, by exchanging information between Member States and with the Commission. But a merely preventive mechanism did not suffice. It was also necessary to establish Union-wide technical specifications, which naturally required harmonisation of national technical requirements. Traditionally, the Parliament and the Council, through legislative process, exercise harmonisation. However, harmonising technical requirements through the legislative process was difficult, as legislators lacked the relevant technical knowledge. Moreover, the process of adopting a legislative act was protracted.[231]

The solution was found in the private sector. The EU opted to use private bodies—ESOs[232]—to harmonise technical specifications. This took place through the New Approach strategy, which established public-private cooperation in the field of technical harmonisation. The primary aim of the New Approach strategy was to achieve a harmonised and genuinely free internal market.[233] To this end, the New Approach employed the HESs as a regulatory solution to the problem posed by the different national standards.

In light of the foregoing, I briefly revisit traditional strategies of integration and the limits thereof that manifest the need for the New Approach strategy. I

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229 Schepel, *The Constitution of Private Governance* (n 111), 38.

230 The original version of this Directive is Council Directive 83/189 of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards [1983] No L 109/8. This Directive was subsequently modified by the European Parliament and the Council Directive 98/34 and has now been replaced by the European Parliament and Council Directive (EU) 2015/1535 (n 153). To avoid any confusion, this thesis will refer to the later version of the Directive. Also, this Directive is discussed in detail in the coming sections.

231 See the discussion of this in section 3.2.1. of this chapter.

232 Officially recognised ESOs are CEN, CENELEC and ETSI. The New Approach strategy employed the CEN and CENELEC.

233 J. Pelkmans, 'The New Approach to Technical Harmonization and Standardisation' (n 15).

also outline the operation of the New Approach, complemented by Regulation 1025/2012.[234] At the end of this chapter, I discuss some of the legal concerns raised in academia against the New Approach strategy.

The remainder of the chapter is divided into the following sections. Section 2 deals with positive and negative integration in the light of legislative harmonisation and judicial activism. In section 3 I describe the Information Directive and explain the New Approach. In section 4 the essential elements of the New Approach strategy are presented. Section 5 outlines the legal concerns expressed against the New Approach, while in section 6 I explain the main features of Regulation 1025/2012, which provides the renewed legal framework for the European standardisation system. The last section concludes the chapter.

3.2. Standards and the Limits of Positive and Negative Integration

The traditional techniques of eliminating technical barriers may be grouped into positive and negative integration strategies. I explain these strategies and their limits in this section. Doing so will reveal the need to find an 'innovative' approach—using private rule-making, i.e. standardisation for public purposes.

The formation of an internal market requires positive measures to be taken toward greater integration.[235] The diversity created by the different national rules can only be properly overcome by harmonising national laws. Harmonisation 'involves the adoption of legislation by the Community institutions that is designed to bring about changes in the internal legal systems of the member states'.[236] The EU primary law enables positive harmonisation by virtue of Articles 114 and 115 of the Treaty on the Functioning of the European Union (TFEU).

[234] Regulation (EU) 1025/2012 (n 14).

[235] A. McGee and S. Weatherill, 'The Evolution of the Single Market: Harmonisation or Liberalisation' (1990) 53 *Modern Law Review* 578.

[236] See: A. Dashwood, 'The Harmonisation Process', in C. Twitchett, *Harmonisation in the EEC* (Macmillan 1981), 7–17.

Negative integration is also regulated through primary EU law and prohibits national rules that hinder cross-border trade.[237] The Court of Justice of the European Union (CJEU) has employed internal market freedoms to actively exercise negative integration. Judicial control has complemented the positive-legislative harmonisation. However, technical standards, which are private rules and not enactments of the Member States, were beyond the reach of both strategies.[238] There was thus a need for an innovative approach to legislative harmonisation.

3.2.1. The Early Years of Legislative Harmonisation: The 'Old Approach'

Harmonisation of the laws of Member States is an 'instrument for shaping European economic cooperation.'[239] Twitchett explains that 'harmonisation is the key to the creation and development of the European common market.'[240] That is because harmonisation changes the Member States' internal legal systems by adopting legislation at the Union level.[241]

As early as 1968, the Commission proposed an ambitious project—the General Programme for Technical Harmonisation.[242] This programme laid down the timetable for legislative harmonisation to be completed by mid-1971.[243] However, agreeing on detailed, exhaustive and complicated legislative requirements made the progress of positive integration extremely slow.[244] It took an exceedingly long time for directives to be adopted, and when they

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[237] Consolidated version of the Treaty on the Functioning of the European Union (TFEU) [2012] OJ C 326/47, Articles 28–30, 34–5 and 110.

[238] Schepel, *The Constitution of Private Governance* (n 111), 50.

[239] T.W. Vogelaar, 'The Approximation of the Laws of Member States under the Treaty of Rome' (1975) 12 (2) *Common Market Law Review* 211.

[240] C.C. Twitchett, 'Introduction', in *Harmonisation in the EEC* (Springer 1981).

[241] Dashwood, 'The Harmonisation Process' (n 236).

[242] D. Lasok, *The Trade and Customs Law of the European Union* (Kluwer Law International 1998), 156 et seq.

[243] See: A. Dashwood, 'Hastening Slowly: The Community's Path towards Harmonisation', in H. Wallace, W. Wallace, and C. Webb (eds), *Policy Making in the European Communities* (John Wiley & Sons 1983).

[244] A good example of a detailed, complicated and lengthy directive is the Council Directive 87/402/EEC of 25 June 1987 on roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors [1987] No L 220/1, which ran for 43 pages.

finally came into force, the technical requirements were often outdated. As an example, Directive 84/526/EEC, on the approximation of the laws of the Member States relating to seamless unalloyed aluminium and aluminium alloy gas cylinders, was only adopted ten years after the Commission's initial legislative proposal.

The result of the Union's legislative harmonisation was far from impressive. By December 1970, the deadline for the General Programme for the elimination of technical barriers to trade[245] was reached, and only nine directives from the original list of 150 had been adopted. The process of adopting technical directives proved to be extremely time-consuming. The directives adopted as a package in 1984 had been before the Council for, on average, nine and a half years.[246]

The difficulty of reaching political consensus among the Member States made legislative harmonisation difficult.[247] Adoption of harmonising measures required, at that time, the Council to act unanimously, which enabled Member States to use veto power. Consequently, only a handful of decisions were adopted. As Egan explains: 'harmonization often fell victim to the varying interests and preferences of member states, and the bargaining and horse-trading that often led to lowest common denominator decisions.'[248]

The adoption of the Single European Act (SEA) provided the means to remedy the hampered process of legislative harmonisation. The SEA's key objective was to add momentum to European integration and complete an internal market.[249] To this end, the SEA changed the Council voting rule from unanimity to qualified majority on matters pertaining to the internal market. This extension of majority voting rule beyond the limited fields[250] was

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[245] For a detailed overview of this matter see: Slot, *Technical and Administrative Obstacles to Trade in the EEC* (n 2), 103–7.

[246] OJ L 300, 19 November 1984, 1–187, cited in J. Falke and C. Joerges, 'The "Traditional" Law Approximation Policy Approaches to Removing Technical barriers to Trade and Efforts at a "Horizontal" European Product Safety Policy' (2010) 6 *Hanse Law Review* 237.

[247] Egan, *Constructing a European Market* (n 29), 62.

[248] Ibid, 65–6.

[249] Treaty Establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. I 1 [hereafter EEC Treaty] (entered into force Jan. 1, 1958), Article 8A, Article 13 added by Single European Act, 30 O.J. EUR. COMM. (No. L. 169) 1 (1987), reprinted in 25 I.L.M. 506 (1986) [hereafter SEA]. See also: G.A. Bermann, 'The Single European Act: A New Constitution for the Community?' (1988) 27 *Columbia Journal of Transnational Law* 529.

[250] Before the adoption of the SEA, the EEC treaty allowed majority voting only in limited fields and only for the adoption of specific measures.

significant in several respects. It meant that much of the harmonisation legislation that sought to complete the internal market would be passed through majority rule. Consequently, the adoption of legislation could not be prevented or delayed by a veto from a single Member State. This change 'made it more difficult for recalcitrant member states to simply veto legislative action.'[251]

The SEA facilitated the construction of an internal market not just by introducing the qualified majority rule; it also promoted constructive harmonisation. Particularly, the Commission was requested to compile an inventory of national legislation or administrative practices that would require Union harmonisation for the completion of the internal market.[252] Then, the Council was free, at any time before the end of 1992, to decide that Member States were bound to treat the measures in force in another Member State (within the inventory) as equivalents to its own.[253] This rule of mutual recognition served as a warning that if the Member States did not vote for the union harmonisation legislation, they could still be bound to accept the national standards of other Member States as equivalent to their own.[254]

The fact that decision-makers lacked the required technical knowledge was also a significant impediment to legislative harmonisation.[255] This was so because 'directives contain[ed] minutely technical regulations,'[256] which did not differ from the technical standards and thus required expert-based decision-making. Moreover, it was impossible to capture national standards through legislative harmonisation because, unlike legislative requirements, they were not adopted by public authorities and were voluntary. On the other hand, technical standards were de facto mandatory for market operators and thus hindered trade between Member States.

To sum up, legislative harmonisation was a slow process that proved ineffective against various national technical specifications. Setting detailed and uniform European standards required expert knowledge and the involvement of industrial organisations, but instead was passed through the process of political decision-making in the Council. Furthermore, it was

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[251] Egan, *Constructing a European Market* (n 29), 80.

[252] EEC Treaty (n 249), Article 100B(1), added by Article 19 of SEA (n 26).

[253] EEC Treaty (n 249), Article 100B(1), para 2, and 100B(3), added by Article 19 of SEA (n 26).

[254] Bermann, 'The Single European Act' (n 249), 529, 546.

[255] Egan, *Constructing a European Market* (n 29), 61–82.

[256] Falke and Joerges, 'The "Traditional" Law Approximation Policy Approaches' (n 246).

extremely strenuous to adapt Directives to ever-changing technical progress. In the wake of incomplete positive harmonisation, the negative integration increased in importance and a need for a non-traditional approach of harmonisation became evident.

3.2.2. Negative Integration: Article 34 TFEU and Mutual Recognition

Negative integration has an important part to play in achieving the internal market. The free movement provisions in particular were effective tools in the hands of the ECJ to tackle technical barriers. However, promoting the common market would not have been possible without a sui generis legal order that conferred judicially enforceable rights and obligations to public and private parties in the Union.[257] By establishing the doctrines of direct effect[258] and supremacy,[259] the Court created a new legal order that was critical in fostering economic and political integration.[260] The mechanism of preliminary ruling, now embodied in Article 267 TFEU, helped courts at both the national and the EU level to develop a legal framework essential for interstate commerce. Moreover, the legal union 'has clearly resulted in a system of judicial decision-making'[261] and the ECJ played a crucial role in the creation of the internal market.[262]

In this section, I explain the reach of negative integration to disparate national standards in the following manner. Firstly, the scope and limits of Article 34 TFEU in addressing the national standards are elucidated. Secondly, I describe the role of the principle of mutual recognition for tackling the technical barriers and underline the limits of this principle.

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[257] A.S. Sweet and T. Brunell, 'Constructing a Supranational Constitution: Dispute Resolution and Governance in the European Community' (1998) 92 *American Political Science Review* 63.

[258] Case 26/62 *Van Gend & Loose*, ECLI:EU:C:1963:1.

[259] Case 6/64 *Costa v ENEL*, ECLI:EU:C:1964:66.

[260] Egan, *Constructing a European Market* (n 29), 83–109.

[261] Ibid, 86.

[262] See: T. Sandalow and E. Stein (eds), *Courts and Free Markets: Perspectives from the United States and Europe* (Oxford University Press 1982).

The legal framework of the free movement of goods comprises Articles 34–36 TFEU.[263] Article 34 TFEU addresses 'quantitative restrictions to imports and all measures having an equivalent effect', while Article 35 concerns the same measures in relation to exports. Finally, Article 36 TFEU allows the Member States to protect vital interests enumerated therein, and by so doing provides exemptions from the general rule of free movement of goods.

The legal regime established by Article 34 TFEU has two key features: first, it covers State measures[264]; and second, it embraces both quantitative restrictions and measures having an effect equivalent to that of quantitative restrictions.[265] The question of what counts as an equivalent measure has been the subject of considerable scholarly[266] and political[267] debate. The Court elaborated on the concept in the seminal *Dassonville* case, stating that 'all trading rules enacted by member states which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having equivalent effect to quantitative restrictions.'[268] Such a broad definition

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263 The treaty Articles concerning the free movement of goods have been renumbered several times. Therefore, only the numbering as it stands in the Lisbon Treaty are used in this thesis. The current numbering is also used while discussing the cases referring to old numbers of those articles.

264 See among the numerous cases: Case 8/74 *Dassonville* ECLI:EU:C:1974:82, para 5; Case C-110/05 *Commission v Italy* ECLI:EU:C:2009:66, para 33; Case C-108/09 *Ker-Optika*, ECLI:EU:C:2010:725, para 47.

265 See: *Dassonville* (Ibid); Case C-481/12 *UAB 'Juvelta'* ECLI:EU:C:2014:11, para 16.

266 Scholars were divided into two groups, one supporting a rather broad interpretation of Article 34 TFEU as to include both measures that discriminate between domestic and imported goods and measures that apply indiscriminately but still effect the trade between member states. See: Slot, *Technical and Administrative Obstacles to Trade* (n 2). The other group of scholars supported a rather narrow interpretation of Article 34 TFEU.

267 The first attempt at an authoritative definition of the measures having equivalent effect to quantitative restrictions appears in March 1967, in response to the parliamentary questions asked by Mr. Deringer to the Commission. See: Mr. Deringer MEP, Written Question 118/1966, *Official Journal of the European Community*; and 64/1966, *Official Journal of the European Community*. Until 1967, the Commission tried to avoid the general definition of what type of state regulation can amount to measures equivalent to quantitative restrictions and rather confined itself in this field by issuing three directives concerning and addressing specific situations. The directives mentioned are Directive No. 641486 of July 28, 1964; Directive No. 661682 of November 7, 1966 (imports only allowed if an equivalent quantity of nationally produced goods is purchased); Directive No. 661683 of November 7, 1966 (obligation to include home-produced materials in products otherwise likely to be made entirely from imported goods).

268 *Dassonville* (n 264), para 5.

allowed for the technical barriers—one of the most pervasive impediments to free trade—to be captured within Article 34 TFEU.

However, at first glance, the national standards—the most common technical barriers—are beyond the reach of Article 34 TFEU, because of their private and voluntary nature.[269] Yet Article 34 TFEU can be used against de jure voluntary rules, if these rules are 'capable of influencing the conduct of traders and consumers in that State and thus of frustrating the aims of the Community.'[270] More problematic is the private nature of the bodies adopting standards, since Article 34 TFEU is addressed to and covers State measures. To address also the barriers created by private parties, the Court widened the concept of a State-public action.

For instance, in the *Buy Irish* case, the action of a private body—the Irish Goods Council—was deemed to be a public-like activity attributable to a State, because the State defined the policy objectives of the council, largely financed its activities and appointed the members of the management committee.[271] By extending the concept of a State action, Article 34 TFEU can be used against the private measures when 'state involvement' is evident.[272]

The voluntary standard was found to constitute a State measure falling under the scope of Article 34 TFEU in *Commission v Belgium*.[273] Here, the Court qualified a standard as a State measure, because the Belge de Normalisation—an organisation adopting a standard—was a public body.[274] Recently, even the

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[269] According to the Commission, the only solution to technical barriers stemming from national standards was a European standard. 'Only European standards will bring about a common economic area. National standards on the contrary compartmentalise the common market. They cannot be the subject of mutual recognition, since, not laid down by authorities, they are not obligatory'. See: Commission Green Paper, Action for Faster Technological Integration in Europe, COM (1990) 456 final (OJ 1990 C 20, para 1, 3). See also Schepel, *The Constitution of Private Governance* (n 111), 51.

[270] Case 249/81, *Commission v Ireland* ECLI:EU:C:1982:402, para 28. See also: Case C-470/03, *A.G.M.-COS.MET Srl v Suomen valtio* ECLI:EU:C:2007:213. In the latter case, non-binding statements of the officials regarding the non-compliance of goods (lifts) with a harmonised standard were considered to be a restriction to the free movement of goods.

[271] *Commission v Ireland* (n 270), para 15.

[272] Schepel, *The Constitution of Private Governance* (n 111), 43.

[273] C-227/06 *Commission v Belgium*, EU:C:2008:160, available only in French. Hence, the summary of this case was found in J. Hettne, 'Standards, Barriers to Trade and EU Internal Market Rules, the Need for a Renewed Approach' (2017) 44 (4) *Legal Issues of Economic Integration* 409.

[274] Ibid.

actions of a private standardisation and certification body were covered by the free movement rules in the *Fra.bo* case.[275]

The Court secured free movement of goods even in cases of barriers stemming from the voluntary standards. Such an approach was mainly based on identifying certain elements, i.e. State involvement, or the public nature of a body developing standards, to extend the reach of Article 34 to voluntary standards. However, Article 36 TFEU can still impinge on the free movement of goods. This is the case since the Member States retain the right to justify the measures falling under Article 34 TFEU by relying on the objective justifications enshrined in Article 36 TFEU and the mandatory requirements established by the *Cassis* case.[276] As such, Member States can adopt stricter health, safety, consumer and environmental protection regulations that may impede the free movement of goods. Objective justification and mandatory requirements thus limit negative integration. This highlights the fact that negative integration cannot replace legislative harmonisation. And the latter is the only solution for overcoming the limits of negative integration.[277] Therefore, it was not surprising that the positive harmonisation exercised through the New Approach covered exactly these fields—namely, the protection of health, safety and the environment.

In addition to the wide exploitation of Article 34 TFEU, the Court introduced the principle of mutual recognition in the *Cassis* judgment. This principle had a significant effect on easing the burden of legislative harmonisation. The *Cassis* case concerned the prohibition of the marketing of an alcoholic beverage on the German market. Due to its low alcohol content, the product was not classified as an alcoholic beverage according to German law. However, the product was already legally marketed in its country of origin, France. In response, the Court ruled that

> There is no valid reason why, provided that they have been lawfully produced and marketed in one of the member states, alcoholic beverages should not be introduced into any other member state.[278]

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[275] Case *Fra.bo* (n 60). For the detailed analysis of this case, see Chapter 6 of this thesis.

[276] Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* (also known as *Cassis de Dijon*), ECLI:EU:C:1979:42, para 8.

[277] N. Burrows, 'Harmonisation of Technical Standards: Reculer Pour Mieux Sauter?' (1990) 53 (5) *Modern Law Review* 597, at 600.

[278] *Cassis de Dijon* (n 276), para 14.

The principle of mutual recognition was deduced from the above-cited paragraph of the *Cassis* case. This principle has been widely exploited by the Union. The Commission referred to this principle in its communication as a follow-up to its Action Plan for the Single Market and emphasised its significance for the European single market.[279] According to the Commission, the benefit of mutual recognition is that 'it allows free movement of goods and services without the need for harmonisation of national legislation at the Community level.'[280]

Despite the fact that the Commission had issued several non-binding communications on the principle of mutual recognition, with very detailed recommendations, survey after survey confirmed that the principle of mutual recognition was not successfully implemented. Economic operators still faced problems obtaining recognition in marketing goods in other Member States.[281] Nonetheless, mutual recognition was important for establishing the free movement of goods. It also shifted the burden of proof to Member States, making them responsible for justifying the trade-restricting measures. In this way, the Commission sought to avoid disguised protectionism.

The mutual recognition principle is closely connected to the principle of origin, according to which Member States allow on their market products that are lawfully produced and marketed in another State. However, a Member State can still restrict or prohibit lawfully marketed products based on the rule of reason—that is, to protect health, safety and/or the environment, and to ensure consumer protection. When the principle of mutual recognition is engaged, it means that the principle of origin is coupled with the rule of equivalence. The ECJ verifies whether the regulatory objectives in the origin and destination countries are similar. If this is the case, the products lawfully produced and marketed in an originating Member State ('origin principle') must be freely allowed in other Member States.

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[279] Action Plan for the Single Market, SEC (97) 1 final; Commission communication of 16 June 1999 on mutual recognition in the context of the follow-up to the Action Plan for the Single Market, COM (1999) 299 final, para 4.

[280] Ibid, para 3.

[281] See for instance Commission report of 23 July 2002 on the application of the principle of mutual recognition in the single market, COM (2002) 419 final. It has confirmed that around 35% of economic operators reported problems with mutual recognition.

The classical case illustrating limitations to the principle of mutual recognition is the *Woodworking Machines* case.[282] Here, the ECJ assessed in detail the equivalence of legislative requirements in France and Germany and concluded that the lack of equivalence ruled out the duty of mutual recognition.

The crucial point in this judgment was its identifying a difference in focus between French and German legislation. The former, requiring the users of machines to be protected from their own mistakes, preferred complete automation of dangerous apparatuses, whereas the latter focused on the appropriate training of workers (users), making them capable of responding to the malfunctioning of the machines. Hence, it was difficult to guarantee the same level of protection when two systems, with fundamentally different approaches to safety, were coupled.[283] For instance, when German machines designed for skilled workers were imported into France, adequate safety protection could not be guaranteed. French workers without sufficient training would expect to be safeguarded from the consequences of their own mistakes by the completely automatised apparatus. The difference lay not in the safety level as such, but in the means by which safety was to be achieved.

This case also shows that successful application of the principle of mutual recognition requires a thorough investigation in each and every case in order to establish the equivalence between two regulatory approaches. Moreover, it also illustrates the limits of mutual recognition. The principle of mutual recognition cannot cope with situations in which regulatory convergence is impossible. This means that mutual recognition cannot replace positive integration. On the contrary, the limits of mutual recognition can only be addressed effectively through harmonisation of national legislations.

To sum up, the rules on the free movement of goods were exploited to make up for the difficulties that the positive harmonisation encountered in the process of tackling technical barriers. The extensive use of Article 34 TFEU against technical barriers indeed stretched the reach of negative integration to include national standards too. In addition, the Court's case law has discharged the regulatory burden by introducing the rule of mutual recognition and demonstrated the need for harmonisation when regulatory measures do not converge.[284] However, even extensive application of the rules on free

[282] Case 188/84 *Commission v French Republic* (Type of approval for woodworking machines), ECLI:EU:C:1986:43.

[283] Ibid, paras 17–22.

[284] Egan, *Constructing a European Market* (n 29).

movement of goods cannot entirely replace positive integration, since under certain circumstances Article 36 TFEU enables Member States to justify measures barring trade. Hence, the introduction of a harmonisation strategy that would reconcile the aims of free trade and the imperatives of regulation stemming from health, safety, and environmental considerations was unavoidable. In short, the successful removal of trade barriers requires a combination of the following approaches: harmonisation; mutual recognition; and standardisation.

3.3. Positive Integration through Standards and Standardisation Bodies

The removal of technical barriers has been incremental due to the slow process of legislative harmonisation and the case-by-case rulings from the Court on the conformity of national technical regulations and standards to free movement rules.[285] To aid this process the so-called 'Information Directive' was adopted. This directive required, primarily Member States, to notify to the Commission drafts of prospective technical regulation and motivate the need for it. In addition, it established an information system for technical standards adopted by standardisation bodies. This marked the beginning of the involvement of private standardisation-organisations in the process of technical harmonisation. Moreover, this Directive paved the way for the New Approach that enabled the use of European standardisation in support of EU legislation and policies.

The Commission's White Paper, issued in 1985, proposed a new legislative technique for technical harmonisation based on mutual recognition. According to this suggestion, mutual recognition was to be employed instead of legislative harmonisation, where appropriate.[286] But when legislative harmonisation was required, it covered only the essential requirements on a given product, while adoption of Union-wide technical standards was left to the ESOs.[287] This strategy was called the New Approach to technical harmonisation and standardisation.

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[285] Bermann, 'The Single European Act' (n 249), 529.

[286] The Commission, White Paper of 14 June 1985 on completing the internal market (also known as Cockfield reform), COM (85) 310 final.

[287] Ibid.

In light of the above, this section explains the positive harmonisation exercised in cooperation with the ESOs. Firstly, the mechanism of notification of technical regulations and standards is presented. Secondly, the New Approach is outlined. The latter strategy established the method of using standards for legislative purposes, and by so doing enabled technical harmonisation through standards and ESOs.

3.3.1. Information Flow on Technical Regulations and Standards

In 1965, the Commission issued a recommendation requiring Member States to provide prior notification of any new national technical regulation.[288] The notification system on technical regulations was formalised by Directive 83/189. This Directive created a procedure for preventing technical barriers in the internal market. Later, Directive 98/34 was adopted, which consolidated and replaced the earlier version of the information directive. To prevent the emergence of technical barriers, Directive 98/34 established a system of exchange of information on technical regulations and standards through public and private channels. The technical regulations adopted by national authorities are notified through the public channel. The private side of notification concerns technical standards drawn up by the national standardisation bodies. By establishing a network of communication among the standardisation bodies, Directive 98/34 expanded regulatory reach and involved private organisations in the process of completing the internal market.[289] Moreover, the flow of information on technical standards aids the legislative harmonisation by enabling the Commission to deliberate upon the need for an HES.

Directive 98/34 required the notification of technical specifications which lay down the various characteristics of products as well as the method and process of production.[290] The technical specifications come in two main forms: technical regulations and standards. The former is mandatory (de jure or de facto) and the latter voluntary, approved by a recognised standard-setting body.[291] Consequently, the obligation to notify the Commission of new

[288] See: Falke and Joerges, 'The Traditional Law Approximation Policy' (n 246).

[289] European Parliament and Council Directive 98/34/EC of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations [1998] OJ L 204/37, Article 2.

[290] Ibid.

[291] Ibid, Article 1.

technical regulations lies with the Member States,[292] while information on national standards is exchanged through the network of the ESOs.

The legislative framework has recently separated the technical regulations and standards and the information exchange about them. Regulation 1025/2012, which provides the formalised legal framework for European standardisation, also incorporates the rules on information exchange on technical standards through private channels. The New Directive—Directive 2015/1535, which has amended and codified the previous Directive 98/34—governs only the procedure for the provision of information on technical regulations.

Below, the public and private sides of the notification procedure are outlined in light of Directive 2015/1535 and Regulation 1025/2012. This is done so as to demonstrate how the information exchange enables the prevention of technical barriers, prompts spontaneous harmonisation and involves the standardisation bodies in the process of tackling technical barriers.

3.3.1.1. The Public Side of Notification: Technical Regulations

Directive 2015/1535 lays down the rules concerning notification of technical regulations.[293] The Member States are obliged to notify the Commission of technical rules that have to be complied with even de facto. This includes technical specifications, which are thereby made more binding than they otherwise would be, given their private origin.[294] Member States are also required to inform the Commission about all requests made to NSBs to draw up technical standards to be used for enacting technical regulations.[295] In a nutshell, a Member State, which prepares the draft of a technical regulation, needs first to notify the Commission of its intention to adopt a technical regulation and await a reply from the Commission before it can enact the

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[292] Case C-267/03, *Lindberg,* ECLI:EU:C:2005:246. This case lists types of technical rules that should be notified by Member States.

[293] According to the ECJ, the concept of a technical regulation encompasses 'four categories of measures, namely (i) the "technical specification", within the meaning of Article 1(3) of Directive 98/34, (ii) "other requirements", as defined in Article 1(4) of that directive, (iii) the "rule on services", covered in Article 1(5) of that directive, and (iv) the "laws, regulations or administrative provisions of Member States prohibiting the manufacture, importation, marketing or use of a product or prohibiting the provision or use of a service, or establishment as a service provider", under Article 1(11) of that directive (judgment of 4 February 2016, *Ince*, C-336/14, EU:C:2016:72, paragraph 70).' See: Case C-144/16, *Município de Palmela*, ECLI:EU:C:2017:76, para 25.

[294] Directive (EU) 2015/1535 (n 153), Recital 12.

[295] Ibid, Article 4.

regulation.[296] The Commission, on its part, forwards the draft to the other Member States.[297] The usual standstill period lasts up to three months.[298] However, it may be extended depending on the reception of the notification. If the Commission is willing to take harmonisation action in the concerned area, the standstill period can be extended up to 12 months.[299] It is important that notification takes place at the draft stage of the technical regulation.[300] This allows modification of the technical regulation if it is seen to create a technical barrier.

The Directive is silent on the consequences of the failure of notification. The principal mechanism to induce Member States to obey the notification obligation is the 'threat' of the infringement procedure.[301] However, the procedure is very slow, and the effectiveness of the Directive cannot be left solely to the incentives created by infringement procedure. Thus, the Commission stipulated that non-notified regulation would be unenforceable against third parties.[302] Moreover, the Court supported this view in its prominent judgment in the *CIA* case, where regulation of which the Commission had not been notified was deemed inapplicable in the dispute.[303] Consequently, CIA's competitors were unable to rely on and invoke non-notified technical regulation against CIA.

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[296] For a detailed review of notification Directive, though the older version, Directive 98/34, see: K. Engsig Sorensen, 'Non-Harmonized Technical Regulations and the Free Movement of Goods' (2012) 23 (2) *European Business Law Review* 163.

[297] Directive 2015/1535 (n 153), Article 5(1).

[298] Ibid, Article 6(1).

[299] Ibid, Article 6(3). For detailed information on the standstill period depending on the outcome of notification, see: Article 6 of the Directive 2015/1535.

[300] The Commission will not accept the notification of the adopted technical regulation, see: Danish Enterprise and Construction Authority, 'The Guidelines on the Notification Procedure', 7 April 2010, para 8 <http://www.ebst.dk/notifi> accessed 15 April 2015; Modification of the technical regulation requires re-notification: Case C-273/94 *Commission v The Netherlands,* ECLI:EU:C:1996:4; See also: Case C-33/97, *Colim,* ECLI:EU:C:1999:274, para 22.

[301] See the cases based on the infringement of the notification obligation: Case C-139/92 *Commission v Italy* ECLI:EU:C:1993:346; Case C-52/93 *Commission v Netherlands* ECLI:EU:C:1994:301.

[302] See in this regard: C. Barnard, *The Substantive Law of the EU* (3rd edn, Oxford University Press 2010), 112.

[303] Case C-194/94, *CIA*, ECLI:EU:C:1996:172.

In Unilever,[304] the ECJ developed the reasoning used in *CIA* to make clear that technical regulation is inapplicable in the legal relationship between two private parties even if a State notified it to the Commission but adopted without waiting for the Commission's reply within the standstill period.[305]

This broad reach has, to some extent, been circumscribed by the Lemmens case.[306] In the latter, the Court clarified that non-notification makes technical regulation inapplicable only in cases where it hinders the marketing of a product incompliant with such a technical regulation, but does not make any use of a product compliant with non-notified regulation unlawful. This stems from the aim of the Directive to ensure the free movement of goods and avoid technical barriers. Thus, it is only in this context that the non-notified regulation is unlawful.

3.3.1.2. The Private Side of Notification: The Network of Standardisation Bodies

Despite the fact that standards are 'voluntary' technical specifications, in practice they may have the same effects on the free movement of goods as technical regulations. This reasoning led to the introduction of the private side of notification.

The obligations to ensure the flow of information on standards among national and European standards bodies are set in Regulation 1025/2012, under the section on transparency of the work programmes of standardisation bodies. According to this Regulation, standards bodies, both European and national ones, have the duty to inform the Commission and other standards bodies about the existence of an annual work programme. The latter should be published on the website of the relevant standardisation body.[307] This guarantees the intentional 'leakage' of information and distribution thereof among the standards bodies throughout EU. The information received from the NSBs provides a sound basis for drawing up a Commission's mandate and requesting the adoption of an HES.

Besides this, the European and national standards bodies are required to send at least electronic versions of drafts of standards to the other standard-setting

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304 Case C-443/98, *Unilever Italia,* ECLI:EU:C:2000:496.

305 Ibid.

306 Case C-226/97, *Criminal proceedings against Johannes Martinus Lemmens*, ECLI:EU:C:1998:296.

307 Regulation 1025/2012 (EU) (n 14), Article 3.

bodies and the Commission, upon request.[308] Subsequently, comments on the draft are to be provided to the initial standard-setting body within three months. If the national body receives comments suggesting that the proposed standard might have an adverse effect on the internal market, then the standards body is expected to consult with the Commission and the ESOs.[309]

Moreover, the national standards bodies are under the obligation not to object to a subject for standardisation in their work programme, being considered at the European level, and may not undertake any actions which could prejudice a decision in this regard.[310] In addition, the national standards bodies may not take any steps to impede the adoption of standards at the EU level. The national standards bodies have a duty not to introduce new standards that are incompatible with the HESs and to recall all standards contradicting the existing HESs.[311]

This means that in standardisation matters, the European and national standards bodies enjoy shared competence. When an ESO adopts a standard, this automatically removes competence from national standards bodies to adopt a standard. National standard-setting bodies are expected to transfer their competence to the ESOs in favour of adopting European standards after the Commission has decided to issue a mandate, or after an ESO has decided to adopt a European standard.

However, neither Directive 2015/1535 nor Regulation 1025/2012 specify what consequences can be expected for those who flout the transparency obligation or infringe on the standstill period. But it is possible to argue that a national standard that contradicts an HES may be caught under Article 34 TFEU. This is because the national standards bodies are the direct addressees of the standstill obligation laid down in Regulation 1025/2012. And according to the *Fra.bo* case, Article 34 TFEU can cover the activities of national standardisation bodies.

To sum up, the notification system operating through both public and private channels is crucial for preventing technical barriers stemming from either State measures (i.e. technical regulations) or private standard bodies (i.e. standards). Moreover, the notification system not only prevents technical barriers, but also

[308] Ibid, Article 5(2).

[309] Ibid, Article 5(3).

[310] Ibid, Article 3(5).

[311] Ibid, Article 3(6).

enables the flow of information about technical standards and allows spontaneous harmonisation.

3.3.2. The New Approach: Harmonised European Standards-a Tool for Market Integration

The New Approach strategy introduced an innovative way of harmonising technical requirements and marked a 'new dynamic' of European integration.[312] In particular, it provided the system under which legal requirements and private rules-standards are coupled. Interestingly, the New Approach was not really new at the time when it was officially introduced. Still, the term 'new' will perhaps always remain as an appropriate part of this strategy's name, indicating as it does a shift from the traditional type of legislative harmonisation.[313]

In 1968, the European Parliament[314] and the Economic and Social Committee[315] recommended reference to standards as an alternative to the 'traditional method of approximation of laws.'[316] The regulatory burden was shifted from the public to the private sector already by the adoption of the 1973 Low Voltage Directive,[317] which introduced reference to the technical standards in the legislative material.[318]

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[312] See: C. Joerges, 'What is Left of the European Economic Constitution: A Melancholic Eulogy' (2005) 30 *European Law Review* 461.

[313] According to AG Sharpston, the New Approach found its origin in the *Cassis de Dijon* case. Meaning that mandatory requirements provided by *Cassis* opened the possibility to reflect on the better strategy for the free movement of goods which would abide with free movement provisions and at the same time ensure the safety of products. See: Opinion of AG Sharpston in Case C-219/15 *Schmitt* ECLI:EU:C:2016:694, para 24.

[314] OJ C 108, 19 October 1968, 39 et seq.

[315] OJ C 132, 6 December 1968, 1, 4 et seq.

[316] The Economic and Social Committee: 'Thus, it would be conceivable for the Community directives first to list the safety objectives to be secured, and then to indicate that these would be taken as achieved as long as a particular standard, initially harmonised at the level of the member states is complied with. This would give a chance to bring proof that the safety objectives have been met even without compliance with the standard concerned.'

[317] Council Directive 73/23/EC of 19 February 1973 on the harmonisation of the laws of member states relating to electrical equipment designed for use within certain voltage [1973], OJ L 77/29.

[318] The Electrical standardisation held a very autonomous position in standardisation as a whole; Directive 73/23/EEC applied to all electrical equipment with a particular voltage level. The most interesting parts of this Directive for the purposes of our discussion are Articles 5 and

Under the New Approach strategy, the tasks of the EU legislator and the ESOs are distinguished. The former adopts essential requirements that are enshrined in a directive, while the latter writes standards that provide the technical ways of compliance with essential requirements.[319] Moreover, the Commission publishes the reference to the HES in an official journal and by so doing entangles the standards with EU law.

By establishing a Europe-wide level of safety, health and environmental protection, the New Approach reaches areas where the Member States usually derogated from the free movement rules. It also enables a rather fast process of harmonisation compared to the time-consuming political wrangling on various technical specifications. According to the European Parliament

> standardisation can constitute an effective, generally acceptable and readily adaptable supplement to legislation, and can in some cases, if given a clear legal framework, provide an alternative to binding rules and regulations.[320]

The Council resolution of 7 May 1985 officially introduced the New Approach and provided the general framework for it.[321] In 2008, the New Approach strategy was updated with a new legislative framework[322] and with the 2012

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6 laying down the ways to meet the safety requirement, suggesting that electrical products meet safety objectives when they comply with the harmonised standards i.e. produced by CENELEC or when the harmonised standards have not been drawn up yet, then with the safety provisions of the International Commission on the Rules for the approval of Electrical Equipment (CEE) or of the International Electrotechnical Commission (IEC). Where no harmonised and international standards exist, the product satisfies the safety requirements if it has been manufactured in accordance with the safety provisions of the manufacturer's state of origin, if it ensures safety required in the country of destination. For more detailed analysis of this Directive, see: J. Falke and C. Joerges, 'The New Approach to Technical Harmonisation and Standards, its Preparation through ECJ Case Law on Articles 30, 36 EEC and the Low-Voltage Directive, and the Clarification of its Operating Environment by the Single European Act' (2010) 6 *Hanse Law Review* 249.

319 For more detailed analysis of the New Approach see: Pelkmans, 'The New Approach to Technical Harmonisation' (n 15).

320 Preamble to Resolution on the Commission report on Efficiency and Accountability in European Standardisation under the New Approach (COM 98) 291 final.

321 Council Resolution 85/C 136/01 (n 14).

322 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, 13 August 2013, 21 et seq.; Regulation No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (n 54), 30 et seq. and Decision 768/2008/EC on a 'Common Framework for the Marketing of Products' (n 54), 82 et seq.

Regulation on European standardisation. The main aim of this new legislative framework was to bring harmonisation legislation in line with the procedure for the use of standards set out in decision 768/2008.[323] Regulation 764/2008 in its turn laid down the provisions concerning accreditation and market surveillance of the products and prescribed the procedures for applying certain national technical rules to the products marketed in another EU country. This New Legislative framework updates and systematises New Approach directives by laying down a common procedure for the marketing of products. In addition, Regulation 1025/2012 on European Standardisation presents adapted and consolidated legal framework for standardisation that lays down the rules for the mandating of European standards, financing standardisation activities and core principles governing the standardisation process. Nonetheless, despite the new legal framework concerning standardisation and the use of standards in legislation, the operating principles of the New Approach remained intact and they are described below.

3.4. Operating Principles of the New Approach

One of the essential features of the New Approach is that it enables harmonisation of entire sectors as opposed to mere product-to-product harmonisation. As a result, by 1992, the Council had already put in place regulatory frameworks for whole industry sectors and had adopted directives on toys,[324] construction products,[325] radio equipment,[326] and electromagnetic compatibility.[327] Later on, the regime was expanded to cover products such as

[323] It is important to mention that this decision is just a political commitment since it does not have addressees. Hence, it means that in order for this decision to apply, it should be referred to and integrated in the future legislation.

[324] Directive 2009/48/EC [2009] OJ L 170/1 which replaced Directive 88/378/EEC [1988] OJ l 187/1.

[325] Directive 89/106/EEC [1989] OJ L 40/12.

[326] Directive 2014/53/EU [2014] OJ L 153/62 revising Directive 1999/5/EC [1999] OJ L 91/10.

[327] Directive 2014/30/EU [2014] OJ L 96/79 repealing Directive 89/336/EEC [1989] OJ L 139/19.

water boilers,[328] explosives,[329] pressure equipment,[330] medical devices,[331] among others.

The successful operation of the New Approach rests on the observance of the operating principles provided in the so-called Model Directive.[332] These operating principles are: a) separation between the legislative requirements—so-called 'essential requirements'—and standards. The former should be clear enough to allow transposition into national laws and to create legally binding obligations;[333] b) the ESOs draw up standards pursuant to the Commission's mandate, which guarantee the quality of those standards;[334] and c) technical standards must remain voluntary.[335] However, the Member States are obliged to recognise products manufactured according to those standards as being in compliance with essential requirements. These principles are addressed more closely below, since they comprise the spine of the New Approach strategy.

[328] Directive 92/42/EEC [1992] OJ L 167/17.

[329] Directive 2014/28/EU [2014] OJ L 96/1 revising Directive 93/15/EEC explosive for civil uses [1993] OJ L121/20.

[330] Directive 97/23/EC [1997)] OJ L 181/1.

[331] Directive 93/42/EEC on medical devices [993] OJ L 169/1. The latter Directive has gone under several modifications such as Directive 2000/70/EC[2000] OJ L 313/22 amending Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma; Directive 2001/104/EC [2001] OJ L 6/50 amending medical devices directive. In 2012, the Commission adopted a package consisting of a communication and two Regulation proposals to revise existing legislation on general medical devices and *in vitro* diagnostic medical devices. On 5 April, two new Regulations on medical devices were adopted, which replaced the previous Directives. These two Regulations are: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. For more information on this see: <http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision/index_en.htm>

[332] Council Resolution 85/C 136/01 (n 14), Annex II: so-called Model Directive.

[333] Model Directive (Ibid), part III.

[334] Ibid.

[335] Ibid.

3.4.1. Self-Standing Essential Requirements

If the basic characteristics of the New Approach had to be summed up in a single sentence, we could say that it conveys the ambition to separate the tasks of Union institutions and the ESOs—in effect, the separation between law and technology.[336] Consequently, the legality of the New Approach strategy has long rested on the 'self-standing' of essential requirements. Hence, the Model Directive urges that the essential requirements should be formulated in such a way as to enable the certification bodies to certify products straight away. Moreover, it is these essential requirements which, after transposition into national law, should create enforceable, legally binding obligations.[337]

This requirement was strictly observed in the first directive(s) submitted under the New Approach. For instance, the directive for simple pressure vessels[338] can be praised for the precision of its essential safety requirements. Annex I to the Directive lays down in detail the characteristics of the materials to be used.[339] Further binding provisions deal with design, manufacturing procedures and requirements for commissioning the vessels. The explanatory statement to that draft directive required that the bodies of the community decided aspects of safety. Otherwise, they would inevitably reappear at the level of European standardisation bodies.[340] However, soon after the introduction of the successful pressure vessels directive, concerns were raised regarding the imprecision of essential requirements.

Although the Model Directive sought a clear separation of the tasks for maintaining standards at the voluntary level, it was not possible to implement this requirement entirely in practice. The 'independence' of legal requirements is unavoidably and inherently unstable. As Previdi states:

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[336] See: F. Nicolas and J. Repussard, *Common Standards for Enterprises* (Office for Official Publications of the European Communities 1988). See also Commission Report, Efficiency and Accountability in European Standardisation under the New Approach, COM (1998) 291, final 3. (The policy objectives of the free movement of goods should not be delegated to the voluntary standardisation).

[337] Model Directive (n 332), part III: essential requirements.

[338] Council Directive 76/767/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to common provisions for pressure vessels and methods of inspecting them [1976] OJ L 262.

[339] See the explanatory statement to the 'proposal for a Council directive harmonizing the legal provisions of member states for simple pressure vessels', COM (86) 112 final of 14 March 1986, 9.

[340] Cited in Falke and Joerges, 'The New Approach to Technical Harmonisation' (n 317).

> No other feature of the New Approach resolution was to raise such debate and opposition as this requisite which the legislator has to meet when formulating the essential requirements.[341]

He argues that most of the essential requirements included in the directives adopted under the New Approach are so general that it is impossible to address a technical risk without the support of 'voluntary' technical standards. The exception from this spill-over effect is the above-mentioned directive on pressure vessels.

There are two primary concerns attached to the lack of 'self-standing' of the essential requirements. Firstly, it poses a threat to the public interest by deregulating and privatising especially sensitive areas such as health and safety. Secondly, if technical standards are to remain voluntary, then there ought to be a clear separation between technical standards and essential requirements. It is precisely the spill-over between technical standards and essential requirements that raises legal concerns over the use of HESs as regulatory tools.

3.4.2. The Voluntary Status of Standards and Types of Referencing

The Model Directive explicitly states that 'technical specifications are not mandatory, and they maintain their status of voluntary standards.'[342] At first sight, this is not a controversial issue since standards adopted by standard-setting organisations are voluntary technical specifications and do not have mandatory legal status. Moreover, there is a clear distinction between the standards and the acts ratifying them.[343] It is only the legal framework and documents referring to standards that grant legal significance to standards or even make them compulsory. Maintaining the voluntary nature of standards is important, since it rules out the constitutional law concerns related to the delegation of rule-making tasks to private standards bodies.

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[341] E. Previdi, 'The Organisation of Public and Private Responsibilities in European Risk Regulation: An Institutional Gap between them', in C. Joerges, K.-H. Ladeur, and E. Vos (eds), *Integrating Scientific Expertise into Regulatory Decision-Making: National Traditions and European Innovations* (Nomos Verlagsgesellschaft 1997), 228.

[342] Model Directive (n 332).

[343] H. Schepel and J. Falke, *Legal Aspects of Standardisation in the Member States of the EC and EFTA* (Office for Official Publications of the European Communities 2000), 170.

The techniques of referencing standards in the legislative material differ and the constitutional law concerns with using standards in a legislative piece vary accordingly. The standards can be referred to in the legislation by using rigid, sliding or general references.

When a legislative rule absorbs the content of a given technical standard without incorporating later amendments to standards, it is a rigid reference. Whereas, a sliding reference enables use of the technical standards in such a way that all the amendments to the standards are incorporated and applicable de jure in the legislation. Finally, by way of the general reference, the legislative act refers in general to all the standards—present or future—in the area.[344]

The rigid reference to standards existed in EU law before the New Approach. It is less problematic since the text of the standard is absorbed in the legislation and goes through the whole legislative procedure. Therefore, the concerns regarding the delegation of rule-making powers in this case naturally do not arise.

However, the New Approach introduced and employs both general and sliding reference strategies.[345] It is exactly these types of references that raise constitutional law concerns about delegation, since the legislator does not have control over the content of standards and the latter does not go through the legislative procedure. Nonetheless, the benefits of sliding reference are clear. The latest technical solutions can meet the essential requirements without there being a need to make changes in the legislation each time standards are modified or recalled.

[344] See: C. Daelemans, 'The Legitimacy and Quality of European Standards', in C. Joerges, K.-H. Lauder, and E. Vos (eds), *Integrating Scientific Expertise in Regulatory Decision-Making* (Nomos Verlagsgesellschaft 1997). On the different style of referencing standards in law and acquiring legal relevance see: Slot, *Technical and Administrative Obstacles to Trade in the EEC* (n 2), 27–31.

[345] On different tactics of referencing standards in legislation see: Joint practical guide of the European Parliament, the Council and the Commission for persons involved in the Drafting of European Union legislation, Guide 16, point 17.

3.4.3. Early days of cooperation between the European Standards Organisations and the Commission

The empowering of the ESOs to draft HESs took place outside the institutional framework established by the EU treaties and was based on a contract.[346] Prior to the New Approach, the Commission was required to issue a call for tender and request the development of a European standard. If an ESO would agree to take on the task, a contract was negotiated between the Commission and the standard-setting body.[347]

In 1984, the Commission and the ESOs agreed on the general guidelines of cooperation, laying down the four main elements:

a The Commission recognises CEN/CENELEC as competent standard-setting bodies, orders the standards from these organisations and consequently provides the financial support.

b CEN/CENELEC for their part guarantee the observance of safety requirements specified in European Directives and the Commissions' mandates for standards.

c Cooperation between them starts from the preparatory stage of the Directives. The Commission representatives are allowed to take part in a meeting of the technical boards and technical committees of standardisation organisations.

d CEN and CENELEC guarantee that interested circles, in particular government authorities, users, consumers, and industries, will be involved in the development of European standards.

Regulation 1025/2012 maintains these elements to guide cooperation between the Commission and the ESOs; in addition, the Regulation provides a more detailed system for mandating standards, which is explained in the next chapter. Furthermore, the Regulation spells out the procedure for observing the protection of the financial interests of the Union, when the standardisation activities are financed. The Union finances only those standardisation activities which support Union legislation and policies.[348]

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[346] See: J. Repussard, 'Comments', in *The New Approach* (CEN 1994).

[347] According to Egan, 'The Commission closely monitored the operation of European Standard Setting Organisations to ensure that they meet the European regulatory objectives'. See: M. Egan, 'Regulatory Strategies, Delegation and European Market Integration'(1998) 5 (3) *Journal of European Public Policy* 485.

[348] Regulation 125/2012 (EU) (n 14), Article 15. The latter Article lists in detail the European standardisation activities that are financed by the Union. Also, the national standardisation bodies and other bodies can get financing from the Union if they undertake standardisation

3.4.4. Commission's Mandates and the Publication of References to Harmonised European Standards

The mandate marks the beginning of the cooperation between the Commission and the ESOs. It is an important document since it details the request for the adoption of European standards. The Model Directive identified the 'standardisation mandate' as the document that 'ensures the quality'[349] of the HESs. The New Approach directives were ambiguous on the nature of this document, and the term used to refer to the Commission's request to standard-setting organisations varies. It is called variously a 'request',[350] a 'remit',[351] and an 'instigation'.[352]

According to Regulation 1025/2012, the Commission, within the limitations of the competencies laid down in the treaties, requests the ESOs to draft a European standard within a set deadline. Before submitting the request, the Commission is obliged to consult ESOs, European stakeholder organisations receiving Union financing, as well as the committee formed by the corresponding Union regulation, when such a committee exists, or after other forms of consultation with sectoral experts.[353]

The mandate must include the detailed elaboration of essential requirements, which has to be technically realised by the standard. The relevant European standardisation organisation must decide within one month of receipt if it accepts the request from the Commission.

When a harmonised standard satisfies the requirements set out in the corresponding Union harmonisation legislation, the Commission publishes a reference to the HES in the official journal.[354] It was the Low Voltage Directive

activities listed in Article 15 and in cooperation with the European standardisation organisations.

349 Model Directive (n 332).

350 Directive 97/23/EC [1997] OJ L 181/1, Recital 17.

351 See: Directive 98/37/EC of 22 June 1998 on the approximation of the laws of Member States relating to machinery [1998] OJ L 207/1, Recital 17; Directive 2006/42/EC of 17 May 2006 on machinery amending Directive 95/16/EC [2006] OJ L 157/24, Article 2(I).

352 Council Directive 89/686/EEC on the approximation of the laws of Member States relating to personal protective equipment [1989] OJ L 399/18, Recital 8. Although recent Regulation 21025/2012 (n 14) uses the term 'request', the term 'mandate' is still widely used in the Court's terminology, in the Commission's documents, and in the scholarship.

353 Regulation 1025/2012 (EU) (n 14), Article 10.

354 Ibid, Article 10(6).

that introduced a requirement to publish the reference in the official journal.[355] The publication has important legal consequence since the compliance with the HES can provide the presumption of conformity with the legislative requirements only after the reference to the HES is published in the official journal.[356] The publication of the reference to standards also creates an obligation for the Member State not to introduce any new requirements that are already covered by an HES.[357]

The publication of the reference, in its turn, raises further legal questions, such as whether the Commission takes responsibility for the quality of standards and is liable for any damages incurred by complying with an HES.[358] The legal aspects of the publication of the reference to standards do not end here. It also includes a debate on public access versus copyright protection of standards referenced in the legislation.[359]

3.4.5. Section Conclusion

The New Approach is commonly considered to be an important regulatory novelty that provides the basis for sharing the regulatory tasks between the EU institutions and private ESOs. Similar strategies, including the reference to standards in the legislative material, have been adopted in several Member States. In the 1970s and 1980s, France, Germany and the UK made use of the private sector to provide assistance with regulatory compliance.[360] In the UK, the government signed a memorandum of understanding with the British Standards Institute in 1982, granting the Institute the status of a national standard-setting body, responsible for providing assistance to the government in referencing standards in the legislation. In France, the standard-setting role

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355 Council Directive 73/23/EC (n 317), Article 5.

356 Member States cannot automatically rebut presumption of compliance, in case of suspicion concerning the standard and its compliance with essential requirements, but rather have to initiate a safeguard procedure. See: Case C-6/05 *Medipac-Kazantzidis AE v Venizeleio-Pananeio* (PE.S.Y. KRITIS) ECLI:EU:C:2007:337.

357 See: Case C-103/01, *Commission v Germany*, ECLI:EU:C:2003:301; ECLI:EU:C:2007:337. Though it could be argued that this judgment is limited to the construction products directive and that a similar obligation does not exist in the cases of other New Approach directives.

358 This issue arises especially in the product liability context. However, this is not the focus of the present work.

359 The issue of copyright on the HESs is discussed in Chapter 4.

360 Egan, *Constructing a European Market* (n 29).

of the Association Française de Normalisation (AFNOR) and standards set by the latter were enhanced in 1984.[361]

Even though these strategies at the national and European level are similar, the delegation of rule-making powers has different implications at the EU level. In the national system, each standard is locked under the hierarchical constitutional frame of law and regulation. To adopt a similar approach at the EU level would require the legal ratification of standards by the Commission, which would in turn require a regulatory-type committee procedure. This would remove all the benefits related to time-elasticity gained from the New Approach.[362] However, one could argue that the reference to standards in the official journal is itself a ratification of a standard by the Commission. This is because the Commission exercises 'significant control' over the HESs.[363] Moreover, the decision to publish, not to publish or publish with restrictions is preceded by the Commission's assessment of the HESs' compatibility with the mandate. The Commission also decides whether to maintain, maintain with restrictions or withdraw a reference to standards. These decisions are adopted by consulting the relevant standards committee.[364]

Although the New Approach was a smart regulatory strategy, the legal scholarship had expressed some concerns about the legality of using standards for legislative purposes. A summary of this debate is presented below.

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[361] A. Thiard, 'Worldwide Standards: The Only Way: AFNOR and International Standardisation' (1986) *ASTM Standardisation News* 34–7; J. Pelkmans and D. Costello, *Industrial Product Standards* (UNIDO Report 1991).

[362] Such a possibility under the New Approach was the subject of much discussion. The possibility that the Community would proceed along this path would mean that Committee procedure known as comitology would be used to check up on the implementing powers conferred to the Commission.

[363] AG in *James Elliott* (n 219), paras 46–93. The Court also stressed the fact that the Commission has a significant role in the process of adopting a harmonised European standard; Case C-613/14, *James Elliott* (n 60), paras 43–5.

[364] Regulation 1025/2012 (EU) (n 14), Article 22. The latter Article establishes the committee of standards. The committee of standards is a comitology committee within the meaning of Regulation (EU) No 182/2011.

3.5. New Approach: Triumph or 'Original Sin'?

Most of the legal concerns expressed regarding the New Approach strategy were already raised against the Low Voltage Directive.[365] This directive introduced, for the first time in EU legislative history, the tactic of referencing standards in the legislation. However, for some time, this technique has been regarded by government officials and the Commission as 'an original sin that ought not to be repeated.'[366] Despite the criticism, this 'original sin' would become well-established practice of the New Approach some ten years later.

One of the main concerns was that the 'essential requirements' laid down by the Directive were ambiguous and thus became 'practically applicable…only by actually adducing the standards.'[367] The legitimacy of such a solution was questioned, because the private standard-setting bodies decided the level of hazard to which the public could be exposed.[368] This criticism strikes at the heart of the unclear separation of the tasks between the legislator and private bodies, leaving considerable leeway for the ESOs.[369] The concerns were exacerbated by the fact that standard-setting bodies were made up mainly of representatives of business circles who were not legally accountable.[370]

The only solution has been to keep the standardisation system at 'arm's length from the legal system, and preferably a bit further.'[371] To achieve this, as already mentioned, the New Approach strategy insisted on the 'voluntary application' of the HESs. In other words, the legality of the New Approach Directives is sought to be maintained by the indicative references to standards. The compliance with the HESs is only one way of showing conformity to

365 Council Directive 73/23/EC (n 317).

366 See: Falke and Joerges, 'The New Approach to Technical Harmonisation' (n 317).

367 Ibid.

368 Ibid.

369 Ibid.

370 E. Röhling, *Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt* (Heymann 1972), 122–7, cited in Falke and Joerges, 'The New Approach to Technical Harmonisation' (n 317). The summary of Röhling's argument has been taken unmodified from above-mentioned work.

371 H. Schepel, 'The New Approach to the New Approach: The Juridification of Harmonised Standards in EU law' (2013) 12 (4) *Maastricht Journal of European and Comparative Law* 521, at 524.

'essential requirements': manufacturers and importers are free to demonstrate conformity by other means.[372]

However, it has been argued that standards are not simply specifications of goals set by legislative organs, but rather rules and goals in themselves. The 2001 General Product Safety Directive[373] can serve as an example in this regard. This directive provides only a very abstract definition of product safety, whose specification is left entirely to standards. In this case, standards even replace the politically agreed legislation.[374] However, the fact that the New Approach has persevered for over thirty years attests to its triumph and demonstrates that it is an 'accepted' 'original sin'.

3.5.1. The Constitutionality of Referencing Standards in the Legislation

German lawyers raised the point of the constitutionality of referencing standards in the legislation. As part of the debate, different types of referencing were distinguished, and their constitutionality analysed.[375]

As mentioned above, an undisputed version of the reference is a rigid reference, where the statutes or legislative acts refer clearly to a determined technical rule, by the date of publication. This type of reference is indisputable since it incorporates the technical rule in the text and does not raise questions concerning the delegation of rule-making power.

The sliding reference employed by the New Approach, or 'dynamic reference' as it is usually called, allows reference to the technical rules in their respective applicable version. In the case of the sliding reference, a legal text is maintained as a blanket law, and its content is supplied and modified from time to time by the private rule-makers, without any control by public authorities.

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372 See: Decision 768/2008 (n 322), Recital 11.

373 Directive 2001/95/EC on General Product Safety (n 18).

374 Ibid, Article 4(3). It reads as follows: 'A product shall be presumed safe as far as the risks and risk categories covered by relevant national standards are concerned when it conforms to voluntary national standards transposing European standards, the references of which have been published by the Commission in the *Official Journal of the European Communities* in accordance with Article 4. The member states shall publish the references of such national Standards'. See also Schiek, 'Private Rule-Making and European Governance-Issues of Legitimacy' (n 104).

375 A short summary of the German lawyers' main arguments on this matter is provided in Falke and Joerges, 'The New Approach to Technical Harmonisation' (n 317).

It has been argued that this type of reference is a hidden delegation of rule-making powers to private bodies, which violates the principles of democracy, the separation of powers, and the clarity and certainty of the law.[376]

The constitutional concerns surrounding standardisation do not arise merely on account of the referencing style or non-autonomous character of the essential requirement. Rather, there is a fundamental constitutional law concern about the apparent impossibility of separating public and private tasks, law and standards. The primary constitutional concern stems from the assumption that a standard fulfils a public function and therefore should be subject to public control. The argument is grounded in the theory of democratic or constitutional legitimacy.[377]

The problem of binding people by the rules and regulations, i.e. technical standards, which are issued by private associations is not a new one. The Kansas Supreme Court ruled on this matter already in 1919. It pronounced that the fallacy of the legislation, which refers to codes and technical rules adopted by private institutions, 'is so obvious that elaborate illustration or discussion of its infirmities is unnecessary.'[378] The judgment indicated the 'law's problem' with referencing standards in the legislation. However, one must keep in mind that the judgment was delivered a century ago. What was felt to be a fallacy by the Kansas Supreme Court a century ago and an original sin in Europe is now well-established practice in the EU.

3.5.2. Suggested Solutions

Different solutions were proposed in order to ensure the legitimacy of involving the ESOs in the regulation of the internal market. According to Schepel, these different suggestions are based on different conceptions of legitimacy. 'One sees the public interest necessarily embodied in public institutions; the other sees the public interest circumscribed by procedural

[376] Ibid.

[377] Joerges et al, 'The Law's Problem with the Involvement of Non-Governmental Actors in Europe's Legislative Process' (n 49).

[378] *State v Crawford* 177 P 360, 36 (Kan 1919). The case concerned the electronic wiring of the theatre, which was not done in accordance with Kansas Fire Prevention Act. The court stated: 'All electrical wiring shall be in accordance with the National Electrical Code (NEC)'. The NEC itself was a collection of standards promulgated by a private organisation. The case is found in Schepel, *The Constitution of Private Governance* (n 111), 1.

criteria of good governance.'[379] Consequently, two main streams of solutions were advocated: a) juridification of standardisation; and b) subjecting the process of standardisation to the constitutional principles.

Juridification of standardisation was considered to be a straightforward solution to resolve the constitutionality debate. Proponents of the 'extreme' level of juridification, like Previdi, advocated for transforming the ESOs into Union agencies and putting standards in the hierarchy of norms.[380] Bleckman shared this view, too. He also demanded complete subordination of European standardisation to the Union administrative lawmaking, and for this he advised the following:

- To create a legal obligation for the Commission to send representatives to meetings of committees of the standard-setting bodies; provide voting rights for those representatives, including a right of veto to block the adoption of a standard for the time it takes the Standard Committee to draw up essential requirements; and to ensure that the final decision of the Commission is open to judicial review.
- To adopt a Regulation establishing the procedures for standardisation; consequently, open the standard-setting bodies for judicial review.[381]

Even the European Parliament seemed to support this view by stating that it is 'necessary to continue working towards a proposal for a statute of a Community agency for the European standardisation bodies.'[382] The disadvantage of this type of solution is that the invigoration of regulation and elevation of the standard-setting bodies at the level of legislative assemblies will take away with one hand the benefits following the deregulation offered with the other.

At the forefront of the proponents of the second solution was Falke. He advocated a sort of middle way. Falke saw the solution in putting standardisation procedure on the 'rails' of constitutionality—in particular, subjecting the standard-setting procedure to the constitutional law requirements. To this end, he proposed that the standardisation process should adhere to the following conditions:

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379 Schepel, *The Constitution of Private Governance* (n 111).

380 Ibid.

381 Bleckmann, *Rechtsfolgeanalyse der Neuen Konzeption* (Münster 1995), found in Schepel, *The Constitution of Private Governance* (n 111).

382 Resolution on the Commission Communication (1996) OJ C 320/208, Recital 23.

- The technical specifications must satisfy essential requirements, must have no legally binding character whatsoever and must be regularly reviewed.
- The relevant expertise must be fully represented in the standardisation committees.
- The interested parties, in particular the public offices, industry, users, consumers, trade unions, environmental protection associations, and representatives of the European Commission, must be able to participate in the making of the technical specifications. The public is to be given the opportunity to express its opinion on the drafts.
- The Draft Standards and the outcome of the standardisation work must be easily accessible to all those parties who are interested.[383]

It is clear that the different solutions described above represent 'different conceptions of legitimacy',[384] meaning that the first sees legitimacy as locked in the hierarchical constitutional structure, whereas proponents of the second solution maintain legitimacy through an inclusive process of standard-setting. Hence, choosing one way of approaching the constitutional problems over the other entails a preference for a particular conception of legitimacy. There is an explicit need to make the standardisation process more open and transparent, to have some mechanisms of legal control over the Commission's implied decisions to publish HESs, and to have judicial review of the standardisation process.[385] The adoption of Regulation 1025/2012 on European standardisation marks an acknowledgement of these concerns and an attempt to juridify the standardisation process.

[383] Falke and Joerges, 'The New Approach to Technical Harmonisation' (n 317).

[384] Schepel, *The Constitution of Private Governance* (n 111).

[385] See: L. Senden, 'The Constitutional Fit of European Standardisation Put to the Test' (2017) 44 (4) *Legal Issues of Economic Integration* 337; M. Medzmariashvili, 'Delegation of Rulemaking Power to European Standards Organisations: Reconsidered' (2017) 44 (4) *Legal Issues of Economic Integration* 353; M. Eliantonio, 'Judicial Control of the EU Harmonized Standards: Entering a Black Hole?' (2017) 44 (4) *Legal Issues of Economic Integration* 395; C. Tovo, 'Judicial Review of Harmonized Standards: Changing the Paradigms of Legality and Legitimacy of Private Rulemaking under EU Law' (2018) 55 *Common Market Law Review* 1187.

3.6. The 2012 Regulation on European Standardisation

The use of harmonised standards as a policy tool and supplement to legislation[386] played an important role in the formation of the single European market.[387] European standardisation had come to play a crucial role in many areas, 'ranging from supporting European competitiveness, protecting the consumer, improving accessibility for disabled and elderly people to tackling climate change'.[388] These advances required a comprehensive legal framework of public-private cooperation in European standardisation. Until recently, European standardisation has been governed by the legal framework consisting of three different legal acts—namely, Directive 98/34/EC, Decision 167/2006/EC and Council Decision 87/95/EEC. This framework was deemed to be no longer capable of meeting future challenges and new developments in European standardisation.

To this end, the 2010 Resolution of the European Parliament welcomed the Commission's intention to review the European standardisation system. It also advocated preserving successful elements of the existing system, refraining from radical changes so as not to undermine the core values, and remedying existing deficiencies.[389] The Parliament made several recommendations for enhancing European standardisation. Firstly, it proposed expanding the use of standards beyond the areas covered under the New Approach, and employing standards in the field of services. Secondly, it proposed facilitating the cooperation between the ESOs, the Commission and the Member States at the stage of drafting mandates. Thirdly, it proposed increasing the monitoring of compliance of standards with the mandates. Finally, it was suggested that standardisation be made more transparent by facilitating the involvement of

386 Regulation 1025/2012 (EU) (n 14), Recital 25.

387 See: The Report from the Commission to the European Parliament and the Council, Article 25 Report to the European Parliament and the Council on the impact of the procedures established by Article 10 of Regulation 1025/2012 (EU) (n 14).

388 European Commission, Proposal for a Regulation of the European Parliament and of the Council on European Standardisation and 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, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council, COM (2011) 315 final.

389 European Parliament resolution of 21 October 2010 on the future of European standardisation (2010/2051(INI)).

Small and Medium-sized Enterprises (SMEs) and stakeholders—such as consumers and environmentalists—in the process of standardisation.[390]

These proposed improvements have in one way or another been realised in Regulation 1025/2012 on European standardisation. This regulation provides an overarching legislative framework for European standardisation and enhances the public-private cooperation sowed in the New Approach strategy. The aim of the Regulation is to establish the rules of cooperation between the Commission, the Member States and European standard-setting organisations so as to facilitate the establishment of European standards covering products and services in support of policy and legislation. It regulates issues of financing and promotes stakeholder participation in the process of standardisation. Further, it provides the principles for identifying the ICT specifications eligible for referencing in the procurement procedure.[391]

The Regulation introduced a committee for standardisation consisting of experts from the Member States. This Committee assists the Commission with all tasks related to the implementation of the Regulation. Furthermore, it delivers formal opinions on mandates and on whether to publish or withdraw a reference to standards.

The Regulation has introduced substantial changes to the process of adopting mandates. The Commission is required to adopt a notification system for all stakeholders. The notification takes place throughout the mandate-adoption procedure, particularly during the planning stage but also when a first draft is prepared and once the final draft is ready to be adopted.[392] The standard committee consisting of sectoral experts from the Member States provides formal opinions on the mandate. These opinions are delivered in the examination procedure governed by Regulation 182/2011. The latter reserves a comitology procedure for the adoption of implementing acts by the Commission. In this way, the legal status of the mandate is formalised and it is an implementing decision adopted by the Commission.

The enhanced cooperation among the Member States, experts and stakeholders in the process of drafting a mandate indeed serves the aim of obtaining the best and most suitable standards for 'implementing' legislative requirements.

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[390] Ibid.

[391] Regulation 1025/2012 (EU) (n 14).

[392] See: European Commission, Enterprise and Industry Directorate General, Sustainable Growth and EU 2020 Standards for Boosting Competitiveness, March 4, 2013.

The publication of references to HESs has also been formalised. The Commission publishes a reference to a standard only after it ascertains that the standard covers the requirements enshrined in the legislation.[393] Hence, publication of a reference to standards is a Commission's decision, subject to judicial review under Article 263 TFEU.[394]

Among the positive changes brought about by the Regulation are the contemplative planning of strategic priorities in European standardisation, the transparency of the working programmes of the NSBs and wider stakeholder involvement. The Commission is required to write an annual working programme for standardisation. The programme is adopted following intensive consultation with national standards bodies and stakeholder organisations receiving EU funding. Moreover, the Commission is asked to make use of its research facilities so as to incorporate environmental sustainability, security and safety concerns.[395] The annual working programmes of the national and European standard-setting bodies are also communicated among them so as to identify the need for European standardisation and prevent the emergence of new barriers to trade.[396]

There is no doubt that the success of standardisation lies in the wider involvement of the stakeholders. One of the criticisms of the process of standardisation pertains to its 'representation deficit.' The 2003 Commission's staff working paper found that the representation of special interests—such as environmental or consumer—were restricted at the national level in NSOs.[397] An updated legal framework of European standardisation, i.e. Regulation, urges the ESOs to facilitate the involvement of stakeholders and SMEs through the bodies receiving EU funding.[398] At the national level, standard-setting bodies are required to facilitate SMEs' participation by granting, for instance, free membership, or free access to a draft of a standard. The national standard-

393 Regulation 1025/2012 (n 14), Article 10(6).

394 The more detailed investigation of this matter is provided in Chapter 7 of this thesis.

395 Regulation (EU) 1025/2012 (n 14), Article 8.

396 Ibid, Article 3.

397 EC Commission Staff Working Document, *The Challenges for European Standardization* (2003). See also ANEC, *Consumer Participation in Standardisation* (ANEC 2001).

398 Regulation 1025/2012 (EU) (n 14), Annex II lists criteria for stakeholder organisations that can obtain Union financing. For instance, in the field of Environment, European Environmental Citizens Association (ECOS) is qualified to represent and defend environmental interests in the process of European Standardisation. See: http://ecostandard.org/

setting bodies are required to send a report to their European counterparts regarding how successfully they have fulfilled this obligation.[399]

To sum up, Regulation on European standardisation covers services and attempts to integrate quickly developing ICT standardisation. To this end, Regulation provides a comprehensive legal framework for the public use of private standards. It has also introduced positive changes to promote stakeholder and SME involvement in the standardisation process. However, these statements remain weak. The planning of standardisation programmes is also made transparent through the exchange of information among standard-setting bodies at the national and EU levels.

Furthermore, the Commission's actions—such as mandating and referencing standards—have acquired a clear legal form. This represents a step toward embedding standards within EU law and juridifying standardisation. However, the core principles of public-private cooperation sown in the New Approach are left untouched. The standards used for legislative purposes remain voluntary, the ESOs are still private bodies rather than agencies of the EU, and the public-private relation (namely, between the Commission and the ESOs) is not formalised by reference to any specific treaty provision.

3.7. Conclusion

In this chapter I demonstrated the limits of positive and negative integration in tackling disparate national technical standards in the context of the EU internal market. Specifically, I explained the motivations for embedding the European standards in EU law. Moreover, I described the essential elements of the public-private cooperation established by the New Approach and complemented by Regulation 1025/2012. It was noted that Regulation on standardisation introduced positive changes in respect of detailing the process of adoption of mandates and providing the comprehensive framework for controlling the legal effects of the HESs before and after the publication thereof in the official journal. However, even after the adoption of Regulation 1025/2012, the legal status of mandated standards and the legal nature of the relationship between the Commission and the ESOs remain unclear.

[399] Regulation 1025/2012 (EU) (n 14), Article 6.

In sum, in this chapter I set out the reasons for resorting to the New Approach strategy and outlined the constitutional law concerns that were already expressed in the early days of the New Approach. Having explicated the rationale for resorting to the HESs for the harmonisation of technical requirements for goods, in the next chapter I focus on the functioning of this co-regulatory strategy. In particular, I analyse the operation of the co-regulation via European standardisation in light of the official documents pertaining to it. By doing so, I construct the 'Official View' on the relationship between standards and New Approach directives and argue that the separation between standards and law constituted a key feature of the New Approach strategy. However, after the adoption of Regulation on European standardisation and in light of the *James Elliott* case, the HESs are brought within the scope of EU law. Moreover, these developments shake the established 'separation framework', as discussed in the next chapter. As such, they can be seen to signal a shift towards the juridification of the HESs.

Part II

Analysing Different Legal Frameworks for Regulation and Accountability of European Standardisation

4. Interplay between New Approach Directives and Harmonised European Standards: A Shift from the 'Separation' Framework

4.1. Introduction

After positioning the European standardisation system in the multilevel governance of standardisation world and explaining in detail its role for the European market integration, in this part of the thesis I map and offer different perspectives on the understandings and regulation of the European standardisation system under EU law. Particularly in this chapter, I construct and present the 'Official View' on the interplay between the New Approach directives and HESs. I call it 'Official View' as it is constructed by analysing EU binding acts[400], the official documents, including the Commission's,[401] on the New Approach and the New Legislative Framework.[402]

In doing so, I argue that the 'Official View' about the New Approach strategy has been based on a clear distinction between law and standards. However, the

[400] Among these EU binding acts are primarily the Council Resolution 85/C 136/01 (n 14) that officially introduced the New Approach strategy and provided the general framework for it. See also The New Legislative Framework consisting of the Regulation 764/2008 (n 322); Regulation No 765/2008 (n 54); and Decision 768/2008/EC (n 54).

[401] These are mainly various documents from the Commission on the implementation of product rules, e.g. Commission, The Blue Guide on the Implementation of the Product Rules (notice) of 26 July 2016, C 272/1; Commission, 'Vademecum on European Standardisation in Support of Union Legislation and Policies and others' of 27 October 2015 (staff working document, in three parts) 205 final. Although these documents do not have binding force, they help us to understand the complex system of the New Legislative Framework, as well as present important legal value in the absence of the judicial decisions.

[402] The New Legislative Framework builds on the New Approach and complements it with all necessary elements for conformity assessment, accreditation and market surveillance.

shift from this 'separation framework' takes place with the adoption of the Regulation on European standardisation. Another brick from the separation framework is removed by the *James Elliott* case,[403] in which the CJEU ruled that the HES is part of EU law.

Originally the New Approach strategy was devised to function on a formal separation between the law and technical standards.[404] It was made clear that the operation of New Approach directives should not depend on harmonised standards.[405] These standards are formally voluntary[406] and provide one of the ways of compliance with legislative requirements. Moreover, the HESs, as said, do not replace the law, but rather 'translate the essential requirements into detailed technical requirements.'[407]

To maintain the separation between legal requirements and technical standards, the following two aspects are critical: a) the voluntary nature of standards—'relegating [them] to the status of voluntary guidelines and recommendations'[408]; and b) the 'bright line'[409] between the tasks of the legislator and the European Standards Organisations (ESOs). The strict separation of functions of public and private bodies was sought to avoid spill-over between legal requirements and technical standards, i.e. 'between the spheres of law and private norms.'[410]

In its turn, the 'bright line' between the directives and the HESs, and between legislators and private bodies, rules out the existence of formal delegation of legislative powers to private bodies and 'keep(s) in place traditional structures of legitimacy and accountability.'[411] Consequently, constitutional law concerns around the delegation of regulatory tasks to private ESOs are avoided. More importantly, the need for legal accountability of European standardisation disappears because in light of the separation framework neither

[403] Case C-613/14, *James Elliott* (n 60).

[404] See fundamental principles of the New Approach in Annex II to the Council Resolution 85/C 136/01 (n 14).

[405] Ibid; Schepel, 'Private Regulators in Law' (n 56), 359.

[406] Regulation (EU) 1025/2012 (n 14), Article 2.

[407] Commission, 'Blue Guide' (n 401), 49.

[408] Schepel, 'Private Regulators in Law' (n 56), 359.

[409] This expression was coined by Schepel in 'Private Regulators in Law' (n 56).

[410] Ibid, 357.

[411] Ibid, 360.

delegation nor concentration of public-like tasks takes place within the ESOs.[412]

Therefore, it is not surprising that the 'Official View' supported by the EU institutions[413] and the ESOs[414] strived to achieve and maintain the distinction between technical standards and law. To this end, the guidance documents on the functioning of the New Legislative Framework continuously stress that the HESs are voluntary rules and do not become laws by being referenced in the official journal. Even more, the ECJ has stated earlier that 'no rule of European Union law provides that a harmonised standard is presumed to have binding effect when it is capable of exercising a direct influence on trade.'[415]

However, the well-established 'Official View' starts to fade in light of the current developments, as argued below and in the next chapters. Recently adopted Regulation on European standardisation reinvigorates the procedural and functional links between EU law and HESs and brings the latter within the ambit of EU law. This trend continues by emerging case law on standardisation.[416] In *James Elliott,* the court looked beyond the formally voluntary status of the HESs and stressed the legal effects these standards

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412 About the necessity of accountability in the context of regulatory governance see: C. Scott, 'Regulatory Capitalism, Accountability and Democracy', in A.C. Bianculli, X.F. Marin, and J. Jordana, *Accountability and Regulatory Governance* (Palgrave Macmillan 2015), 189–208.

413 However, the CJEU does not entirely concur with the 'Official View' since it regarded the harmonised European standard as a part of EU law in Case 613/14 *James Elliott* (n 60). In contrast, the official documents from the Council, Commission and European Parliament stress the voluntary nature of standards and distinguish it from law. See for instance Council Resolution 85/C 136/01 (n 14), Annex II; Commission, 'Blue Guide' (n 401), paras 40–2. See also Regulation (EU) 1025/2012 (n 14), Recital 1, that states: 'The primary objective of standardisation is the definition of *voluntary* technical or quality specifications'. See also EU Parliament, Resolution of 4 July 2017 on European Standards for the 21st Century (2016/2274 (INI)), that states: 'standards are a voluntary, market-driven tool providing technical requirements…(and) standards cannot be seen as EU law'.

414 See for instance CEN-CENELEC's position paper, 'On the Consequences of the Judgment of the European Court of Justice on James Elliott Construction Limited v Irish Asphalt Limited', available at: <https://www.cencenelec.eu/news/policy_opinions/PolicyOpinions/PositionPaper_Consequences_Judgment_Elliott%20case.pdf> accessed 5 June 2017. Here the ESOs emphasise the need to maintain the distinction between the legal requirements and the HESs, by keeping the latter voluntary and stressing their private nature.

415 Case C-367/10P, *EMC*, ECLI:EU:C:2011:203, para 105.

416 Case C-613/14, *James Elliott* (n 60). Also, Case C-171/11, *Fra.bo SpA* (n 60). However, the latter case did not concern the New Approach, the apparent similarities with the New Approach Strategy makes the *Fra.bo* case relevant in the context of the New Approach.

entail[417], concluding that the HES is part of EU law that is susceptible to interpretation by the court in preliminary ruling procedures.

The remainder of this chapter is divided into the following sections. In section 2, European standardisation is presented as a form of private regulation and distinguished from pure self-regulation. In section 3, I explain the operation of product rules, focusing on the process of requesting HESs and the role thereof vis-à-vis legislative requirements. In section 4, I unpack the 'Official View' on the legislative use of European standardisation and argue that the interplay between the HESs and Directives was originally based on the separation framework, but the latter becomes shaky in view of current developments. In section 5, the separation framework is presented and questioned further by using the example of the Directive on the Safety of Toys.[418] The latter Directive is one of the so-called 'New Approach' directives that uses the HESs to harmonise the technical requirements for toys. To this end, the process of ascribing the CE mark on toys is explored, which suggests that HESs play a crucial role therein. By doing so, it demonstrates that notwithstanding the stated aspiration to separate legal requirements and standards, the HESs are closely interlinked with the operators' right to market goods in the EU and leaves no choice but to follow the HESs.

The last section concludes the chapter and suggests that the desired separation between EU law and standards is more 'fiction than reality'.[419] European standardisation cannot be insulated from the reach of EU law and falls under the scope of EU constitutional and economic laws.

4.2. European Standardisation: Private Regulation Used for Public Purposes

Standardisation is commonly described as a 'closed, private club', 'under the control of the business sector'[420] with no interest in being subject to public

[417] Case C-613/14, *James Elliott* (n 60), para 42.

[418] The (EC) Directive 2009/48/EC of 18 June 2009 on the Safety of Toys, OJ L 170/1.

[419] See also: Schepel, 'Private Regulators in Law' (n 56), 359.

[420] Gestel and Micklitz, 'European Integration through Standardization' (n 63), 149–55. See also L. Bernstein, 'Opting out of the Legal System: Extra-legal Contractual Relations in the Diamond Industry' (1992) 2 (12) *Journal of Legal Studies* 115; L. Bernstein, 'Private

supervision or intervention. Interested parties get together, agree on technical matters and, by setting standards, regulate themselves.[421] In this sense, standardisation is self-regulation. According to Black, self-regulation refers to a situation in which a group of persons or bodies 'act together, perform a regulatory function in respect of themselves and others who accept their authority.'[422] In precisely this way, industry representatives get together in the standard-setting process and agree on the technical rules that will regulate their actions.

Although standardisation can be described as a self-regulatory activity, the European standardisation that is used to define and implement EU policies and legislation is outside pure self-regulation, for two reasons: a) the European standard-setting process includes parties not directly regulated by the standards developed[423]; and b) the ESOs interact in the process of developing the HESs with public officials—EU institutions.[424] These aspects are explained below in turn.

The use of European standardisation in EU legislation and policy documents entails breaking up the 'club house'[425] mentality of standard-setting bodies and requires the inclusion of a wide range of stakeholders. To this end, Regulation 1025/2012 encourages the involvement of consumers, as well as social and environmental stakeholders,[426] in the process of standard-setting. The inclusion

Commercial Law in the Cotton Industry: Creating Cooperation through Rules, Norms and Institutions' (2001) 99 *University of Chicago Law School* 1724.

421 Enterprise Directorate-General, 'Vademecum on European Standardisation' (2003), part II, chapter I: 'Standardisation Setting and Governance', para 1. Further on the concept of self-regulation see: S. Rodriquez, 'The Self-Regulation as a Regulatory Strategy: The Italian Legal Framework' (2007) 3 *Utrecht Law Review* 140.

422 J. Black, 'Constitutionalising Self-regulation' (1996) 59 (1) *Modern Law Review* 24.

423 According to Cafaggi, when the regulatory activities include the parties not directly regulated then it is outside the framework of pure self-regulation. See: F. Cafaggi, 'Rethinking Private Regulation in the European Regulatory Space', in *Reframing Self-Regulation in European Private Law* (Kluwer Law International 2006), 18–19.

424 The elements which put the regulatory activities beyond the pure self-regulation are explained by L.A.J. Senden, E. Kica, M. Hiemstra, and K. Klinger, 'Mapping Self- and Co-regulation Approaches in the EU Context' (2015) Utrecht University, RENFORCE, 1–84.

425 See: Gestel and Micklitz, 'European Integration through Standardization' (n 63), 154.

426 Regulation (EU) 1025/2012 (n 14), Article 5. For instance, European Association for the Co-ordination of Consumer Representation in standardisation (ANEC) created in 1992, is an international, non-profit organisation that aims to represent consumer interests in standardisation. See: <https://www.anec.eu/about-anec/our-mission>. The environmental interests are represented by the European Environmental Citizens Organisations for

of such interest groups, which are not directly regulated by standardisation, collapses the self-regulatory frame of European standardisation, but does not change the private nature of such rulemaking.[427] In its turn, expanding the circle of the parties taking part in the process of standard-setting grants legitimacy to these standards[428] and guarantees a wider acceptance of these rules. Although these groups aim to represent the interests that are commonly affected by standardisation, they do not enjoy voting rights in the process of standards development and have only a weak right to participation.

The interplay between legislation and standardisation is not a new phenomenon. European standardisation following the adoption of the New Approach is a tool used to harmonise the technical requirements of products. According to Ladeur, once the administration becomes dependent on technical specifications and technical expertise, standardisation is no longer a 'legal no-man's land'.[429] Similarly, European standardisation is no longer self-regulation. The Commission interacts with private ESOs, and the HESs are the products of this public-private cooperation. The European Economic and Social Committee has labelled the HESs as products of the 'co-regulation' exercised by the ESOs and EU institutions.[430]

The 'employment' of private regulators for public purposes through the mechanism of co-regulation has been praised for many reasons—inter alia, for accumulating technical expertise in the private field[431] and for enhancing democratic legitimacy. In addition, allowing the regulatees to become regulators is deemed to enhance the regulation's legitimacy. Lastly, the

Standardisation (ECOS); ECOS is a partner organisation of CEN and CENELEC and member of ETSI. See: <http://ecostandard.org/?page_id=14>.

427 Cafaggi, 'Rethinking Private Regulation' (n 423), 18–19.

428 F. Cafaggi, 'A Coordinated Approach to Civil Liability and Regulation in European Law, Rethinking Institutional Complementarities', in *The Institutional Framework of European Private Law* (Oxford University Press 2006), 191–245.

429 K.H. Ladeur, 'The Emergence of Global Administrative Law and the Evolution of General Administrative Law' (2010) *Express0* <http://works.bepress.com/karlheinz_ladeur/1> accessed 10 May 2017.

430 European Economic and Social Committee Pamphlet Series, 'Current Stand of Self-Regulation and Co-Regulation in the Single Market' (2005) <http://www.eesc.europa.eu/resources/docs/2018_cahier_en_smo_def.pdf> accessed March 2015.

431 E.g. I. Ayres and J. Braithwaite, 'Responsive Regulation, Transcending the Self-Reregulation Debate', in A. Ogus, *Regulation, Legal Form and Economic Theory* (Oxford University Press 1994).

involvement of private actors in regulation increases the chance of voluntary compliance with the rules established by the private parties themselves.[432]

The co-regulation encompasses mainly two types of situation: either 1) the legislative act delegates the regulatory activities to the private bodies; or 2) the legislative act recognises private regulation as an expression of the exercise of power by private bodies.[433] This distinction affects the extent of control that should be exercised over the private regulator. If the private regulatory activities fall into the first category, then the public should exercise stricter scrutiny. But if the private power is original, then co-regulation is close to the principles of private regulation.[434]

Under the system of co-regulation via European standardisation, the development of technical means to fulfil legislative requirements is entrusted to recognised bodies in the standardisation field.[435] However, the procedure for adopting the HESs does not differ from the process of adopting other non-mandated standards,[436] and thus remains governed by the principles of private rule-making. Moreover, the ESOs enjoy autonomy in deciding on the suitable technical means of fulfilling the legislative requirements. The Commission has no right to intervene in this process, and the Commission representatives attending the process of writing standards do not have voting powers.[437]

Regulation 1025/2012 reinforces public control over the HESs by monitoring only the public side of the co-regulation process. The committee of standardisation[438], established by Regulation 1025/2012, does not have the competence to intervene in the standard-setting exercised by the ESOs. Rather, it is involved only in the process of drafting mandates and also participates in delivering the opinions concerning the publication of the references to standards or removal thereof.[439]

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[432] See: R. Baldwin and M. Cave, *Understanding Regulation: Theory, Strategy, and Practice* (Oxford University Press 2012).

[433] Cafaggi, 'Rethinking Private Regulation' (n 423), 27–33.

[434] Ibid, 27–35.

[435] Interinstitutional Agreement on Better Law-Making [2003] (n 39).

[436] In addition, Regulation (EU) 1025/2012 (n 14) requires subjecting standard-setting to the principle of openness, transparency and non-discrimination.

[437] CEN-CENELEC, 'Internal Regulations, Part I-Organisation and Structure' (2017), para 3.

[438] On the Committee of standardisation see: Regulation (EU) 1025/2012 (n 14), Article 22.

[439] Regulation (EU) 1025/2012 (n 14), Articles 10 and 11.

Furthermore, the assessment of the compatibility of an HES with the Commission's mandate takes place with the close cooperation with the ESOs,[440] making it less likely that the appropriateness of the chosen technology will come into question. This manifests the Commission's trust in the ESOs and in their unique expertise. As the Commission itself lacks technical knowledge, the technical side of assessment is left to the ESOs or to independent experts such as New Approach consultants that are appointed by the ESOs.[441]

In short, the inclusion of stakeholders that are not directly regulated by adopted standards and collaboration with the EU institutions pushes European standardisation outside the sphere of pure self-regulation. However, European standardisation is still a private regulation since it is exercised by private bodies according to their by-laws, without direct supervision from public authorities. At the same time, though, the part of standardisation that is used for legislative purposes and entails development of the HESs is a system of co-regulation. Although the HSEs are developed by the private ESOs, they are initiated on the basis of the Commission's request, conditioned by a mandate and acquire legal relevance after the publication of a reference in the official journal. Hence, the HESs are products of co-regulation, involving EU institutions and private standards organisations.

4.3. Regulating Free Movement of Goods by EU Directives and Standards: General Overview

In this section, I unpack the operation of product rules through standards and legislative requirements. In particular, I explain the process of requesting an HES and by doing so explicate the nature of the relationship between the Commission and ESOs. The formal function and role of the HESs in the system of product rules are also spelt out.

The New Legislative Framework comprising Regulation 765/2008[442] and Decision 768/2008/EC[443] lays down the comprehensive framework for

[440] Regulation (EU) 1025/2012 (n 14), Article 10(5).

[441] Commission, 'Vademecum (n 401), Part I: Role of the Commission's Standardisation Request to the European Standardisation Organisations, sections 3 and 7.

[442] Regulation (EC) 765/2008 (n 54).

[443] Decision 768/2008/EC (n 54).

industrial products and protects various public interests. Regulation 765/2008 establishes the legal basis for accreditation and market surveillance, and consolidates the meaning of CE marking, whereas Decision 768/2008/EC updates and harmonises the various technical instruments already used in existing Union harmonisation legislation. More precisely, it prescribes the provisions for designation of conformity assessment bodies,[444] and stipulates the rules on the conformity assessment process,[445] lays down the responsibilities of economic operators,[446] as well as those of public authorities and the Member States.[447]

It is important to note that Decision 768/2008/EC is not directly applicable, but rather embodies the political commitments of the three EU institutions.[448] This means that the EU institutions commit themselves to adhere to the provisions of this Decision in their future, pertinent legislative proposals.

In short, the New Legislative Framework brings together all elements that are important for marketing the products in the EU. It includes rules on 'organisation and accreditation of conformity assessment bodies performing conformity assessment activities';[449] it also incorporates the requirements for national accreditation bodies[450] and the process of affirming CE marking.[451] In addition, it covers the measures taken by public authorities after the products are placed on the market—such as surveillance—to ensure the safety of goods are prescribed.[452] In other words, the New Legislative Framework addresses the public and private bodies and imposes obligations on them so as to guarantee the safety of products marketed in the EU.

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444 Ibid, Chapter R4, Articles R15, R17.

445 Ibid, Articles 4–6.

446 Ibid, R2–R7.

447 Ibid, Chapter R4, Articles R31–R34.

448 Commission, 'Blue Guide' (n 401), section 1.2.2. – The Legal Nature of the NLF Acts and their relationship to other EU Legislation.

449 Regulation (EC) 765/2008 (n 54), Article 1, para 1, and the requirements applicable for conformity assessment bodies are provided by Decision 768/2008/EC (n 400), Chapter R4, Articles R15, R17.

450 Regulation (EC) 765/2008 (n 54), Article 1, para 1.

451 The general principles of CE marking are provided in Regulation (EC) 765/2008 (n 54), Article 30, while the conditions of affixing CE marking are enshrined in Decision 768/2008/EC (n 54), Articles R11–R12.

452 Decision 768/2008/EC (n 54), Chapter R4, Articles R31–R34.

The New Approach is part of the New Legislative Framework. The former combines the legal requirements and their technical transpositions. The technical specifications for complying with these essential requirements are provided by the HESs. These standards, while remaining formally voluntary, grant a presumption of conformity with essential requirements to the companies using them. This means that private operators have the option—though, arguably, only on paper—to use other technical means to satisfy the essential requirements.[453]

The declared voluntary status of the HESs aims to distinguish these technical rules from binding legal requirements. This separation between the legislative requirements and the technical standards is a necessary and crucial component for the operation of New Approach directives. According to the EU institutions, the use of this strategy is only appropriate when it is possible to distinguish between laws and standards.[454]

The essential requirements that are laid down in each New Approach directive address and ensure the protection of public interests. Particularly, these essential requirements concern the health and safety of users of products and provide protection of the environment. In other words, the legislative provisions envisage the results to be achieved by a manufacturer of a product while addressing possible hazards. For instance, essential requirements might relate to different hazards associated with a product—such as radioactivity, flammability, chemical, electrical or biological properties, etc. These essential requirements are listed in a harmonisation directive concerning relevant products or spelt out in the annex to that directive. These legislative requirements set the goals of safety, health and environmental protection. The technical means of achieving these goals are laid down by the mandated technical standards referenced in the official journal.

Decision 768/2008/EC requires that the essential requirements are worded in a precise manner, i.e. while transposing them in national legislations they should provide clear, legally binding obligations, so as to ensure the separation between the spheres of law and technical rules. The essential requirements should also be explicit enough to enable the assessment of products'

[453] Ibid, Article 3, para 2; Voluntary nature of harmonised standards allows its optional usage. See Regulation (EU) 1025/2012 (n 14) that states that standards are voluntary. Also, the Commission, 'Blue Guide' (n 401), section 4.1.2. Conformity with the Essential Requirements: Harmonised Standards.

[454] Decision 768/2008/EC, (n 54), Article 3, para 1.

compliance directly with them. However, the degree of the detailed wording of essential requirements varies across different harmonisation directives.[455]

4.3.1. The Relationship between the Commission and ESOs: Process of Requesting European Harmonised Standards

The relationship between the Commission and ESOs goes back to the 1980s when the New Approach strategy for harmonisation of technical requirements was adopted. Much time has passed since then, but the main principles of this public-private cooperation have changed little until recently. An updated legislative framework in the form of Regulation 1025/2012 set out in more detail the process of cooperation between the Commission and the ESOs leading to the development of the HESs.

This section explicates the relationship between the Commission and the ESOs by focusing primarily on the process of drafting a mandate[456] and requesting a development of a standard in light of Regulation 1025/2012. Consequently, I argue that although a Commission's mandate bears some similarities to a contract, the relationship between the Commission and ESOs after Regulation 1025/2012 can no longer be regarded as 'strictly contractual'.[457] As the AG explains in *James Elliott*, the development of HESs was previously 'governed by an agreement'—between the ESOs and the Commission—in the form of General Guidelines for Cooperation.[458] According to these Guidelines, the ESOs were to commit to producing and updating the HESs in line with the interests, objectives and policies of the Union and in return were to receive a

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[455] Commission, 'Blue Guide' (n 401), para 40, provides on this matter the following example: According to the Directive 2008/57/EC on the interoperability of the rail system each sub-system is covered by a Technical Specification of Inter-operability (TSI), which specifies the essential requirements. According to Regulation (EC) No 552/2004 on the interoperability of the European Air Traffic Management network, in case of necessity, the essential requirements are refined or complemented by implementing rules for interoperability.

[456] Although Regulation (EU) 21025/2012 (n 14) now uses the term 'request', though the term 'mandate' is still widely used in the Court's terminology, in the Commission's documents, and in the scholarship. Therefore, I will use mandate and request interchangeably throughout this thesis.

[457] See the somewhat concurring opinion of Tovo, 'Judicial Review of Harmonised Standards' (n 385), para 1198.

[458] General Guidelines for the Cooperation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association – 28 March 2003, OJ 2003, C 91/7.

significant financial contribution from the EU.[459] Now this relationship has acquired a legal form as it is circumscribed by a public law, namely, Regulation 1025/2012. This means that after accepting a Commission's mandate, the cooperation is governed by directly applicable obligations stemming from the Regulation on European standardisation.

It is the latter Regulation that provides the legal basis for the Commission to request a development of an HES.[460] To this end, the Commission issues a mandate which is 'a necessary condition for the status of a harmonised standard.'[461] A mandate describes the requested work and specifies the deadline. It also determines the public authorities' expectations of the ESOs,[462] and by so doing separates the tasks of the EU legislator from those of the ESOs.

The Commission explains in its Vademecum on European Standardisation that by issuing a mandate, 'it does not delegate political powers to the ESOs, but recognises their specific technical roles in the process.'[463] This, it explains, is because the tasks assigned to the ESOs are purely technical, and the adoption of a standard does not automatically provide compliance with the essential requirements. Rather, an HES acquires this effect only after the publication of a reference to it in the official journal.[464]

According to the Commission, mandates play an important role in ensuring a clear division of the tasks between the Commission and the ESOs.[465] To this end, a mandate should state clearly the reasons for a request, and describe in detail the requirements that a technical standard should satisfy, as well as the deadlines for delivering a standard.[466] The European Parliament exhorted the Commission to clearly and accurately define the objective of the

[459] AG in *James Elliott* (n 219), paras 57–8.

[460] Regulation (EU) 1025/2012 (n 14), Article 10. See Also: Commission, 'Vademecum' (n 401), Part I: Role of the Commission's Standardisation Request to the European Standardisation Organisations.

[461] Schepel, *The Constitution of Private Governance* (n 111), 239.

[462] Commission, 'Vademecum' (n 401), Part I: Role of the Commission's Standardisation Request to the European Standardisation Organisations, section 3: Concept of standardisation request.

[463] Ibid.

[464] Regulation (EU) 1025/2012 (n 14), Article 10(6).

[465] Commission, 'Vademecum' (n 401), Part I: Role of the Commission's Standardisation Request to the European Standardisation Organisations, section 3: Concept of standardisation request, para 4.1.

[466] Ibid, Part I.

standardisation work in the mandates. It stressed 'that the role of standardisation should be limited to defining the technical means of reaching the goals set by the legislator.'[467] This statement also demonstrates that, according to the European Parliament, a mandate is crucial in separating the tasks of the public authorities and private ESOs.

The precision of a standardisation request minimises misinterpretation thereof on the part of the ESOs. In addition, a precisely drafted mandate and detailed essential requirements can guarantee that public authorities make the political choices. For instance, setting limits to a person's exposure to a hazard should, as argued by the Commission, be decided by public authorities and not by the ESOs.[468]

The mandated European standardisation incorporates the efforts of public authorities and private parties. It includes the EU legislator and the Commission (public authorities), as well as ESOs and European stakeholder organisations (private parties). The roles of these actors and the relationship between them are illustrated below.

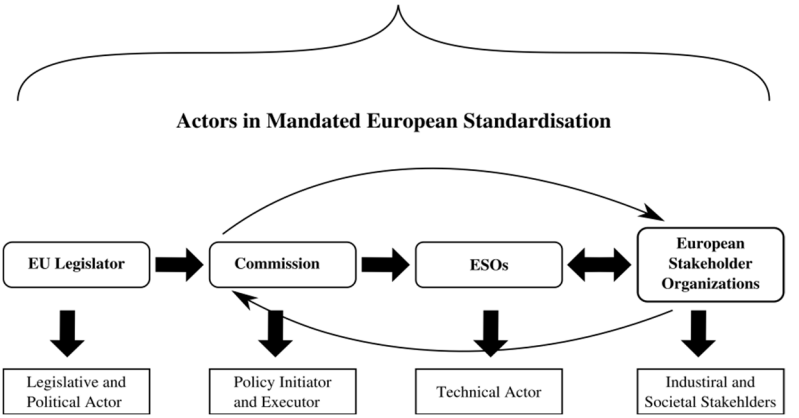

Figure 2
The private and public parites and their roles in the mandated European standardisaion

[467] European Parliament Resolution of 21 October 2010 on the Future of European Standardisation (2010/2051(INI)).

[468] Commission, 'Vademecum' (n 401), Part I, section 3: Concept of standardisation request. See also: Directive 2006/42/EC on machinery that gives no limit values for noise emissions as a condition for placing on the market and provides that such values cannot be given in voluntary harmonised standards either.

As the picture above shows, the EU institutions and private bodies have distinct functions in the EU-mandated standardisation. The EU legislator sets the legal framework for the standardisation policy[469] and may also raise formal objections to the HESs.[470] The Commission adopts a Union Work Programme (UWP) for European standardisation, which establishes standardisation needs for public policy purposes.[471] In this process, the Commission cooperates closely with the European stakeholder organisations.[472] The ESO's task is to execute the mandate by writing a standard.

The mandate that marks the beginning of the cooperation between the ESO and the Commission is issued only within the limitations of the Commission competencies.[473] Union legislation may also limit the subject matter that can be covered by European standards. Such limitation appears in cases where a legislative act explicitly requires the Commission to adopt technical rules or standards in the form of delegated or implementing acts.

Regulation 1025/2012 formalised the procedure of adopting a mandate, which shows the importance of mandates as instruments outlining public-private cooperation.[474] In accordance with this Regulation, a mandate is adopted based on a procedure set out in Regulation 182/201126[475] (Comitology Regulation) and issued as a Commission's implementing act. Before adopting a mandate as an implementing act, the Commission obtains the consent of the Committee of standards set up according to Article 22(1) of Regulation 1025/2012. In order to obtain consent, the Commission undertakes wide consultations with sectoral authorities at the national level. In short, a mandate depicts the expectations of public authorities from a standard, and the latter should be developed according to the requirements of the mandate.

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469 For instance, the adoption of the Regulation (EU) 1025/2012 (n 14) is an example of such an action.

470 Regulation (EU) 1025/2012 (n 14), Article 11(1).

471 Ibid, Article 8.

472 Ibid, Article 8(4).

473 Ibid, Article 10(1).

474 Commission, 'Vademecum' (n 401).

475 Regulation (EU) 182/2011 of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers OJ L 55/13.

The flowchart below depicts the process of issuing a mandate to the ESOs.[476]

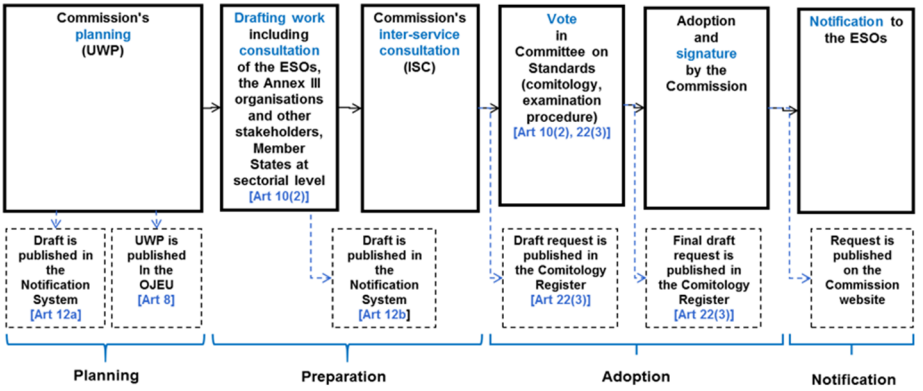

Figure 3
The process of issuing a mandate to the ESOs

Although a mandate is adopted as an implementing act of the Commission, it is not binding on the ESO, which may refuse to carry out the mandate.[477] This aspect is usually used to argue that the relationship between the Commission and the ESOs is contractual and not based on delegation of powers. As already noted, however, it is rare in practice for the ESOs to reject a Commission's request.[478] After accepting a mandate, an ESO commits itself to provide a standard within the time limit specified therein.[479] Financial support of the ESOs depends on their performance-development of a mandated standard within the time limit.

Furthermore, acceptance of a mandate by the ESO marks the beginning of a standstill period for the national standards bodies that are required not to object to or undermine the work of standardisation being exercised at the EU level.[480]

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[476] This flowchart is taken from the Commission, 'Vademecum' (n 401), Part II: Preparation and Adoption of the Commission's Standardisation Requests to the European Standardisation Organisations.

[477] Regulation (EU) 1025/2012 (n 14), Article 9(3).

[478] See: Hofmann et al, 'Rule-Making by Private Parties' (n 63), 13.

[479] Commission, 'Vademecum' (n 401), Part II: Preparation and Adoption of the Commission's Standardisation Requests to the European Standardisation Organisations, section 3.3.

[480] Regulation (EU) 1025/2012 (n 14), Article 3(5).

The standardisation request does not expire automatically unless the Commission repeals it. It applies to the updates and revisions of the HESs covered by the mandate. In other words, there is no need to issue a new mandate when the HESs are periodically reviewed, as long as an updated standard covers the same essential requirements. The Commission references the revised versions of the HESs in the official journal; thereafter, these standards become attached to a relevant directive. Such a procedure enables the new version of a standard to be available immediately for Union legislation. The revision of the HESs means the removal of the old reference from the official journal, and unless decided otherwise it does not automatically invalidate certificates issued by notified bodies in accordance with old harmonised standards.[481]

In sum, a mandate is an important document that prompts cooperation between the ESOs and the Commission and ensures separation between public and private tasks. Since a mandate is not a binding document, it simply conveys the wishes of public authorities concerning technical harmonisation. In this sense, it is close to a contract aiming to 'purchase' a standard. But since the process of developing and adopting a mandate, as well as the consequences of accepting it, are strictly detailed by Regulation 1025/2012, the relationship between the Commission and the ESOs after accepting a mandate are not purely contractual. Rather, this cooperation is governed by public law, which in its turn has implications for the obligations that ESOs have in developing the HESs, as well as for the legal status of HESs.

4.3.2. Harmonised European Standards—Technical Equivalents of Legislative Essential Requirements

The product-to-product legislative harmonisation showed that agreeing on detailed technical specifications in the political setting of the Council and Parliament was doomed to fail.[482] In response to this, the New Approach strategy introduced a technique of harmonisation where the development of detailed technical specifications is 'outsourced' to the private ESOs. The latter are equipped with the expertise to find the technical solutions for implementing the essential legislative requirements.

[481] See on the revision of an HES and the Commission's obligation to update the list: Case T-474/15*, Global Garden Product Italy SpA (GGP Italy) v Commission*, ECLI:EU:T:2017:36.

[482] See Chapter 3 of this thesis.

The EU official documents on this strategy and sectoral directives repeatedly reassure us that HESs do not replace binding essential requirements.[483] Rather, these standards are seen as technical means of complying with essential requirements and in no circumstances alternatives to them.[484] However, the formally voluntary nature of the HESs is controversial due to the legal effects of these standards for business operators, national standards bodies and Member States.[485]

The harmonised standard is 'a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation'.[486] Even where these standards are used for legislative purposes, they remain formally voluntary.[487] The HESs become intertwined with a relevant directive after the references to them are published in the official journal. The references to the HESs, until recently, were published as Commission's communications in the C series of the official journal.[488] Clearly, the publication of the reference by the Commission is an administrative task and entails significant legal consequences, i.e. sets the date from which the presumption of conformity takes effect. Perhaps it is a recognition of the important role that the Commission's act to publish a reference plays, in that the Commission recently published the reference to the harmonised standards through the implementing decision in the L series of the official journal.[489] This is a remarkable fact, removing another brick from the 'Official View' and recognising the legal effects of the HESs, entangling them tightly with EU directives and making the HESs inalienable parts of EU law.

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[483] Council Resolution 85/C 136/01 (n 14), Section 4.1.2.2: The Role of Harmonised Standards.

[484] However, this statement is debatable in practice, because in many instances the HESs provide rather detailed requirements and even extend on the essential requirements.

[485] This is elaborated in detail in Chapter 5.

[486] Regulation (EU) 1025/2012 (n 14), Article 1(c).

[487] Council Resolution 85/C 136/01 (n 14), Annex II; Commission, 'Blue Guide' (n 401), 40–2.

[488] For the recent example of publishing references to harmonised standards in the C series of the official journal see: Commission Communication (2018/C 326/04) of 19 September 2018 on publication of titles and references of harmonised standards under Union harmonisation legislation OJ C 326/114, <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1550250745734&uri=CELEX:52018XC0914(06)> accessed 30 October 2018.

[489] Commission implementing decision of 20 December 2018 on the harmonised standard for website and mobile applications drafted in support of Directive (EU) 2016/2102 of the European Parliament and of the Council <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1547314570417&uri=CELEX:32018D2048> accessed 29 December 2018.

Having said all of this, one still has to emphasise that nothing officially indicates that operators are under any obligation to comply with the HESs; rather, they are required to comply with essential requirements of the legislation. It is against these requirements that a notified body assesses the compliance of a product. In practice this means that a manufacturer even using an HES is responsible for identifying risks that the product might pose and consequently determining which essential requirements apply. Having done so, a manufacturer might use an HES to 'implement risk reduction measure.'[490] The HESs are extremely beneficial for businesses, since they play an essential role in complying with legislative requirements. The chart below depicts the role of HESs in the process of complying with essential requirements.[491]

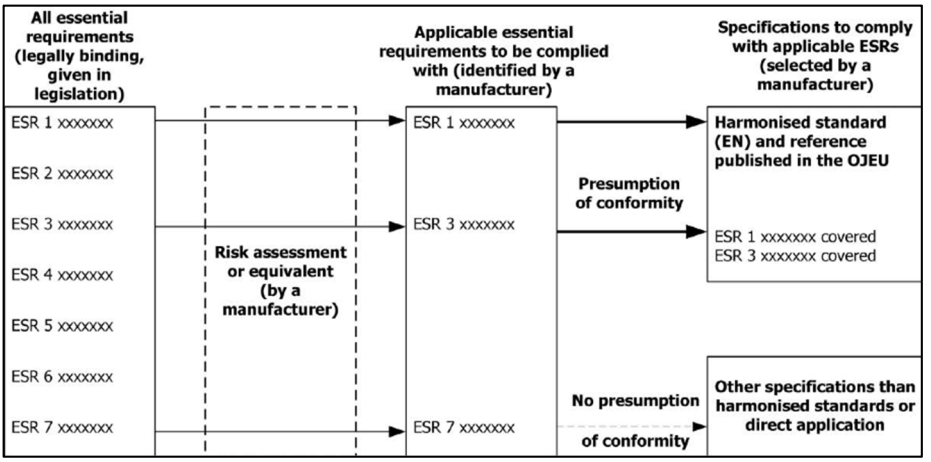

Figure 4
The relation between the Essential Requirements of a Directive and the HESs

The use of the HESs applicable to a pertinent product saves time and money that product developers and designers would typically spend on assessing the risk and adopting strategies for safety. The HESs usually incorporate the state of the art for either the product production or the safety procedure. Therefore, these standards do not apply retrospectively to the products already placed on the market; in addition, since the state of the art develops over time, these standards are withdrawn or modified periodically by the ESOs. The

[490] Commission, 'Blue Guide' (n 401), 42.

[491] This chart is taken from the Commission, 'Blue Guide' (n 401), 43.

Commission makes the respective changes in the official journal, by publishing the new references to the standards.

As mentioned above, a manufacturer remains free to not use an HES, although in practice these could be rare cases. On paper, the option remains available. By stressing the existence of this option, HESs are distinguished from binding legal requirements. But it must be stressed that the use of means of compliance other than HESs places the burden on a manufacturer to prove that other ways ensure the same level of safety and health protection as the HESs. A similar burden is imposed on a manufacturer when an HES does not cover all essential requirements or covers them only partially.

It follows that although the HESs are developed to be attached to directives, with the aim to harmonise technical specifications throughout the Union, their use remains, strictly speaking, voluntary. To this end, the HESs are distinguished formally from the mandatory legal requirements—although, in practice, it is arguable how voluntary the HESs are, since the use of these standards carries the presumption of conformity with essential requirements and are, as such, 'de facto mandatory' for business operators.

4.4. The 'Official View' on the Use of European Standardisation in EU Legislation and Policy: Separation Framework

The legal framework that enables the use of the HESs alongside the EU harmonisation directives was discussed above. To understand the operation of this co-regulatory strategy, the binding EU legal acts, the official guidance documents and notices were reviewed. Although the latter documents are only advisory, they help to present the 'Official View' on the interplay between the legislative requirements and standards. What is more, in the absence of judicial decisions on this matter, the significance of these documents is even more crucial. It must be stressed that the 'Official View', on the operation of the co-regulation via European standardisation based on the separation between the fields of law and technical standards, remains aspirational, and whether or not separation works in practice is an open question.[492]

[492] The separation view is questioned in the next section on the basis of the Directive on the Safety of Toys (n 418).

For the officially promoted 'separation' framework, two elements are crucial: 1) The distinction between the tasks of the EU institutions and ESOs. The latter ought to exercise purely technical functions that do not fall under the domain of EU institutions and hence, writing of standards ought to be the sole task of the ESOs. In this manner, the process of standard-setting is insulated from the actions of public authorities and remains governed by by-laws of the ESOs; 2) The HESs ought to differ from binding legal acts and, therefore, the HESs' legal status has to resemble voluntary guidelines. Consequently, the current regime of copyright protection over these standards depends on the private and voluntary status of these technical rules.

4.4.1. Development of the HESs—Sole Task of the ESOs?

This section describes key aspects of the standard-setting procedure, in accordance with the Regulation on European Standardisation,[493] General Guidelines for cooperation between the ESOs, the Commission and EFTA[494] and internal regulations and the statutes of the ESOs. By doing so, it is demonstrated that the standard-setting process is largely a private activity. However, I argue that the development of the HESs is not merely a private one and the sole task of the ESOs since this process is initiated, conditioned and influenced by a Commission mandate. Moreover, the framework agreements concluded by the Commission and ESOs constrain the functional autonomy of the latter.[495] Beyond specifying the common cooperative objectives, these agreements also spell out conditions for the awarding of financial grants to the ESOs.[496] The financial contribution of the EU to the ESOs is significant, as these grants form more than a third of the ESOs' incomes.[497] This financial dependency also circumscribes the autonomy of the standards organisations.

The process of developing an HES is both prompted and influenced by a mandate from the Commission. The latter sets out the conditions and time

[493] Regulation EU 1025/2012 (n 14). See also Commission, 'Vademecum' (n 401), Part III, which sets out guidelines for the execution of standardisation requests accepted by the ESOs and lays down the principles for elaboration and adoption of HESs.

[494] General Guidelines for the Cooperation (n 458).

[495] See the concurring opinion of Tovo, 'Judicial Review of harmonised Standards' (n 385), 1193.

[496] See Regulation (EU) 1025/2012 (n 14), Article 17(5).

[497] Report from the Commission to the European Parliament and the Council on the Implementation of the Regulation (EU) 1025/2012 from 2013 to 2015, COM (2016), 212, 6.

limits for the adoption of the 'requested products' (HESs).[498] In the court's words, the mandates 'set out precisely [the] scope and a technical reference framework' of the HESs[499], meaning that 'the scope of a harmonized standard cannot be interpreted more broadly than that of the mandate on which it is based'.[500] After acceptance of a mandate, the Commission also has a duty to inform the ESOs within the timeline prescribed in Regulation 1025/2012[501] about the award of the grant for standardisation activity.

The finding of a technical solution in response to a Commission mandate is entirely the responsibility of the relevant technical committee of the ESOs. To this end, the committee must identify and write an HES that is in line with the mandate and relevant internal market legislation. In other words, to 'give a technical answer for the determination of the characteristics of that mandate, taking into account the conditions set out therein'.[502] Even though the HESs are developed to provide the 'technical translations' of essential requirements, this does not prevent ESOs from developing a standard which has a broader scope and covers specification other than that provided in the essential requirements. It is also possible that an HES covers only part of the essential requirements. In either case, the standard should state explicitly which essential requirements are dealt with and which are not covered by its scope. Ordinarily, such information is included in a separate informative annex[503] or explicitly stated in the scope of the pertinent HES. Having this information is important since compliance with an HES can grant a presumption of conformity only in relation to the essential requirements that are covered by the latter standard.

One should keep in mind that preparing the HESs does not always include the development of a new standard, but the ESOs are free, after careful examination, to identify an existing standard and modify it in light of the terms of the mandate. In a similar vein, the ESOs use international standards, transpose them and adapt to the requirements of the mandate. Transposition of international standards that are used in response to the Commission's mandate

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498 Regulation (EU) 1025/2012 (n 14), Article 10(1) and (2).

499 Case C-613/14, *James Elliott* (n 60), paras 44–5. However, the ESOs are free to propose amendments to the Commission's mandate.

500 Case C-630/16 *Anstar*, EU:C:2017:971, para 36.

501 Regulation (EU) 1025/2012 (n 14), Article 10(4).

502 Case C-613/14, *James Elliott* (n 60), para 44.

503 European standardisation organisations usually name these annexes as 'Annex ZA, ZB or ZZ', etc.

and acquire the status of the HESs could exacerbate legitimacy concerns. This is because it cannot be taken for granted that international standards bodies abide with the procedural requirements—such as openness, inclusiveness and transparency[504]—that usually constrain the standardisation process in the ESOs. However, such fear dissipates in the case of standards adopted by well-established international standard organisations, such as the ISO, which follows the WTO principles of transparency, openness, consensus and voluntary application.

The European standardisation process is founded on the above-mentioned WTO principles, as well as on sector-specific principles—such as consensus, effectiveness and relevance.[505] The above-listed WTO principles are similar to the general principles applicable to all EU actions by virtue of Articles 11 TEU, 298 TFEU and 41 of the Charter of fundamental rights.

It is important to note that Regulation 1025/2012 took steps towards a more open and inclusive process of standardisation and explicitly requires stakeholder participation—including SMEs, consumer[506] and environmental associations,[507] trade unions and so on[508]—as well as transparency of draft standards and standards programmes.[509] Participation of interested groups is supported financially by EU grants.[510]

This Regulation also facilitates the involvement of public authorities in the process of standardisation,[511] which is crucial especially where health, safety

[504] See J. Mendes, 'EU law and Global Regulatory Regime: Hollowing out Procedural Standards?' (2012) 10 (4) *International Journal of Constitutional Law* 988. Here the discussion is about the depletion of the procedural standards established in EU law, which results from reception of decisions in EU law, that are adopted at the global level. However, this article is not limited to discussing only international standards, but also considers generally the reception of all sorts of global decisions in EU law and gives examples concerning the Fisheries policy, Wildlife trade and Medicines fields.

[505] The criteria of 'relevance' means that ESOs are obliged to take into consideration technological developments and market needs.

[506] ANEC, <https://www.anec.eu/>

[507] ECOS, <http://ecostandard.org/>

[508] Regulation (EU) 1025/2012 (n 14), Articles 3–6. See also General Guidelines for the Cooperation (n 458).

[509] See Regulation (EU) 1025/2012 (n 14), Articles 3 and 5.

[510] Regulation (EU) 1025/2012 (n 14), Annex III.

[511] Regulation (EU) 1025/2012 (n 14), Article 7.

and environment are at stake.[512] But neither public bodies nor societal organisations have any formal rights in the process of standardisation. Even more, the Union harmonisation legislation for products does not envisage the procedure for verifying or approving the standards by public authorities systematically, either at the national or the Union level. The exception to this being the requirement laid down by Regulation 102572012 that the Commission has to assess the HESs' compatibility with the sectoral legislations before publication of the references in the official journal.[513] This has been heralded as a main innovation of this Regulation and also as the main indication towards juridification of the legal status of the HESs. However, one would have to ask how satisfactory such a level and quality of scrutiny actually is in practice.[514]

One of the crucial steps in the process of standards drafting is public enquiry, i.e. publication of the draft standard and gathering comments on it through national standardisation organisations.[515] These comments are then incorporated into the standard before the latter is put for voting. The voting procedure is organised according to the internal guidelines of the ESOs.[516] After adoption, the relevant ESO ratifies and publishes the European standard (EN). An EN that is developed in light of the mandate is a harmonised EN, but for it to carry legal effects—such as the presumption of conformity—the Commission should publish a reference to it. After the publication of a reference to an HES in the official journal, the standard becomes attached to the relevant directive.

After a short overview of the standardisation process with respect to the development of the HESs, it is fair to conclude that the development of the

[512] For instance, New Approach consultants who are independent experts participate in the standards writing process and ensure the dialogue between the Commission and ESOs.

[513] Prior to publication of the reference to an HES in the official journal, the Commission shall assess the compatibility of an HES with essential requirements: Regulation (EU) 1025/2012 (n 14), Article 10(6).

[514] On the material constraints of the Commission's control over the compatibility of HESs with the essential safety requirements, see C. Colombo and M. Eliantonio, 'Harmonized Technical Standards as Part of EU law: Juridification with a Number of Unresolved Legitimacy Concerns?' (2017) 24 (2) *Maastricht Journal of Comparative and European Law* 323, at 338; and Medzmariashvili, 'Delegation of Rulemaking Power to European Standards Organizations: Reconsidered' (n 385), 362.

[515] Regulation (EU) 1025/2012, Article 4(3).

[516] The process of development of a standard was discussed on the example of CEN in Chapter 2 of this thesis.

HESs cannot be regarded as an entirely private and exclusive task of the ESOs. This is so because the process of drafting the HESs is initiated and conditioned by a Commission mandate and the HESs acquire legal effects only after publication of the reference in the official journal. The whole process—starting from prescribing the legislative requirements until the publication of the references to technical standards implementing these legislative requirements—incorporates the efforts of and close cooperation between public and private bodies. The first stage—writing of a relevant product legislation, identifying the essential safety and health requirements and preparing a mandate—is undertaken mainly by the EU institutions (the Council, the Parliament and the Commission). The development of the standards is left in the domain of the ESOs. And at the final stage, it is the action of public authority, i.e. the Commission, that attaches a standard to the relevant EU directive and ascribes the presumption of conformity. The chart I construct below depicts this process.

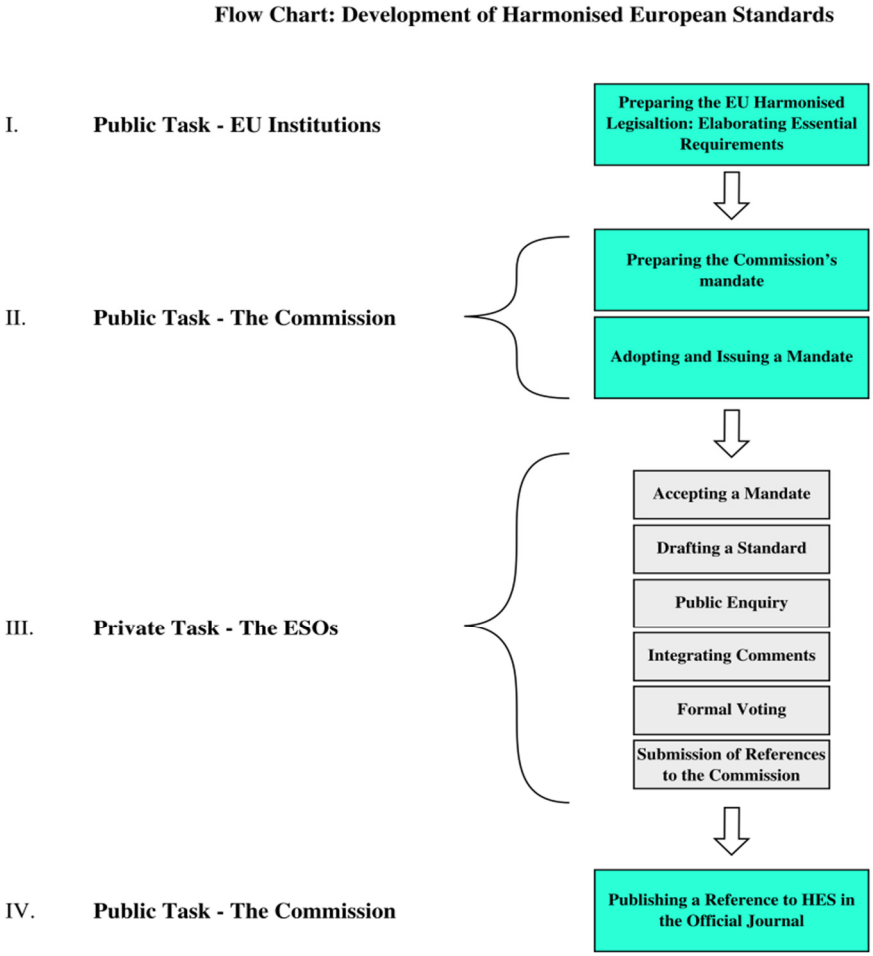

Figure 5
Development of HESs

4.4.2. Private, Non-binding Nature of Standards and their Copyright Protection

Prima facie, European standards are voluntary rules written by standardisation bodies. It is a legislator and not a standardisation body that finally grants to standards a mandatory status and confers legal significance upon them. In the EU, the legislator opted formally for the voluntary application of the standards attached to the New Approach directives. The voluntary nature distinguishes these standards from binding legal provisions, which is also reflected by the copyright regime over these standards. Formally, the HESs are similar to voluntary guidelines and recommendations.[517] Hence, all European standards including harmonised ones are protected by copyright law, like other works of authorship such as books, films or musical compositions.

According to CEN and CENELEC, the reference to standards in legislation or technical regulations does not rule out copyright protection.[518] The ESOs hold copyright on standards in the three official languages—English, French and German. The members of the ESOs that translate standards into other languages own the copyright in the translated versions but cannot assign this right to any third parties.[519]

The ESOs assign the right to exploitation of the European standards to NSBs. Each standardisation body has an exclusive right to sell its standards within its own territory and can distribute them in other territories only in exceptional cases.[520] A member of the ESOs cannot distribute national standards transposing the HESs free of charge. If it wishes to do so, the request must be referred to the ESOs.[521] This is because the ESOs consider the commercial exploitation of the European standards to be fundamental for sustaining their work.[522]

Belgian law, which is the country of origin of the European standards, governs all matters concerning the European standards—such as copyright, selling and

[517] Schepel, 'Private Regulators in Law' (n 56), 359.

[518] CEN-CENELEC, 'Policy on Dissemination, Sales and Copyright of CEN-CENELEC Publications: Guide 10' (2017), para 3.4.

[519] Ibid, para 11.2.

[520] Ibid, paras 4.3, 5.3.1 and 5.4.

[521] Ibid, para 5.1.

[522] Ibid, para 3.2. The commercial exploitation of standards is the case in CEN and CENELEC, whereas ETSI provides access to standards free of charge.

exploitation.[523] The issue of copyright to standards is mentioned only briefly and casually in official documents.[524] For instance, Regulation 1025/2012 is silent on this matter and on the legal status of the standards referenced in the legislation.[525]

Yet, there is an inherent connection between the legal status of standards and copyright protection. The ESOs enjoy copyright on standards as long as these standards can be regarded as private and voluntary rules, since according to a general rule, the law cannot be copyrighted.[526] This principle dates back to Roman times when public access to legal documents was made a key feature of law-based civilisation.[527] Furthermore, it is a basic standard of democracy that laws should be accessible free of charge to everyone.[528]

In the EU, public access to all official documents of Union institutions, bodies and agencies is an accepted principle enshrined in Article 15 TFEU. However, the principle of authorship can limit public access to official documents.[529] This happens in cases where EU institutions, bodies or agencies are in possession of a document but do not own it since another party holds the authorship rights. In our context, this means that the Commission cannot publish or make the full text of standards available free of charge since the ESOs own copyright on them.

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[523] Ibid, paras 3.7 and 4.2.

[524] See for instance: Report of the expert panel for the review of the European standardisation system, 'Standardisation for a competitive and innovative Europe: a vision for 2020', (Brussels February 2010) <http://www.anec.eu/attachments/Definitive%20EXPRESS%20report.pdf> accessed 10 February 2015.

[525] See discussion of the copyright protection of European standards used for legislative purposes in B. Lundqvist, 'European Harmonised Standards, Part of EU Law and, Thus, Not Copyrighted?' (2017) 44 (4) *Legal Issues of Economic Integration* 418.

[526] E.S. Bremer, 'On the Cost of Private Standards in Public Law' (2014) 63 *Kansas Law Review* 279. On the general background to copyright, see Article 2, section 4, of the Berne Convention for the Protection of Literary and Artistic Works, that allows signing parties to exclude official texts from copyright protection. See also the WIPO, Guide to the Copyright and Related Rights Treaties, 30.

[527] L.A. Cunningham, 'Private Standards in Public Law: Copyright, Law-making and the Case of Accounting' (2005) 104 (2) *Michigan Law Review* 291, at 295.

[528] Gestel and Micklitz, 'European Integration through Standardisation' (n 63), 146.

[529] Case T-188/97, *Rothmans v Commission*, ECLI:EU:T:1999:156, para 55. Although in this case the comitology committee was seen as under the Commission; consequently, the minutes of the committee were considered to be the document of the Commission and the public access to it should have been guaranteed; see paras 55–63.

But the copyright protection of the HESs becomes questionable, especially after the *James Elliott* case. Although the case does not directly concern copyright protection of the HESs, it can have consequences on this matter too. In this case, the court found that an HES forms part of EU law. This statement has direct implications for the copyright protection of standards. Conferring legal effects on the HESs according to AG Sanchez-Bordona strikes at the heart of the issue of whether complete publication of these standards 'is necessary for those standards to have legal effect'.[530] Although the AG avoids this matter, stating that the issue is not essential for the reference at hand, he admits that such a 'requirement would have a very significant impact on the European standardisation system, and in particular on the sale of harmonised technical standard by national standardisation bodies.'[531]

It follows that there is a strong interdependence between the legal status of standards and their copyright protection. If standards that are used for legislative purposes have mandatory force and are regarded as public rules, then they should be accessible free of charge.[532] On the other hand, if standards are private voluntary rules, then copyright shall be upheld. The crux of a debate about public access to the standards over copyright protection is the legal status and the nature of these standards, i.e. whether these rules have a law-like function.

The copyright versus public access dilemma is a complex one. The argument that standards are in practice mandatory for operators speaks in favour of removing the copyright protection. The fact that revenue received from selling standards is fundamental for the sustainability of the ESOs' activities speaks

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[530] AG opinion in *James Elliott* (n 219), para 51.

[531] Ibid, para 51. The ESOs are against giving away copyright protection on the HESs, see on this: the CEN-CENELEC's position paper, 'On the Consequences of the Judgement of the European Court of Justice on James Elliott Construction Limited v Irish Asphalt Limited' <https://www.cencenelec.eu/news/policy_opinions/PolicyOpinions/PositionPaper_Consequences_Judgment_Elliott%20case.pdf> accessed 10 June 2017.

[532] The vigorous discussion about the copyright protection of standards referenced in legislation has been ongoing in US academic circles. See on this matter: N.A. Mendelson, 'Taking Public Access to the Law Seriously: The Problem of Private Control Over the Availability of Federal Standards' (2015) 45 (8) *Environmental Law Report* 10776; P.L. Strauss, 'Private Standards Organizations and Public Law' (2013) 22 *William & Mary Bill of Rights Journal* 497; E.S. Bremer, 'Incorporation by Reference in an Open Government Age' (2013) 36 *Harvard Journal of Law & Public Policy* 131; Bremer, 'On the Cost of Private Standards in Public Law' (n 526).

for granting them copyright protection. This demands taking into consideration the ESOs' business model.[533]

The point of departure in this discussion is whether the mere reference to a standard in legislation turns this standard into law. The ECJ has not dealt with this issue so far. Thus, two important cases are presented below as a basis for discussion: one from the US, and one from the European continent.[534]

The *Veeck v Southern Building Code Congress International, Inc.* is the seminal case from the US on the copyright protection of standards referred in a legislative act.[535] Peter Veeck operated a non-commercial website providing information about northern Texas. Veeck had decided to give information on the local building codes of Anna and Savoy, two small towns in this region. The towns adopted editions of the standard building code that was developed by the private non-profit Southern Building Code Congress International (SBCCI). The latter enjoyed copyright on its developed codes. Veeck purchased the standard building code and published it on its website, without indicating that SBCCI was its author. SBCCI subsequently brought an action against Veeck alleging copyright infringement.

The sharply divided court held that the private author of the code could not claim copyright once the code had entered the public domain.[536] The court stated that, for copyright purposes, laws are equivalent to facts.[537] According to copyright law, 'all facts—scientific, historical, and biographical and the news of the day…may not be copyrighted.'[538] Once they were adopted as town building codes, the model codes of SBCCI became 'laws' for purposes of copyright protection. They were then to be regarded as facts—incapable of expression in any other way and thus not subject to copyright protection.[539]

The court found it necessary to distinguish the case at hand from another situation, the so-called weak form of incorporation of a standard, which would

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[533] As Gestel and Micklitz claim, the national standard bodies have failed to provide evidence that income from selling standards is vital for them. In this regard see Gestel and Micklitz, 'European Integration through Standardisation' (n 63), 147 (footnote 6).

[534] The aim here is not to compare these two jurisdictions. The US case is referred to simply because of the lack of case law on this matter at the EU level.

[535] *Veeck* 293 F.3d 791 (5th Cir. 2002).

[536] See: *Veek* 293 F.3d 791 (5th Cir. 2002), at 800–2.

[537] Ibid, at 32.

[538] Ibid.

[539] Ibid, at 30–3.

call for a different reasoning and result,[540] meaning that the mere passing reference to standards in legal materials would neither turn these standards into law nor eliminate the copyright protection. However, the *Veeck* case was considered to be different from the weak reference, hence, it entailed the removal of copyright protection from standards incorporated in the building codes of Anna and Savoy.

In Europe, the national courts, unlike the ECJ, have had the opportunity to rule on this matter.[541] The *Knooble* case from the Dutch courts is an interesting example for this discussion.[542] In 2006, Knooble sued both the Dutch state and the Netherlands Standardisation Institute after it did not get permission to publish NEN standards to which the Dutch Building Decree (DBD) referred. According to DBD, these standards needed to be taken into account in the construction or renovation of buildings. In lodging the case, Knooble claimed that the NEN standards, which were copyrighted, could not have binding force like law, because they were not published in accordance with certain provisions of the Dutch constitution, which requires the publication of the full text of laws and decrees in the official Dutch Gazette.

Knooble asked the court to declare the standards void or else make them publicly accessible. He argued that the standards at hand became mandatory or were treated as having legally binding force once they were included in a legislative act. Therefore, the standards should be published and accessible free of charge, just like any law.

The district and appeals courts delivered contradictory judgments. The district court ruled that since the standards were not published officially, they should not be mandatory. The appeals court took a different path and stated that the

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[540] Ibid, at 804.

[541] For instance, see the German Bundesgerichtshof (BGH, 30 June 1983, GRUG 1984, 17–119) and the Bundesverfassungsgericht (BVerfGE, 29 July 1998, ZUM 1998, 926) that held that technical standards adopted by the German standards institute were not protected by intellectual property and thus should be published. However, the latter decision by the *Bundesverfassungsgericht* was not the end of the story. The German legislature changing the copyright law in 2003 added a separate third paragraph to Article 5 UrhG, which states that the copyright on DIN standards remains when laws or agency regulations refer to the standards, unless the text of the private standards is taken over verbatim into the text of a law. In the latter case, Article 5(1) and (2) UrhG are still applicable, which guarantees free access. On this matter, see the discussion of this in Gestel and Micklitz, 'European Integration through Standardisation' (n 63).

[542] The content of this case, as well as relevant discussions were found in the article by Gestel and Micklitz, 'European Integration through Standardisation' (n 63).

reference to standards in the legislation pulled them into the public domain and made them generally applicable but did not turn them into law.

The appeals court's decision was underpinned by the argument that an essential condition of law was missing—namely, that the NEN standard was not based on delegation of lawmaking powers by a public authority, but relied purely on private agreements.[543] The court seemingly took an overly formalistic approach. It reasoned that a standard is not a law if it was neither adopted through the legislative procedure nor the 'product' of the delegation of lawmaking powers from public authority to private bodies. If we were to accept the appeals court's reasoning, it would mean that it is possible to bypass the whole lawmaking procedure by simply transferring it to private bodies. Whether the standards are de facto binding or create legally binding effects would not matter. Later, this case was appealed to the Supreme Court of the Netherlands, which upheld the appeals court's decision.

The case clearly had wider European relevance given the Dutch system's close resemblance to the EU's New Approach.[544] The AG of the Dutch Supreme Court explained that the system of 'non-obligatory' references to standards in the DBD was copied from the 1985 Commission's White Paper announcing the New Approach.[545] The AG stressed that both the Commission and the Council have emphasised that voluntary acceptance of standards forms the spine of the New Approach—and hence of the Dutch approach too. This point deserves attention. The standards remain voluntary if compliance can be demonstrated by other means. But these alternatives should not simply exist as a possibility on paper. In this regard, the reasoning of the District Court of the Netherlands is interesting. If one first has to purchase the relevant standard to find out how to develop an equivalent means of compliance with an underlying piece of legislation, then it is still not realistic to suggest that standards are completely voluntary.[546]

In light of the two discussed cases, the argument supporting the copyright protection of standards in the context of New Approach strategy could be that the HESs are ideas and not facts for copyright purposes. The publication of the reference to an HES in the official journal is simply a weak form of reference and does not make standards compulsory. This means that reference to the

[543] Ibid, 162.

[544] Ibid, 145–81.

[545] White Paper from the Commission on Completing the Internal Market, COM (85)310.

[546] Gestel and Micklitz, 'European Integration through Standardisation' (n 63), 176.

HESs still leaves the option of complying by other means, which would not be the case if standards were laws.

On the other hand, the existence of copyright might be an impediment to using the alternative means of compliance since the operators first need to know a standard in order to be able to comply by alternative means. But if standards are protected by copyright, then the only way to know a standard is to buy it. This issue goes even deeper to the inability of the clear separation between the technical and legal requirements. If the essential requirements were detailed and gave a clear understanding of what the law requires, then there would be no need to know the contents of an HES in order to comply with the law by alternative means. Usually, however, it is the HESs that provide detailed elaborations of legislative requirements. The copyright on standards might also entail increased costs for business operators. Firstly, businesses have to invest resources and participate in the standardisation process,[547] and secondly, they must pay fees for the standards, the writing of which they have already contributed to.

The resolution of this dilemma is inhibited by fear of upsetting the public-private partnership in European standardisation. 'The best approach must reconcile two apparently incompatible rights: the public right to freely access the law and the private copyright of standards developers'.[548] This reconciliation must also occur 'within the broader context of a longstanding, complex, and highly valuable public-private partnership in standards.'[549] One way of achieving this is to provide the public with read-only access to standards online. The latter version of access is practiced in the US, by American National Standards Institute (ANSI) which ensures controlled, read-only access to standards incorporated by reference.[550] This model has already been used also by some Member States in connection with Eurocode and its national Annexes. However, in these cases too, access is sponsored.[551]

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[547] The cost of standards development is usually paid by industry. Over 90% of the cost is covered by the industry. See: 'Impact assessment Accompanying the Proposal for a Regulation on European Standardisation' SEC (2011) 671 final, 8.

[548] Bremer, 'On the Cost of Private Standards in Public Law' (n 526).

[549] Ibid.

[550] See: J.L. Contreras, 'Technical Standards, Standards-Setting Organizations and Intellectual Property: A Survey of the Literature (with an Emphasis on Empirical Approaches)' (2017) *Utah Law Faculty Scholarship* 11, at 40 <https://ssrn.com/abstract=2900540> accessed 15 May 2018.

[551] See: CEN-CENELEC, 'Guide 10' (n 518), Annex A.

In sum, since the 'Official View' aspires to maintain a 'bright line' between the HESs and directives, the former rules are relegated to the status of voluntary private rules. This view is reflected in the regime of access to standards. In particular, the HESs are regarded officially as voluntary private rules—the products of the ESOs' authorship—and hence protected by copyright. However, following the court's finding in the *James Elliott* case, i.e. recognising the legal effects of the HESs and regarding them as part of EU law, at worst shakes the formally voluntary status of these standards, and at best urges a change in the current copyright policy over the standards that are used for legislative and policy purposes.

4.5. Interplay between Law and Standards: Directive on the Safety of Toys as an Example

Here I examine the operation of the co-regulation via European standardisation and the role of the HESs in the marketing of goods in the EU by using an example of the Directive on the Safety of Toys. By doing so, I raise further questions with regard to the separation framework and the interplay between standards and law presented above. The legal framework for the operation of the toys' industry is a lucid illustration of so-called New Approach directives. The choice of this industry is not motivated by specific reasons, and it merely serves the aim of providing a practical example of the operation of the New Legislative Framework in a certain industry.

According to the Commission: 'Toys contribute to child development, and play is an essential part of growing up.'[552] Hence, ensuring children's safety while playing with toys is crucial. To this end, toys are one of the most heavily regulated sectors in the EU. The requirements for toys are harmonised by the 2009/48/EC Directive, which has strengthened the rules on safety and enforcement of the earlier Directive from 1998. The safety requirements for toys provided by Directive 2009/48/ is also one of the strictest in the world, particularly when it comes to the use of chemicals in toys.[553]

The implementation and operation of the Toys Directive is aligned with the New Legislative Framework and relies heavily on the private rules-standards

[552] The Commission, The Toys safety in the EU <https://ec.europa.eu/growth/sectors/toys/safety_en>

[553] Ibid.

and private bodies such as ESOs and notified bodies. The risks identified by the Directive are addressed and tackled by means of the Commission-mandated HESs, which are developed by CEN and CENELEC.

Below, the operation of the Toys Directive and the importance of standards in this regard are unpacked. It is shown that the HESs complementing the essential requirements are crucial for the marketing of toys in Europe. Consequently, it is argued that while the HESs are voluntary, their use is the easiest and most convenient way for placing the toys on the EU market. This is so because, firstly, some essential requirements are formulated broadly—e.g. toys should be safe for children—entailing a heavy burden of proof, meaning that it is not surprising that manufacturers find it easier to comply with more detailed HESs.[554] Secondly, the use of the HESs influences the type of conformity assessment procedure that must be undertaken by a manufacturer. Therefore, these standards become 'de facto mandatory' and have similar importance for business operators as legal requirements. Also, the HESs that complement the essential requirements address the most crucial risks to ensure a child's safety, which demonstrates the significance of the HESs and pierces the private veil of standardisation.

4.5.1. Directive on the Safety of Toys: General Overview

The first version of the Toys Directive was adopted in 1998, but with the technological developments in the production of toys, new challenges regarding safety emerged. The new Toys Directive adopted in 2009 addresses these challenges. The preamble to this Directive informs us that employment of EU standards alongside the Directive is a success story and one to be preserved.[555] Therefore, the new Directive too resorts to the HESs, with the latter implementing the essential requirements and granting the presumption of compliance.[556]

The scope of the Toys Directive from 2009 is noticeably wider than that of its predecessor. The former covers products 'whether or not exclusively intended

[554] See similar reasoning in A. van Waeyenberge and D.R. Amariles, 'James Elliott Construction: A "New(ish) Approach" to Judicial Review of Standardisation' (2017) 42 (6) *European Law Review* 882.

[555] Directive 2009/48/EC on the safety of toys (n 418), Recitals 2–4.

[556] Ibid.

for use by children under age 14'[557], meaning that even toys with double functions fall under the regulatory framework of this Directive.[558]

The Directive adopts new essential requirements concerning the use of chemicals in toys and pays special attention to this. More specifically, any substances classified as 'carcinogenic, mutagenic or toxic for reproduction, all allergic substances and certain metals [are to be] subject to careful attention.'[559] The essential requirements against which the conformity of toys are assessed before marketing in the EU are divided into two groups: general and more specific.[560]

Article 10(2) of the Directive embodies the general safety requirements and states: 'Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.' More detailed essential requirements addressing each hazard—such as physical and mechanical properties, flammability, chemical properties, electrical properties, hygiene and radioactivity—are enshrined in Annex II to this Directive. The toys should be in conformity with the essential requirements throughout the foreseeable and normal period of use.[561]

However, the Directive is silent about the technical ways of toy production or design that would ensure the safety and conformity with the essential requirements. The technical ways for compliance are laid down in the HESs. The latter are attached to the Directive by means of publication of a reference in the official journal. Below, the currently published list of references to the HESs concerning the Toys Directive are attached. This list also provides information on the scope of each HES, that is to say, it explains which essential requirement of the Directive on the safety of toys is covered by a relevant HES.[562]

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[557] Ibid, Article 2, para 1.

[558] For instance, a keyring with a teddy bear attached to it. See: European Commission, Enterprise and Industry, Ensuring Children benefit from the Highest Level of Protection <http://ec.europa.eu/growth/sectors/toys_en>

[559] Directive 2009/48/EC on the safety of toys (n 418), Recitals 21–2.

[560] Ibid, Article 10(1).

[561] Ibid, Article 10, para 3.

[562] The list of references to harmonised standards related to the Directive on the safety of Toys <https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/toys_en>

4.5.2. Importance of the HESs for Marketing Toys in the EU

The primary obligation to ensure the safety of toys marketed in the EU lies with a manufacturer. It is the latter who must design and produce toys in accordance with the essential requirements of the Directive.[563] Then it follows that manufacturers are the key users of the HESs.

The directive states explicitly:

> Toys which are in conformity with harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof set out in Article 10 and Annex II.[564]

In order to ensure that only safe toys are marketed in the EU, a manufacturer shall undertake safety and conformity assessment procedures.[565] Moreover, a manufacturer should document these procedures by drawing up the technical file and keeping it for a minimum of 10 years after the toys are placed on the market.[566] The file includes information on the toy's design and the process of manufacturing, including the list of components and materials used in toys, as well as a data sheet on the chemicals used, safety assessment, conformity assessment, a copy of EC declaration, test result and so on.

The safety and conformity assessment procedures are mandatory and distinct. Under the safety assessment procedure, a manufacturer identifies potential hazards and assesses the exposure of the toys to these hazards.[567] In other words, within the safety assessment procedure, a manufacturer identifies the essential requirements that apply to the toys. Meanwhile, the conformity assessment procedure aims to demonstrate and document the compliance with essential requirements in the process of toy design and production.

The safety assessment procedure should take place before placing the toys in the market. The safety assessment procedure covers various hazards—such as chemical, physical, mechanical, electrical, flammability, hygienic and radioactivity—that a toy may present. The legal requirements addressing these hazards are the essential requirements that the toys should meet. Most of these

563 Directive 2009/48/EC on the safety of toys (n 418), Article 4, para 1.

564 Ibid, Article 13.

565 Ibid, Articles 18–20.

566 Ibid, Article 4(3).

567 Ibid, Articles 18 and 19.

essential requirements are complied with by means of the HESs. Using harmonised standards in the process of toy manufacture or design conveys the presumption of conformity with essential requirements for those toys. Also, the use of the HESs influences the type of conformity assessment procedure applicable to a toy in the following manner.

The conformity assessment procedure that aims to verify the compliance of toys with essential requirements can be undertaken by a manufacturer himself, i.e. self-verification or exercised by a third party notified body. The type of a necessary conformity assessment depends on the technical means a manufacturer uses for production and design. According to the Toys Directive where the HESs exist that cover all applicable essential requirements and a manufacturer decides to use them, the self-verification procedure suffices. This is so because the HESs carry a presumption of compliance. Then a manufacturer need only use these standards and put in place an internal production procedure in accordance with module A of Annex II to Decision No. 768/2008/EC. The self-verification procedure does not entail the involvement of a third party for assessing the conformity of a toy. At the end of the self-verification procedure, a manufacturer ascertains the CE marking on the toys that indicates compliance with the essential requirements of the Directive.[568]

The third-party verification is necessary for the cases where a manufacturer does not use the HESs, or the HESs do not exist or do not cover all applicable essential requirements. In this scenario, a manufacturer is under the obligation to submit a model of a toy to a notified body for an EC-type examination. Notified body is mostly a private body that is accredited within the territory of a Member State to conduct conformity assessment with regard to particular products and their scope of actions is notified to the Commission.

The Toys Directive following to the Regulation No 765/2008 lays down the criteria applicable to these notified bodies so as to ensure their high level of expertise and freedom from influence. The task of a notified body under the Directive is to examine the technical design of a toy so as to assess its conformity with the essential requirements. As a result of conformity assessment undertaken by a notified body, the latter issues an EC-type examination certificate and attests compliance.[569]

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[568] Directive 2009/48/EC on the safety of toys (n 418), Articles 4(2) and 17.

[569] Ibid, Article 20.

It follows that the use of the HESs are beneficial for manufacturers. Firstly, these standards save time and resources spent on searching for adequate engineering solutions for design and manufacture. Also, importantly, the use of the HESs removes the need to involve the notified body for assessing the conformity since the self-verification procedure suffices. In light of these, it is obvious that most business operators would opt for the HESs; therefore, the latter becomes de facto mandatory. Overall, the HESs provide the easiest, fastest and cheapest way of complying with essential requirements.

Private standards usually 'transgress the boundary between merely technical construction issues and normative definition of tolerable risk…'.[570] Similarly, the HESs provide the technical means to address the crucial hazards that are vital for health and safety. Whereas the Toys Directive demonstrates that the HESs are the sole trustable means of compliance with essential requirements, not requiring third party verification procedure, which itself collapses the non-binding nature of these standards.

4.6. Conclusion

In this chapter, I explored and presented the 'Official View' on the interplay between the directives and the HESs in light of the principles of the New Approach complemented with the New Legislative Framework. In doing so, I revisited the EU binding acts, as well as the Commission's documents concerning the use of standardisation for marketing goods within the EU. It was explained that the 'Official View' offers a separation framework on the interplay between law and standards. The separation is sought as a means of avoiding spill-over between legal requirements and technical standards, i.e. 'between the spheres of law and private norms.'[571] Consequently, following the separation framework, the constitutional law difficulties with using the HESs in EU policy and legislation disappear. Although the EU has tried to put in place arrangements to ensure the separation between the Directives and the HESs, this, as Schepel has noted, 'is a rather obvious piece of fiction.'[572]

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[570] G. Spindler, 'Market Processes, Standardisation and Tort Law' (1998) 4 (3) *European Law Journal* 319.

[571] Schepel, 'Private Regulators in Law' (n 56), 357.

[572] Ibid, 359.

By using the example of the toy industry, the significance of the HESs, their interconnectedness with essential safety requirements and de facto mandatory nature of standards was demonstrated. What follows is that the separation between the HESs and the essential requirements of the New Approach directives can only exist on paper. The fact that the HESs grant a presumption of conformity with legal requirements carries important legal effects for business operators. What is more, the HESs fulfil a public function by encoding technical translations of legal requirements on matters of high importance—such as health, safety and the environment. Since the legislative requirements cannot always be set out in detail, the standards fill the vacuum left by the legislator and, thus, are necessary complements to the legislation. As such, they not only provide technical translations, but also replace legislative requirements and determine vital aspects of public concern. This pierces through the private and voluntary nature of standardisation and moves it into the public realm.

The Commission and even the ESOs have recognised that 'standardisation has acquired a high political profile', unlike 'other forms of specification', and that 'although standardisation is a voluntary and independent activity, CEN, CENELEC, ETSI, the European Commission and EFTA recognised that it has an effect on a number of areas of public concern.'[573]

Adoption of EU Regulation 1025/2012 on European standardisation in tandem with the *James Elliott* case puncture the private framework of standardisation and remove the cornerstones from the separation framework presented in this chapter. More precisely, in the light of Regulation 1025/2012, cooperation between the Commission and the ESOs is no longer contractual but is governed by public law. In addition, following this Regulation, three important developments in standardisation policy are noticeable. Firstly, setting the clear legal requirements for more transparent and inclusive standardisation process. Secondly, establishing the surveillance of work by standards bodies and strengthening Union control over the legal effects of the HESs. Thirdly, spelling out in detail the conditions for granting funding to ESOs for the task of developing the HESs. All three of these outcomes belie the notion that European standardisation can be insulated from public involvement.[574]

Consequently, the *James Elliott* case is a logical continuation of breaking down the private and closed club mentality of the standardisation process. As the AG

[573] General guidelines for the cooperation (n 458).

[574] Hofmann et al, 'Rule-Making by Private Parties' (n 63).

in *James Elliott* opined, the public-private cooperation in European standardisation 'is a case of "controlled" legislative delegation in favour of a private standardisation body.'[575] Although the court did not use such language, it came to the same conclusion, namely, that an HES is a part of EU law, since it is

> …a necessary implementation measure…initiated, managed and monitored by the Commission and its legal effects are subject to prior publication by the Commission of its references in the 'C' series of the Official Journal of the European Union.[576]

The assumption that standardisation regulates important spheres for the public supports the argument that the ESOs perform tasks that traditionally belonged to public authorities. This reasoning undermines the 'separation framework' and supports the opinion that the use of European standardisation in connection to EU legislation and policies is a form of delegation, which is discussed in the next chapter.

[575] Opinion of AG in the Case C-613/14, *James Elliott* (n 219), para 55.

[576] Case C-613/14, *James Elliott* (n 60), para 43.

5. European Standardisation System under EU Constitutional Law: The 'Delegation Framework'

5.1. Introduction

Here, I unfold and present the EU constitutional law perspective on the use of European standardisation in EU policies and legislation. More precisely, I discuss how EU constitutional law could regard, regulate, and control the co-regulation via European standardisation. Consequently, I argue that through the lens of EU constitutional law, the legislative use of European standardisation is a case of delegated rule-making. This is so, because taking a constitutional law perspective on private rules with legal effects such as the HESs implies delegation of rule-making power. In its turn, the EU constitutional law prescribes the conditions for the lawfulness of such delegation and requires administrative and judicial control of delegated powers.

The investigation conducted in this chapter aims to envisage the legal framework offered by the EU constitutional law, to juxtapose it with the previously described 'Official View' and to reflect on what it offers in respect of regulation and accountability of the European standardisation system.

The 'Delegation Framework' for the understanding and regulation of the European standardisation system, which is presented here, provides a contrasting image of the previously discussed 'Official View'. Under the 'Delegation Framework', the HESs are 'quasi-legal' acts, whereas following the 'Official View' the HESs are entirely voluntary, private rules. The crucial difference between these two perspectives is that different understandings of the co-regulation via European standardisation also entail different legal frameworks for the regulation, accountability, and legitimacy thereof. Particularly, under the 'Official View' the ESOs do not exercise the delegated public (legislative) tasks, and the need for public accountability in the form of judicial and administrative control of the European standardisation system disappears. Following the 'Official View', the European standardisation is a

purely private regulation that falls under the private law sphere and could be subject to, for instance, copyright or competition law provisions.

In contrast, seen through the prism of EU constitutional law, the ESOs exercise public tasks when developing the HESs according to the Commission's mandate and for the purposes of transposing the essential requirements of safety, health, and environment. Exercising the public tasks by private bodies such as the ESOs immediately raises legitimacy and accountability concerns. In response to such concerns, the constitutional law demands that standards-making should be close to the principles of public rule-making, i.e. follow the principles of good governance and be subject to legal accountability through administrative and judicial control. In sum, the 'Official View' and the EU constitutional law perspective provide divergent images of the European standardisation system, and as such require different legal mechanisms for its regulation and accountability.

Now, I shall turn to the examination of the European standardisation system under the EU constitutional law. At the outset, it should be stressed that the constitutional law provides the autonomy and unity of the legal system[577] and maintains the distinction between law and non-law. The law can originate only from the constitutional machinery of lawmaking.[578] This means that in a democratic constitutional order, only parliament and the executive can exercise rule-making power to regulate public interests or delegate this function to non-governmental bodies. It follows then that the development of HESs, which are de facto mandatory and entail legal effects, is a result of the Commission delegating rule-making power to the ESOs.

The delegation view on the use of European standardisation in EU legislation and policy is prevalent in the constitutional and administrative law scholarship.[579] Moreover, in his recent opinion to the *James Elliott* case, the AG Sanchez-Bordona described the co-regulation via European standardisation as a '…legislative delegation in favour of private

[577] D. Chalmers, 'Post-Nationalism and the Quest for Constitutional Substitutes' (2000) 27 (1) *Journal of Law and Society* 178, at 184.

[578] Ibid, 178–217. See also: G. Teubner, 'The King's Many Bodies: The Self-Destruction of Law's Hierarchy' (1997) 31 *Law & Society Review* 763, at 768.

[579] In the legal scholarship, the use of European standardisation for legislative purposes is regarded commonly as a system of delegated rule-making. See for instance Gestel and Micklitz, 'European Integration through Standardization' (n 63), 151, 177; Hofmann et al, 'Rule-Making by Private' (n 63). For a general conceptualisation of delegation to private parties see: Donnelly, *Delegation of Governmental Power to Private Parties* (n 63); for a contradicting view see: Joerges et al, 'The Law's Problems' (n 49).

standardisation bod[ies]'.[580] The Court, as opposed to the AG, called it a case of 'entrusting' the development of harmonised standards to private bodies.[581] The ECJ's wording leaves us wondering, if not delegation, what could be the mechanism through which the private bodies are 'entrusted' with the development of measures implementing an EU act?

To unpack the European standardisation system through the 'Delegation Framework' and consider the EU constitutional law requirements for the regulation and accountability of it, the remainder of this chapter is divided into the following sections. In section 2, I discuss the quasi-legal nature of the HESs and provide reasons to consider formally voluntary standards as delegated rules with legal effects. In section 3, the nature and rationale of delegation in the EU is sketched out. In section 4, the EU constitutional framework of delegation is outlined. This is done so as to place the cooperation between the EU institutions and ESOs within the different types of delegation, namely to agencies and private bodies. In section 5, the lawfulness of delegation to the ESOs in the light of Articles 290 and 291 TFEU and the current case law is considered. In section 6, I discuss whether the current system of the co-regulation via European standardisation is followed by the mechanism of legal accountability. Section 7 concludes the chapter.

5.2. A Harmonised European Standard—A Quasi-Legal Act?

The resemblance of standards to laws has been widely noted. Standards are called 'global law',[582] 'proto law' or the 'custom' that is immanent law.[583] In the *James Elliott* case,[584] the Court viewed HES as a 'necessary

[580] AG in C-613/14, *James Elliott* (n 219), para 55.

[581] Case C-613/14, *James Elliott* (n 60), para 43.

[582] G. Teubner, 'Global Bukowina: Legal Pluralism in the World-Society', in *Global Law Without a State* (Dartmouth 1997), 3–28.

[583] K. Webb, 'ISO 26000 Social Responsibility Standard as "Proto Law" and a New Form of Global Custom: Positioning ISO 26000 in the Emerging Transnational Regulatory Governance Rule Instrument Architecture' (2015) 6 (2) *Transnational Legal Theory*, 466–500.

[584] Case 613/14, *James Elliott* (n 60), para 43.

implementation measure'[585] forming part of EU law.[586] Consequently, this section argues that although the HESs are formally voluntary, they entail legal effects and have regulatory functions.

A standard is officially defined as 'a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory.'[587] Following this description, standards are not mandatory and cannot be enforced through law. However, standards can acquire mandatory force in the following three ways: by membership of the *association* issuing the standards; from the *state* (public authority) adopting these technical rules as legal acts; and through the *market*, e.g. when standards provide easier access to a market, these standards become de facto mandatory for business operators.[588]

Although, formally, the HESs have voluntary status, they still entail legal effects. This was confirmed by the Court in *James Elliott*, stating that the voluntary status of the HESs 'cannot call into question the existence of the legal effects of a harmonised standard.'[589] Below, the legal effects of the HESs *vis-à-vis* the National Standard Bodies (NSBs), the Member States and business operators are considered.

The HESs have legal effects for the NSBs similar to that which EU law has for the Member States. According to Regulation 1025/2012, the NSBs are obliged to 'withdraw conflicting national standards, to freeze national standardisation

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585 Ibid, para 43.

586 Ibid, para 34.

587 Regulation (EU) 1025/2012 (n 14), Article 2.

588 C. Lane, 'The Social Regulation of Inter-Firm Relations in Britain and Germany: Market Rules, Legal Norms and Technical Standards' (1997) 21 (2) *Cambridge Journal of Economics* 197. This article provides the above-mentioned classification of possible mandatory nature of standards. P. Westerman, 'Regulation and the Rule of Law' (2013) *Law Ukraine Legal Journal* 39. This article offers an illustration of de facto binding effects of standards followed. The Netherlands required that companies using harbour facilities took appropriate safety measures to prevent accidents during the loading and unloading of vessels. The legal provision was broad and did not set the certain ways to ensure safety, meaning that companies were free either to use ladders, gangways or comply in some other way. However, inspection drew up very detailed and precise standards specifying the size and location of escape routes. These standards were not legally binding and were considered costly. However, the companies spent 400 million euros together in order to comply with these 'non-binding standards since the companies regarded these standards as the only way of complying with the legislation and, hence, binding. Moreover, the companies believed that the conformity with these standards secured them from sanctions and future litigations.

589 Case C-613/14, *James Elliott* (n 60), para 42.

activities when a similar standard is under way at the EU level, and to refrain from publishing new or revised versions of the national standards that contradict an HES.'[590] Moreover, the NSBs have to give effect to an HES by transposing it as a national standard. The NSBs have this obligation due to their membership in the ESOs, in addition to the legal framework, i.e. Regulation 1025/2012, which aims to make the HESs effective.

Moreover, the HESs have binding consequences for the Member States too. Firstly, a Member State is under the obligation to respect the presumption of conformity, which the use of the HESs entails. Secondly, it is unlikely that a Member State can adopt a technical regulation or introduce new requirements for a product that contradict an HES.[591] Finally, the imposition of additional requirements on products that are covered by harmonised standards could lead to the infringement action under Article 258 TFEU against a pertinent Member State.[592]

Although the HESs are formally voluntary for business operators,[593] in practice this is questionable, for the following reasons. The public authority—the Commission—grants presumption of conformity to an HES by connecting it to a relevant directive[594] and publishing a reference to the HES in the official journal.[595] The products following the HESs benefit from the presumption of compliance with the legislative requirements.[596] Hence, compliance with the HESs provides an easier road for the CE marking. In its turn, the CE mark opens the internal market for business operators.[597] In the *Commission v*

[590] Regulation (EU) 1025/2012 (n 14), Article 3(6).

[591] A Member State intending to adopt a technical regulation is under the obligation to provide the Commission with a draft of that technical regulation, as to avoid the emergence of new technical barriers. From this, it follows that the Commission would not give the green light to a draft of national technical regulation, which is inconsistent with an HES. See: Directive (EU) 2015/1535 (n 153), Article 5.

[592] Case C-100/13, *Commission v Germany*, EU: C:2014:2293 (the case is available only in German and French), it is also referred in the case C-613/14, *James Elliott* (n 60), para 46. However, one could argue that this conclusion applies only and is specific to the construction products directive, which the case concerned.

[593] Regulation (EU) 1025/2012 (n 14), Article 2.

[594] By doing so, the Commission provides 'a quasi-legislative status to the output of European Standards organizations'. See: P. Delimatsis, 'Standardisation in Services: European Ambitions and Sectoral Realities' (2016) 41 (4) *European Law Review* 513, at 520 and 525.

[595] Regulation (EU) 1025/2012 (n 14), Article 10(6).

[596] Case 613/14, *James Elliott* (n 60), para 38.

[597] Compliance of goods with harmonised standards confers the reputation of certain quality. See: Case C-470/03, *A.G.M.-COS.MET Srl* (n 270) where the statements made by a state

Greece, the Court made clear that authority cannot reject a medical device which bears the CE mark.[598] The easiest way to obtain the CE mark is through compliance with the HESs. The goods following the HESs enjoy 'the ability to circulate, be placed on the market and to be used freely within the territory of all Members States of the European Union.'[599] Therefore, the business operators, in practice, have no choice but to comply with the HESs, as compliance with these standards affords legal and practical advantages particularly for companies engaged in cross-border trade. Such legal effects of the HESs is partially due to the legislative framework, as well as market acceptance; in other words, the success of the HESs makes them *de facto* mandatory.

In addition, as Schepel rightly notes, the General Product Safety Directive regarding the products following European standards as 'safe', ultimately, removes the separation between legal requirements and standards and makes the latter mandatory.[600]

Moreover, the HESs are not merely technical rules; they 'involve more than just implementation or concretization of political choices made by the Council and the Parliament.'[601] In many cases, the HESs replace the legal requirements. Especially where the legal requirements are drafted broadly, then the HESs provide detailed technical 'translations' of these legal requirements. Consider, for instance, the directive on machinery,[602] which sets out in general terms the essential health and safety requirements concerning the design and

official about the goods' (lifts') non-compliance with harmonised standard were considered to hinder the free movement of these goods.

598 Case C-489/06, *Commission v Hellenic Republic*, EU:C:2009:165.

599 Case 613/14, *James Elliott* (n 60), para 39.

600 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), 201; Directive 2001/95/EC on General Product Safety (n 18), Article 4(3), which reads: 'A product shall be presumed safe as far as the risks and risk categories covered by relevant national standards are concerned when it conforms to voluntary national standards transposing European standards, the references of which have been published by the Commission in the *Official Journal of the European Communities* in accordance with Article 4. The Member States shall publish the references of such national Standards'.

601 J. Mendes, 'Executive Rule-making: Procedures in between Constitutional Principles and Institutional Entrenchment', in C. Harlow, P. Leino-Sandberg, and G. della Cananea (eds), *Research Handbook in EU Administrative Law* (Edward Elgar 2017).

602 The European Parliament and the Council Directive 2006/42/EC of 17 May 2006 on machinery amending Directive 85/16/EC (recast) [2006] OJ L 157/24.

construction of machinery.[603] The Annex I of this directive lays down various essential requirements in a general manner. For example, the required characteristics of guards and protective devices read as follows:

The guards and protective devices must:

- - be securely held in place,
- not give rise to any additional hazard,
- not be easy to by-pass or render non-operational,
- be located at an adequate distance from the danger zone…[604]

This legal provision is the guiding frame for an ESO when drafting the relevant HESs for machinery. For instance, the harmonised standard EN 60335-2-77:2010 is developed to ensure compliance with the above-mentioned essential requirements, in particular, with the provision that protective devices must be located at an adequate distance. Consequently, this harmonised standard sets the limit of what counts as an adequate distance. It suggests that distance between the edge of the mobile cutting device and the rear wall of the cutting device enclosure must comply with the minimum distance of 120mm.[605] It follows that this harmonised standard functions as detailed legislation rather than as a purely technical rule, since it defines what can be considered as an 'adequate' distance to ensure the safety of a user of the lawn mowing machine.

The standard-setting clearly 'requires an estimate of acceptable levels of risk.'[606] Such assessment has an important ethical and political dimension alongside the technological considerations. The regulatory nature of the HESs in the context of New Approach strategy is clearly noticeable, as these standards harmonise technical specifications connected to public concern in the areas of health, safety, and environmental protection. In this way, regulatory standards differ from the purely economic regulation of rates and services and the standards in the latter context.

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[603] Ibid, Annex I, Essential Health and Safety Requirements Relating to the Design and Construction of Machinery.

[604] Ibid, provision 1.4.1.

[605] See Case T-474/15, *GGP Italy* (n 481). The latter case concerns the harmonised standards referred to in the text above.

[606] R.W. Hamilton, 'Prospects for the Nongovernmental Development of Regulatory Standards' (1982) 32 *American University Law Review* 455.

To summarise, HESs might be considered as quasi-legal acts forming part of EU law. Although they are privately adopted rules, these standards are requested, conditioned, 'assessed' and recognised by the public authority—that is, the Commission. Moreover, the HESs entail legal effects for the Member States, the NSBs and are even de facto mandatory for business operators. When it comes to the substance, the HESs are not purely technical rules, but rather regulate important aspects of public life. In turn, if the HESs are rules with legal effects and regulate essential parts of public life, the authority to develop these rules stems from the delegation of rule-making power from the EU institutions to the ESOs. Therefore, it is possible to view the development of the HESs as executive rule-making exercised by private bodies. This means that the quasi-legal status of the HESs is a precondition for the 'Delegation View', since only public authorities can adopt rules with legal effects that regulate public interest or delegate this task to non-governmental bodies such as the ESOs. This implies the existence of delegation of powers from the EU to the private ESOs, which is discussed below.

5.3. The Nature and Rationale of Delegation in the EU

Delegation is an inevitable process because the institutions constitutionally entrusted to perform particular public tasks are in most cases incapable of dealing with complex technical and scientific issues, in addition to lacking the resources needed to tackle them.[607] According to AG Mengozzi, 'delegation is not an obligation, but an instrument, or rather an option which the legislature may choose to employ in order to simplify and accelerate the regulatory process.'[608] Moreover, delegation makes it possible to utilise the expert knowledge of the agent and increases the efficiency of public policymaking.[609]

By means of delegation, administrative or specialised bodies exercise powers that actually belong to another body. Since the founding of the EU, the Treaties have explicitly recognised only one form of delegation, namely inter-institutional. The latter concerns the case of the delegation of power from the

[607] H.C.H. Hofmann, G.C. Rowe, and A.H. Türk, 'Delegation and European Union Constitutional Framework', in *Administrative Law and Policy of the European Union* (Oxford University Press 2011), 223.

[608] AG Mengozzi's opinion in Case C-88/14, *European Commission v European Parliament and Council*, ECLI: EU: C: 2015:304, para 31.

[609] Egan, 'Regulatory Strategies, Delegation and European Market Integration' (n 347).

Parliament and the Council to the Commission. However, delegating the rule-making power to the Commission is not sufficient to cope with the regulatory challenges facing the establishment and smooth functioning of the internal market.

To function well, the internal market requires the swift adoption of regulatory measures affecting the free movement of goods and services, and the establishment of rules on safety and consumer protection. In addition, these measures must deal with rapid technological developments.[610] Given these factors, the delegation of powers beyond the EU institutions and to the agencies and private bodies becomes inevitable. The delegation of rule-making power to private bodies, such as the ESOs, falls under this trend.

Although delegation of powers outside the formal institutions is often the result of non-functioning 'government', it requires the good government to function.[611] Meaning that an effective system of control and accountability over the delegated powers is necessary.

In its turn, the delegation doctrine can justify the exercise of certain powers by the specialised bodies. First of all, delegation doctrine prescribes the 'conditions under which it takes place and is used.'[612] Secondly, it links the exercise of delegated powers by specialised bodies to the will of the people.[613] Specifically, it demonstrates an unbroken chain going back to the principal-

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[610] X.A. Yataganas, 'Delegation of Regulatory Authority in the European Union: The Relevance of the American Model of Independent Agencies' (2001) 3/01 *Jean Monnet Working Paper*, 6.

[611] See: M. Taggart, 'From "Parliamentary Powers" to Privatization: The Chequered History of Delegated Legislation in the Twentieth Century' (2005) 55 (3) *University of Toronto Law Journal* 575. This article presents the fierce discussion that the delegation of parliamentary powers to the executive entailed in the context of the English government in the 1930s. It summarises the discussion between two prominent scholars of the time: Lords Hewart and Willis. The former saw the danger of compromising the rule of law, by allowing the executive bureaucrats to legislate. See: L. Hewart, *The New Despotism* (Ernest Benn Limited 1929). Hewart was dismayed at the delegation of legislative powers from parliament to governments. One of the concerns expressed by Hewart was that smart bureaucrats using the delegated power to enact the rules of so-called 'Parliamentary forms' can avoid judicial reach by inserting provisions limiting or negating judicial review. In contrast, Willis thought that delegation is inevitable and necessary in a welfare state that 'is to look after their subjects from the cradle to the grave'. He even argued that rules enacted through delegation should be immune from the judicial review. For more detailed discussion, see: J. Willis, *Parliamentary Powers of English Government Departments* (Harvard University Press 1933).

[612] Hofmann et al, 'Delegation and European Union Constitutional Framework' (n 607), 223.

[613] Ibid.

people, and also activates a mechanism for holding the ones entrusted with the task accountable.[614]

The so-called 'principal-agent' theory is often used to justify delegation and to explain its theoretical underpinning. According to this theory, it is possible to trace delegation from the principal—the people—to the legislature and from the legislature to administrative or private bodies.[615] The main principal delegates the powers or transfers authority to an agent. An agent who is unable to perform a particular task—in our case, technical harmonisation—delegates it further to a sub-agent, i.e. the ESOs.[616] The latter regulates the matter for the initial principal-people under the control of an agent—the legislature.[617]

However, as argued, the principal-agent theory has limited value in the context of the EU.[618] This is because of the multiplicity of the principals and agents in the EU legal order and especially the alternation of their roles depending on context. For instance, the EU itself is an agent, deriving its power from the Member States; whereas when it comes to the implementation and enforcement of EU law, the Member States are the agents of the EU.[619] Therefore, instead of the principal-agent theory, the legal requirements circumscribing the delegation of the powers in the EU are construed according to the special constitutional characteristics of the EU that are based on a 'carefully crafted institutional balance.'[620]

In sum, the increasing need for expert knowledge to tackle the regulatory challenges entailed resort to specialised private bodies such as the ESOs. The delegation doctrine explains and justifies the conferral of rule-making powers to private bodies. To do so, it provides the conditions for exercising delegated

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614 The prevalent political theory justifying and explaining delegation is principal-agent theory. See: Ibid, 223–4.

615 See: Egan, 'Regulatory Strategies, Delegation and European Market Integration' (n 347). According to Egan, this approach could be traced back to the work of A. Berle and G. Means, *The Modern Corporation and Private Property* (Macmillan 1932). There, the principal-agent theory was used to explain the role of delegation in the Firms.

616 R. Kiewit and M.D. McCubbins, *The Logic of Delegation* (University of Chicago Press 1991), 22–39.

617 Ibid.

618 D. Curtin, 'Holding (Quasi-)Autonomous EU Administrative Actors to Public Account' (2007) 13 (1) *European Law Journal* 523.

619 See: Hofmann et al, 'Delegation and European Union Constitutional Framework' (n 607), 224–45. The principle of institutional balance is discussed in more detail in the coming sections.

620 Ibid, 224.

powers and for holding a delegate to account, in addition to furnishing the rationale for delegating certain powers. The doctrine of the delegation of powers in the EU is shaped by the specific constitutional characteristics of the EU legal order, which are discussed below.

5.4. The EU Constitutional Framework of Delegation and the European Standardisation System

Here, the ESOs' rule-making power with respect to the HESs, as a result of delegation, is positioned within the EU's constitutional structure. To this end, I sketch out, on the one hand, the division of competences between the EU and the Member States, i.e. vertical power balance. On the other hand, I explain the allocation of powers horizontally, i.e. among the EU institutions or delegating institutional powers to agencies and private bodies. The focus of this section is on delegation of powers in the EU, i.e. from the EU institutions to agencies and private bodies, and it is unpacked according to Treaty provisions and the case law. In particular, the delegation of powers to the ESOs is addressed by reviewing the different types of delegation such as inter-institutional and outside the EU institutions, i.e. to agencies and private bodies. By doing so, the conditions applicable to the delegation of rule-making power to the ESOs are distilled, and the constitutional law concerns thereof are discussed.

In doing so, the specificities of the EU legal order that have a bearing on the delegation doctrine in the EU are identified. In addition, I briefly overview inter-institutional delegation since this is the only type of delegation that the Treaty recognises explicitly and for which it provides the conditions. However, the transfer of rule-making powers to the ESOs goes beyond the inter-institutional delegation and is close to delegation of powers to agencies. Therefore, similarities and differences between the agencies and the ESOs are also discussed. Consequently, I argue that the empowerment of the ESOs is distinct from the delegation of powers to agencies and is a form of private delegation. To maintain an unbroken chain with the Treaty provisions on the inter-institutional delegation, I suggest viewing the delegation of rule-making power to the ESOs as a sub-delegation, namely from the EU legislator to the Commission and from the latter to the ESOs.

The delegation of powers and its constitutional restrictions are important pillars of EU constitutional law. Unlike the state model, the EU is not based on

the separation of powers but on the separation of institutional powers.[621] However, the principle of institutional balance has in the Union system a role similar to the separation of powers in modern constitutional democracies.[622] Under the EU Treaties, each organ is vested with a specific power to exercise the tasks assigned to it and to represent their institutional interests. Therefore, the delegation of powers 'constitutes a break with the constitutionally established order of distribution of competences'[623] and poses a threat to 'a carefully crafted' institutional balance.

Understanding the constitutional character of the EU and its institutional structure is essential to the discussion on delegation. Despite diverging views on the EU's constitutional character, it is agreed that the EU Treaties 'display the minimal content of constitution,'[624] as the Treaties legalise political power. However, unlike other democratic constitutions, the Treaties lack legitimation from the *demos.* The powers of the EU do not derive directly from the people but are mediated through the Member States. This implies that private delegation to the ESOs is another layer in the complex system of delegation in which the EU exists.

In addition, portraying the EU as an order created in the absence of a *demos* undermines the legitimacy of delegation to private bodies which is usually substantiated by enhancement of participatory democracy.[625] However, the changes introduced by the Lisbon Treaty, i.e. inclusion of the title on democratic principles and the strengthened role of the European Parliament, heightens the democratic legitimacy of the EU.[626] Article 9 TEU makes clear that the Union is founded on the principle of representative democracy, through the European Parliament. The latter links the EU to the people.

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621 Ibid.

622 G. Majone, 'Delegation of Regulatory Powers in a Mixed Polity' (2002) 8 (3) *European Law Journal* 319, at 323.

623 Hofmann et al, 'Delegation and the European Union Constitutional Framework' (n 607), 225.

624 K. Lenaerts, 'The Constitution for Europe: Fiction or Reality?' (2005) 1 (11) *Columbia Journal of European Law* 465; A. Mads and J. Gardner, 'Introduction: Can Europe Have a Constitution?' (2011) 12 (1) *King's Law Journal* 1–4.

625 A. Follesdal, 'The Political Theory of the White Paper on Governance: Hidden and Fascinating' (2003) 9 (1) *European Public Law* 73.

626 In the Laeken declaration, it was agreed that there was a need to increase the democratic legitimacy of the Union and the transparency of its institutions. It was pointed out that bringing the EU's decision-making process into close association with the national parliaments would help to enhance the legitimacy of the European project.

Moreover, the principles of openness, transparency, and participation are connected with democracy at the Treaty level.[627] In addition, Article 11 TEU enhances participatory democracy by urging the EU institutions to take decisions in close association with citizens and complements representative democracy.

The EU has a unique institutional system[628] which differs from the classic example of *trias politica*. 'In the Community system the modes of governance and distribution of powers simply do not divide neatly into traditional constitutional categories—legislative, executive and judicial.'[629] In the EU, powers are distributed among the institutions established by the Treaties[630] and each of the institutions act within the limits of the powers conferred by the Treaties.[631] Particularly, it is the principle of conferral that governs the limits of the powers of the EU.[632] The very strict understanding of the principle of conferral excludes delegation. However, in exercising its own powers, institutions rely on each other and sometimes even delegate their tasks to other institution—the Commission or to bodies outside the institutional framework.

The inter-institutional delegation has existed in the EU from very early on.[633] Implementing powers have been delegated to the Commission and in exceptional cases to the Council. The Lisbon Treaty envisages only inter-institutional delegation. Particularly, Article 290 TFEU confers on the Commission the power to adopt delegated acts, while Article 291 TFEU delegates adoption of the implementing acts to the Commission only when common implementation at the EU level is required, since, generally, the task of implementing the EU law falls into the realm of the Member States.

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627 D. Curtin, H. Hofmann, and J. Mendes, 'Constitutionalising EU Executive Rule-Making Procedures: A Research Agenda' (2013) 19 (1) *European Law Journal* 1, at 5.

628 On the unique institutional structure of the EU see: J. Monnet, 'A Ferment of Change' (1963) 1 *Journal of Common Market Studies* 203.

629 P.L. Lindseth, 'Delegation is Dead, Long Live Delegation: Managing the Democratic Disconnect in the European Market-Polity', in C. Joerges and R. Dehousse (eds), *Good Governance in Europe's Integrated Market* (Oxford University Press 2002), 140.

630 J.P. Jacqué, 'The Principle of Institutional Balance' (2004) 41 (2) *Common Market Law Review* 383.

631 Article 5, paras 1 and 2, TEU.

632 Ibid.

633 The first management committee was established in 1962. The management committee procedure allowed the Commission to adopt the measures concerning agricultural management faster.

Although the Treaties do not provide rules concerning the delegation outside the institutional structure, delegation of power to agencies is a well-accepted practice in the EU. Moreover, the Court circumscribed the criteria for private delegation already in 1956, in the *Meroni* case.[634] Though much has changed since the *Meroni* judgment, it remains relevant to the discussion on the delegation of powers, as demonstrated by continuous reference to that case in the Court's subsequent rulings.[635]

5.4.1. The Co-regulation via European Standardisation in the Context of Vertical Distribution of Powers in the EU

The EU legal order is founded on and functions through the principle of conferral. Following the principle of conferral, the Union 'can act only within the limits of competences [which] are conferred upon it by the Member States'.[636] The division of competences laid down in the Treaties explains that the Member States and the EU share competences in the area of internal market.[637] Whereas the power to adopt measures for 'establishing and ensuring the functioning of the internal market' is conferred to the Union.[638] To this end, Article 114 TFEU empowers the European Parliament and the Council 'to adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.'

Following this power balance between the EU institutions and the Member States, the EU assumed the power to lay down the detailed legislative requirements from product to product under the so-called 'old approach'.[639] However, the difficulties of harmonising technical requirements through

634 Case 9/56, *Meroni v High Authority,* ECLI: EU:C:1958:7 (Meroni I).

635 The references to the *Meroni* case appear continuously in recent cases too. See inter alia: Case C-147/13, *Kingdom of Spain v Council of European Union;* ECLI:EU:C:2015:299, paras 49–56; Case C-146/13, *Kingdom of Spain v European Parliament and Council*, ECLI:EU:C:2015:298, paras 59–69 and 84, 87; Case C-270/12, *United Kingdom of Great Britain and Northern Ireland v European Parliament and Council* (*ESMA*), ECLI:EU:C:2014:18, paras 41–65 and 66.

636 Article 5(2) TEU.

637 Article 4(2)(a) TFEU.

638 Article 26 TFEU.

639 In 1968, the Commission proposed the General Programme for Technical Harmonisation, which had envisaged adoption of 150 Directives to eliminate technical barriers and harmonise product requirements. See discussion on this matter in Chapter 3 of this thesis.

legislative means forced the EU to resort to private rules—the HESs developed by the ESOs so as to harmonise technical requirements for products. This means that the power to establish rules for the proper functioning of the internal market conferred on the EU by the Member States is then delegated to the private bodies.

The legal framework enabling the Commission to request the ESOs to develop the HESs is Regulation 1025/2012. The legal basis of this Regulation is the above-mentioned Article 114 TFEU. However, it is contestable whether the provision that authorises the Council and the Parliament to lay down measures approximating the Member States laws also allows delegation of regulatory powers from the EU institutions to private bodies.

The Court made clear that Article 114 TFEU can be used by the EU legislator as a legal basis for a harmonisation act which 'genuinely [has as] its object the improvement of the conditions for the establishment and functioning of the internal market.'[640] The importance of European standardisation for the proper functioning of the internal market is reiterated in the recitals of the above-mentioned Regulation. It is stated that 'European standards play a very important role within the internal market.'[641] Moreover, 'standards produce significant positive economic effects, for example by promoting economic interpenetration on the internal market and encouraging the development of new and improved products or markets and improved supply conditions.'[642] Could these factors warrant the EU legislator to use Article 114 TFEU as a proper legal basis to entrust the ESOs with regulatory powers?

The Court has interpreted Article 114 broadly, giving the EU legislator the green light for the extensive use of this Article. Moreover, this provision has been used to establish new bodies or agencies. In the *ENISA* case,[643] the Court did not agree with the UK's allegation that Article 114 was not an appropriate legal basis to create the Union body and concluded that:

> […] The legislature may deem it necessary to provide for the establishment of a Community body responsible for contributing to the implementation of a process of harmonisation in situations where, in order to facilitate the uniform implementation and application of acts based on that provision, the adoption of

[640] See: Case C-376/98 *Germany v Parliament and Council* (*Tobacco Advertising*), ECLI:EU:C:2000:544, para 84.

[641] Regulation (EU) 1025/2012 (n 14), Recital 5.

[642] Ibid, Recital 3.

[643] Case C-217/04, *United Kingdom v Parliament and Council (ENISA),* ECLI:EU:C:2006:279.

> non-binding, supporting and framework measures seems appropriate. It must be emphasised, however, that the tasks conferred on such a body must be closely linked to the subject-matter of the acts approximating the laws, regulations and administrative provisions of the Member States.[644]

However, it is important to mention that the ESOs are not created by Regulation 1025/2012. Rather the latter Regulation, on the basis of Article 114 TFEU, provides a legal framework under which the EU institutions entrust the ESOs with the task of development of technical rules for implementing EU acts and harmonising product requirements.

It is not unheard of to use Article 114 TFEU as a legal basis to delegate to a Union body powers 'for the implementation of the harmonisation thought'.[645] As stated in *ESMA*, delegation of implementing powers for harmonisation purposes to the Union agency on the basis of Article 114 TFEU is allowed especially 'where the measures to be adopted are dependent on specific professional and technical expertise and the ability of such a body to respond swiftly and appropriately.'[646]

Following the Court's broad interpretation of Article 114, the latter can formally be regarded as a correct legal basis for Regulation 1025/2012, enabling the Commission to employ European standardisation for the purposes of harmonising requirements in the fields of products and services. Especially since European standardisation is regarded as one of the essential tools for establishing and maintaining the proper functioning of the internal market:

> [t]he European standardisation supports European legislation establishing the Single Market and contributes to increasing the competitiveness of European industry. The harmonisation of standards of products at European level

644 *ENISA* (Ibid), paras 44 and 45.

645 Ibid, para 105; see on Article 114 TFEU, P. Van Cleynenbreughel, 'Meroni Circumvented? Article 114 TFEU and EU Regulatory Agencies' (2014) 21 (1) *Maastricht Journal of European and Comparative Law* 64; See also Senden, 'The Constitutional Fit of European Standardisation Put to the Test Kluwer International' (n 385).

646 Case C-270/12*, ESMA* (n 635), para 105. In general, AG Jaäskinen in *ESMA* case also came to the similar conclusion that Article 114 TFEU could be a proper legal basis for the functions of ESMA in the context of approximation of the Member States' rules. However, according to AG, transferring the power to ESMA for adoption of special measures should have been based on Article 352 TFEU instead of 114.

> overcomes technical barriers to trade, which could be caused by conflicting national standards.[647]

However, on the other hand, it could also be contested whether entrusting private bodies such as the ESOs with regulatory tasks based on Article 114 is justified, especially since these bodies do not qualify as bodies, offices or agencies of the EU.[648]

5.4.2. Horizontal Distribution of Powers: The Principle of Institutional Balance and Inter-Institutional Delegation

In this section I explain the delegation in light of the horizontal power balance within the EU, i.e. the delegation of powers among the EU institutions. To start with, the principle of institutional balance is clarified. Although this principle is closely connected to the inter-institutional delegation, it is also guiding for any form of delegation, including the transfer of rule-making power to the ESOs.

The principle of institutional balance is omnipresent in EU constitutional discourse[649] and is a fundamental consideration in the delegation context. In the *Meroni* case,[650] for instance, the Court declared the delegation of discretionary powers to private bodies unlawful because it would upset the institutional balance. However, the wisdom of ascribing such significance to the principle of institutional balance has been debated. Some scholars hold that, like the separation of powers, the principle of institutional balance has

[647] Explanatory Memorandum of Proposal for a Regulation of the European Parliament and of the Council on European Standardisation and 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, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council, COM/2011/0315 final.

[648] See similar discussion in Senden, 'Constitutional Fit of European Standardisation Put to Test' (n 385).

[649] K. Lenaerts and A. Verhoeven, 'Institutional Balance as a Guarantee for Democracy in EU Governance', in C. Joerges and R. Dehousse, *Good Governance in Europe's Integrated Market* (Oxford University Press 2002).

[650] Case 9/56, *Meroni* (n 634).

constitutional value.[651] For others, this principle is an 'empty formula'[652] leaving a great deal of leeway for different interpretations by interested parties. Lenaerts rightly notes that 'as always, the truth lies probably in the middle.'[653]

The Court clarified the meaning and the function of the principle of institutional balance in the *Chernobyl* case.[654] Specifically, the principle of institutional balance requires from each institution in exercising its task to respect the powers of the other institutions and not infringe upon them.[655] According to Lenaerts, three key components of the principle of institutional balance can be traced in the Court's case law.[656] First, each institution shall enjoy sufficient independence to exercise its functions.[657] Second, institutions shall not unconditionally transfer and assign their powers to other institutions.[658] Third, institutions shall not encroach upon the powers of other institutions.[659] These components provide the important conditions for the delegation of power in the EU. Meaning that each institution can delegate only the powers with which it is vested and cannot extend its competence or impinge on the powers of other institutions through delegation.

The principle of institutional balance, as already mentioned, played an important role in the context of inter-institutional delegation. This form of delegation takes place through the transfer of implementing powers from the Council to the Commission. The Court allowed the adoption of implementing measures by the Commission, as long as this was not an essential element of a legislative act. What constituted an essential element was left to be defined at

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651 Lenaerts and Verhoeven, 'Institutional Balance as a Guarantee for Democracy in EU Governance' (n 649); E.U. Petersmann, 'Proposals for a New Constitution for the European Union: Building-blocks for a Constitutional Theory and Constitutional Law of the EU' (1995) 32 (5) *Common Market Law Review* 1123.

652 R. Bieber, 'The Settlement of Institutional Conflicts on the Basis of Article 4 of the EEC Treaty' (1984) 21 (3) *Common Market Law Review* 505, at 519.

653 Lenaerts and Verhoeven, 'Institutional Balance as a Guarantee for Democracy in EU Governance' (n 649), 35.

654 Case 70/88, *European Parliament v Council* (Chernobyl case), ECLI:EU:C:1991:373.

655 Ibid, para 22.

656 K. Lenaerts and P.V. Nuffel, in R. Bray (ed.), *Constitutional Law of the European Union* (Sweet and Maxwell 1999), 414.

657 Meaning that each institution shall organise its internal decision-making process according to the limits imposed by the Treaty. See: Case 5/85, *AKZ0 Chemie v Commission*, ECLI: EU:C:1986:328, paras 37–40.

658 Case 98/80, *Romano*, ECLI:EU:C:1981:104, para 20.

659 Case 25/70, *Einfuhrund Vorratsstelle Getreide v Köster*, ECLI:EU:C:1970:115, paras 8–9.

the political level, by a legislative act.[660] In his opinion in the *Romonta* case, AG Mengozzi reiterated that the essential elements of the legislative act must be adopted by the EU legislator and thus may not be delegated.[661]

The EU legislator cannot release itself from responsibility by delegating rule-making power to the Commission. A delegator bears political responsibility for the actions of a delegate and hence must establish an adequate system of supervision. To this end, the so-called 'comitology' mechanism was created—committees consisting of representatives of Member States.[662] These committees oversee the Commission's exercise of implementing powers delegated to it. The extent of control over the powers delegated to the Commission depends on the type of powers conferred on the Commission, particularly whether it is the power to enact delegated or implementing acts. The Parliament and the Council in accordance with Article 290 TFEU monitor the former type of delegation.

The effective functioning of comitology procedure and the possibility for the Council to intervene[663] justified the Commission's wide implementing powers. Although extensive implementing powers were tolerated in the agricultural sector,[664] a more limited right of the delegation was recognised in other sectors.[665]

In the *Romano* case, the Court[666] did not allow delegation of powers that would result in the adoption of acts with the force of law. The rationale for prohibiting the delegation of regulatory powers to the administrative commission established under EC secondary law was that the judicial system did not permit review of the acts of such a body, under Articles 173 and 177 (now 263 and

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660 See: Case C-156/93, *Parliament v Commission of the European Communities*, ECLI:EU:C:1995:238, para 18.

661 Opinion of AG Mengozzi in Cases C-540/14 P, C-551/14 P, C-564/14 P and C-565/14 P, *Romonta and others v Commission*, ECLI:EU:C:2016:147, para 38.

662 See: C.F. Bergström, *Comitology. Delegation of Powers in the European Union and the Committee System* (Oxford University Press 2005). This book discusses the comitology procedure and provides the history of it.

663 Case C-296 and 307/93, *French Republic and Ireland v Commission of the European Communities*, ECLI:EU:C:1996:65, paras 19–22.

664 See: Case 22/88, *Industrie-en Handelsonderneming Vreugdenhil BV and Gijs van der Kolk - Douane Expediteur BV v Minister van Landbouw en Visserij*, ECLI:EU:C:1989:277.

665 See: Case C-314/99 *Kingdom of the Netherlands v Commission of the European Communities,* ECLI:EU:C:2002:378.

666 Case 98/80, *Romano* (n 658), para 20.

267 TFEU).[667] This implies that powers delegated should, according to the Court, be subject to conditions of control similar to the ones it would have been if exercised by the delegator. Subjecting delegated powers to judicial review is thus an important requirement for the lawfulness of delegation. Especially since the Court is the guarantor of institutional balance.

The conferral of rule-making powers to the ESOs, which results in the adoption of the HESs with legal effects, goes against the doctrines provided by the *Romano* and *Meroni* cases. The standards developed by the ESOs that are not the bodies, offices, or agencies of the EU, can be left beyond judicial review. However, the recent *James Elliott* case changes the status quo. In this case, the Court regarded an HES as a provision of EU law and delivered a preliminary ruling interpreting a harmonised standard. This opens the Courts'[668] door for the privately developed HESs and can impact the legality of the delegation of rule-making power to the ESOs, as will be discussed in subsequent sections.[669]

To sum up, the principle of institutional balance is a fundamental consideration for the legality of the delegation of powers in the EU. It plays an important role especially in the inter-institutional delegation, which is different from the delegation of rule-making powers to private bodies. The former is controlled by the comitology procedure and judicial review. Similar mechanisms of control are not always present in the case of delegation outside the EU institutions.

5.4.3. Delegation to EU Agencies and European Standardisation Bodies: Similarities and Differences

Neither the institutional arrangements under the original Article 202 EC nor the current Articles 290 and 291 TFEU envisage delegation of rule-making power beyond the EU institutions. However, assigning tasks to agencies is common practice in the EU.[670] The rationale of delegating powers to agencies

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667 Ibid.

668 The Courts include both the Court of Justice and the General Court.

669 See: M. Medzmariashvili, 'Opening the ECJ's Door to Harmonised European Standards? (Opinion of the AG in C-61314 James Elliott Construction)', *European Blog Post*, <http://europeanlawblog.eu/2016/03/01/opening-the-ecjs-door-to-harmonised-european-standards-opinion-of-the-ag-in-c-61314-james-elliott-construction-2/>

670 See for instance, the following agencies and their functions: The European Food Safety Agency (EFSA) (see Articles 22–3, Reg (EC) No. 178/2002 of the European Parliament and of the Council of 28 Jan. 2002, laying down the general principles and requirements of food

is similar to that of involving the ESOs in the governance of the internal market. This section highlights the similarities and differences between the EU agencies and private ESOs. In doing so, the constitutional law challenges with the delegation of powers to the ESOs, as opposed to agencies, are underlined.

In the 1970s and 1980s, the first agencies emerged in the EU. Since then, the agencies in the EU landscape have mushroomed. They are entrusted with and perform different tasks,[671] from collecting information to adopting implementing acts or exercising implementing powers. Although Treaties refer to agencies in some instances, the definition of an agency is not given in the Treaties.[672] The secondary EU law refers to the agencies with different names, inter alia, 'centres', 'foundations', 'offices', 'agencies.'[673] The most common term also used by the EU institutions is an agency.[674]

Listing the common features of agencies helps to establish some sort of common definition of an agency. These bodies 'carry out technical, scientific or managerial tasks' that help to 'implement EU policies' and 'support

law, establishing the European Food Safety Authority and laying down procedures in matters of food safety) [2002] OJ (L 31), the European Medicines Agency (EMEA) (see Article 57; Reg. (EC) No. 726/2004 of the European Parliament and of the Council of 31 Mar. 2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency), the European Chemicals Agency (ECHA) (see Article 77, Reg. (EC) No. 1907/2006 of the European Parliament and of the Council of 18 Dec. 2006, concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Reg. (EEC) No. 793/93 and Commission Reg. (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC); and the Financial Supervisory Authorities (see Reg. (EU) 1093/2010 of the European Parliament and of the Council of 24 Nov. 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No. 716/2009/EC and repealing Commission Decision 2009/78/EC).

671 A classification of agencies and their activities are provided in E. Chiti, 'The Emergence of a Community Administration: The Case of European Agencies' (2000) 37 *Common Market Law Review* 309, at 315–17.

672 The following articles in the treaties refer to agencies. Article 9 TEU (democratic equality); Article 15 TFEU (Transparency); Article 16 TFEU (data protection); Article 24 TFEU (right to communication); Article 71 TFEU (Internal security); Articles 263, 265, 267 and 277 (judicial review); 298 TFEU (European administration); Article 235 TFEU (anti-fraud); The Charter also refers to agencies, see Articles 41, 42, 43, 51 and 52.

673 S. Grilles, 'Everything Under Control? The "Way Forward'' for European Agencies in the Footsteps of the Meroni Doctrine' (2010) 26 (1) *European Law Review* 3, at 7.

674 See for instance R. Lauwaars, 'Auxiliary Organs and Agencies in the EEC' (1979) 16 *Common Market Law Review* 365, at 368.

cooperation between the EU and national governments by pooling technical and specialist expertise from both the EU institutions and national authorities.'[675] In general, a European agency is '…a relatively independent, permanent body with legal personality, emanating from secondary Union law and charged with specific tasks'.[676]

The agencies were not entities envisaged by the European constitutions and EU Treaties. They were established due to pragmatic considerations, and 'their *modus operandi* was gradually developed…through imaginative legislation and innovative legal rulings.'[677] Nowadays, the Lisbon Treaty recognises[678] the EU agencies and lays down the fundamental principles for governing administrative powers.[679] Likewise, Regulation 1025/2012 recognises the ESOs as leading standardisation bodies in the field and provides the guiding principles for the standard-setting process.

The agencies were established because the development and implementation of some areas of EU law required technical expertise and specialisation.[680] The exact same rationale motivated the 'employment' of the ESOs for legislative purposes. The EU institutions use the expertise of the ESOs for the purposes of harmonising technical requirements for products, and now for services too.[681] The ESOs, like the EU agencies, were important for European market integration.[682] In short, the recourse to the ESOs is motivated and justified by

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675 See: <https://europa.eu/european-union/about-eu/agencies_en>; The typology of the agencies stems from the Commission Communication from 2002, 'The Operating Framework for the European Regulatory Agencies' COM (2002) 718.

676 Grilles, 'Everything Under Control? The "Way Forward" for European Agencies in the Footsteps of the Meroni Doctrine' (n 673), 7.

677 Yataganas, 'Delegation of Regulatory Authority in the European Union' (n 610), 38.

678 Article 298 TFEU.

679 The principles of transparency, independence and efficiency in decision-making as applied to the EU administrative power stems from the joint reading of Articles 298 TFEU and 41 of the Charter. Also, the acts of the agencies are subject to a judicial review; see Articles 263 TFEU.

680 M. Simoncini, 'The Erosion of Meroni Doctrine: The Case of the European Aviation Agency' (2015) 21 (2) *European Public Law* 309, at 310.

681 Regulation (EU) 1025/2012 (n 14), Article 1.

682 See H.C.H. Hofmann and A. Morini, 'Constitutional Aspects of the Pluralization of the EU Executive through "Agencification"' (2012) 37 *European Law Review* 419; P. Magnette, 'The Politics of Regulation in the European Union', in D. Gerardin, R. Muñoz, and N. Petit (eds), *Regulation through Agencies in the EU: A New Paradigm of European Governance* (Edward Elgar 2005), 3, at 7–10. (Here the need for agencies is presented from the

the similar reasons as the use of agencies. Some of the common rationales for using agencies and private bodies include their expertise in technical matters, independence vis-à-vis the executive power, ability to make decisions in closer association with civil society, and flexibility.[683]

Irrespective of the above-mentioned similarities,[684] there is a significant institutional difference between the agencies and the ESOs. More precisely, they differ in terms of their legal forms and links to the EU institutions. These differences affect the legal framework governing the agencies and the ESOs. In addition, it exacerbates the constitutional law problems with the delegation of rule-making power to the ESOs. These differences are discussed in turn.

In the EU legal order, the agencies are public bodies usually created by EU secondary legislation, i.e. an act of Parliament and Council, and have their own personality[685] and autonomous management board to exercise well-defined missions.[686] Unlike agencies, the ESOs are not established by a legislative act of the EU. Rather the ESOs are associations of national standard organisations created by a statute like any other private body.[687]

Moreover, all agencies are in one way or another attached to the Commission through the relevant Directorate-General.[688] The Commission has representatives in the management board of the agencies, while these boards

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perspective of the principal-agent approach). In addition to the agency system, the EU uses a shared method of administration with the national level in EU multilevel governance.

683 See: R. Baldwin and C. McCrudden, *Regulation and Public Law* (Weidenfeld and Nicolson 1987).

684 See: H. Abramson, 'A Fifth Branch of Government: The Private Regulators and Their Constitutionality' (1989) 16 *Hastings Constitutional Law Quarterly* 165. This article describes private regulators as 'fifth branch' of government, while the administrative agencies are the 'fourth branch'.

685 Council Regulation (EC) 58/2003 of 19 Dec. 2002 laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes, OJ 2003, L 11/1; see, in particular, Article 4.

686 On the website about 'Agencies of the EU' <www.europa.eu/agencies/index_en.htm> the Community agencies are defined as 'distinct bodies from the EU institutions—separate legal entities set up to perform specific tasks under EU law'. It is set up by an act of secondary legislation in order to accomplish a very specific technical, scientific or managerial task in the framework of the European Union.

687 See more on this in Chapter 4 of this thesis.

688 G. Permanand and E. Vos, 'Between Health and the Market: The Roles of the European Medicines Agency and European Food Safety Authority', *Maastricht Working Papers* 2008/4, 28.

pass their budget and elect their executive directors.[689] In contrast, the Commission observers in the ESOs are not members of managerial boards nor do they vote for drafts of the HESs.

In addition, the ESOs, contrary to the EU agencies, are not found to implement EU policy or to assist the Commission. Rather, the Commission establishes close ties with and harnesses the ESOs' activities for the purposes of market integration. But it must be stressed that the ESOs are not entirely dissociated from the EU institutional structure and legal order, especially during the development of an HES on the basis of a Commission mandate. In the latter case there is a functional similarity between the ESOs and the EU agencies. In particular, those ESOs, similar to the agencies are entrusted with a 'public service role' and are asked to 'translate political choices into action',[690] i.e. prepare an HES in response and according to the requirements of the Commission's mandate. It follows that from the functional perspective, the ESOs are close to the agencies. Where the ESOs act in response to the Commission's mandate, they are something in-between entirely private organisations and EU agencies.

From the institutional perspective, the EU agencies and ESOs could be distinguished by using planets and satellites as metaphors. Agencies function as satellites of the Commission or other institutions, because they are established by an EU legal act, and are attached to and operate within the realm of the EU institutions.[691] The ESOs, on the other hand, may be seen as planets, as they are not attached to the EU institutions and interact with them only sporadically.

The institutional differences between the agencies and the ESOs result in differences in mechanisms of accountability. In the national legal systems, agencies are mainly governed by administrative procedures prescribed by national law. At the EU level, a general administrative procedure act for EU institutions and agencies is missing, although the European Parliament has requested the Commission to submit a legislative proposal, for European law

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689 Ibid.

690 See Council Regulation (EC) 58/2003, Recitals 5 and 9, and Articles 4(1) and 6(1). In a similar manner, under Articles 8(1) and 10(1) of Regulation (EU) 1025/2012, it is the Commission that identifies strategic priorities and 'indicate(s) the European standards…that the Commission intends to request' and the 'Commission may within the limitations of the competences laid down in the Treaties, request' such standards.

691 The Commission, *Communication from the Commission on the Operating Framework for the European Agencies*, COM (2002) 718 final, Brussels, 11 December 2002.

of administrative procedure.[692] Meanwhile, an important development in holding the agencies legally accountable is the change introduced in Article 263 TFEU that subjects the acts of the agencies to judicial review. However, such a clear possibility does not exist in the case of the ESOs.

In sum, the delegation of powers to the agencies and the ESOs is underpinned by similar rationales and displays a similar functionality; however, these bodies are institutionally different. This difference also entails disparities in the mechanisms of holding the agencies and the ESOs legally accountable. Consequently, the lawfulness of delegation is influenced by the fact of who exercises the delegated power, i.e. agencies or the private bodies such as ESOs.

5.4.4. Delegation of Rule-making Power to Private Bodies: The Case of European Standardisation

The European standard-setting bodies, as explained above, are distinct from the EU agencies. They are neither EU institutions nor bodies; rather these ESOs are private, not-for-profit organisations. Consequently, mandating from these bodies adoption of the HESs falls within the framework of private delegation.

The delegation of rule-making powers to the private bodies in the EU legal order is a contested issue following the old case of *Meroni*. The importance of this case for discussion on the lawfulness of private delegation has been widely recognised in the legal scholarship and by the Court.[693] At the same time,

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[692] European Parliament, Resolution of 15 Jan. 2013 with recommendations to the Commission *on a Law of Administrative Procedure of the European Union,* 2012/2024. However, the Commission remains unconvinced about the need to codify administrative law. See also the European Law Institute (ELI) and the Research Network on EU Administrative Law (ReNEUAL) which conducted the joint project 'Towards Restatement and Best Practices Guidelines on EU administrative Procedural Law' and in accordance with the principles of the European Parliament resolution drafted model rules for an EU administrative procedure law. The details of the project are available at <www.reneual.eu>. See also: European Parliament resolution of 9 June 2016 for an open, efficient and independent European Union administration (2016/2610(RSP)). On the need for an EU administrative procedure law see: J. Ziller, 'Is a Law of Administrative Procedure for the Union Institutions Necessary? Introductory Remarks and Prospects' (2011) *Policy Department C: Citizens' Rights and Constitutional Affairs* (Brussels).

[693] Gestel and Micklitz, 'European Integration through standardization' (n 63), 151. See the recent cases citing Meroni: Case C-147/13, *Kingdom of Spain* (n 635), paras 49–56; Case C-146/13, *Kingdom of Spain* (n 635), paras 59–69, 84 and 87; Case C-270/12, *ESMA* (n 635), paras 41–65 and 66.

Tridimas questioned whether strict Meroni doctrine is still alive or whether the EU legislator has side-stepped this doctrine.[694] In contrast, for Micklitz and Van Gestel, *Meroni* is a guiding authority until the Court defines the boundaries of Article 290 TFEU in a standardisation context.[695]

The *Meroni* case[696] concerned the delegation of powers from the High Authority to private bodies. Specifically, the High Authority assigned the responsibility for administering the financial arrangements of the ferrous scrap scheme to two private law entities, with separate legal personalities. The purpose of this delegation was to stabilise community prices. In assessing the legality of this delegation, the Court first distinguished between the clearly defined executive powers and the delegation of discretionary powers and stated:

> A delegation of the first kind cannot appreciably alter the consequences involved in the exercise of the powers concerned, whereas a delegation of the second kind since it replaces the choices of the delegator by the choices of the delegate, brings about an actual transfer of responsibility.[697]

It follows that delegation of discretionary powers outside the EU institutions is not permitted[698] because it entails the transfer of responsibility which is not allowed under the EU Treaties and goes against the inviolable principle of the institutional balance.

The concerns about the lawfulness of the delegation of rule-making power to ESOs in light of *Meroni* criteria were raised since the conception of the New Approach strategy.[699] According to Hoffman, it is contestable whether the

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694 T. Tridimas, 'Community Agencies, Competition Law, and ECSB Initiatives on Securities Clearing and Settlement' (2009) 28 (1) *Yearbook of European Law* 216.

695 The discussion on delegation in light of the treaty requirements will be extended in the coming chapters of this thesis.

696 Case 9/56, *Meroni* (n 634).

697 Ibid, 152.

698 According to Chiti too, the *Meroni* case laid down the restrictive delegation doctrine that does not allow delegation of discretionary powers 'to EU "satellite" administrations'. See: E. Chiti, 'Is EU Administrative Law Failing in Some of its Crucial Tasks?' (2016) 22 (5) *European Law Journal* 576, at 589.

699 See: Röhling, *Überbetriebliche technische Normen als nichttarifäre Handelshemmnisse im Gemeinsamen Markt* (Koln 1972), 122–7, as cited in Falke and Joerges, 'The New Approach to Technical Harmonisation and Standards' (n 317); also: H. Hofmann, 'Legislation, Delegation and Implementation under the Treaty of Lisbon: Typology Meets Reality' (2009) 15 (4) *European Law Journal* 482, at 501–2; J. Falke, 'Achievements and Unresolved

drafting of the New Approach type directives—in which lawmaking powers are moved away from the Council and the European Parliament to the European Commission and in the end to private standard-setting bodies—is compatible with primary EU law.[700]

These constitutional concerns are twofold. Firstly, the task of standard-setting is sought to involve discretionary power, because the HESs are not merely technical rules but entail political judgments too.[701] Secondly, there is a lack of legal accountability in the form of administrative and judicial control over the standardisation process, i.e. the Commission is not responsible for the HESs, nor are the latter directly scrutinised by the Court.

Although the concerns about the lawfulness of delegation in the context of standardisation have been expressed widely, the Court has not ruled on this matter so far. One could say that the reason is that the Court has never been asked to do so. However, the ECJ has provided indirect support for a regulatory strategy of employing standardisation, in the *Cremonini* case.[702] Here, the ECJ urged a Member State to comply with the Low Voltage Directive using a reference to standards without questioning its legality, at least, *obiter dictum*.

Much has changed since the *Meroni* case, which was decided more than 50 years ago. Hence, in the next section, the lawfulness of delegation of rule-making power to the ESOs will be assessed in light of current developments at the legislative level and in case law.

Problems of European Standardisation: The Ingenuity of Practice and the Queries of Lawyers', in C. Joerges, K.-H. Lauder, and E. Vos (eds), *Integrating Scientific Expertise into Regulatory Decision Making: National Traditions and European Innovations* (Nomos 1997), 187.

[700] Hofmann, 'Legislation, Delegation and Implementation under the Treaty of Lisbon: Typology Meets Reality' (n 699), 501–2. It is argued that the Lisbon Treaty (Articles 290/291) does not take into account implementation through private contracts and agency regulations. See also the discussion on the legality of delegation in the case of standardisation in Falke, 'Achievements and Unresolved Problems of European Standardisation: The Ingenuity of Practice and the Queries of Lawyers' (n 699), 187.

[701] Schepel, *The Constitution of Private Governance* (n 111), 256.

[702] Case 815/79, *Cremonini & Vrankovic,* ECLI:EU:C:1980:273.

5.4.5. Delegation of Rule-Making Power to the ESOs as Sub-Delegation

As mentioned above, the Lisbon Treaty recognises only the inter-institutional delegation. More precisely, Article 290 TFEU deals with the delegation of rule-making power from the legislator to the Commission. Article 291 TFEU confers on the Commission the implementing powers where uniform conditions for the implementation of the EU act are necessary. At first glance, this leaves the delegation of rule-making tasks to the ESOs outside the Treaty framework. However, regarding it as a form of sub-delegation from the legislator to the Commission and from the latter to the ESOs enables an unbroken link with the Treaty provisions on delegation to be maintained.

According to Regulation 1025/2012 the Commission issues a mandate requesting an HES from the ESOs. The mandate is a Commission's implementing act.[703] By issuing an implementing act, the Commission delegates further to the ESOs the drafting of technical rules. According to Hofmann et al, it is beyond doubt that non-legislative acts envisaged by Articles 290 and 291 TFEU can lead to further delegation.[704] It follows then that the legislator, by adopting Regulation 1025/2012, delegates to the Commission the task of implementing the essential requirements of the directives, when necessary. To this end, the Commission is empowered to adopt an implementing act by virtue of which it delegates the task of writing detailed technical rules to the ESOs.[705] Conceiving the delegation of rule-making powers to the ESOs as a form of sub-delegation provides the invisible link with the Treaty provisions.

5.4.6. Section Conclusion

In this section, I have outlined the EU constitutional framework of delegation and applied it to the case of delegation via standardisation. During the course of this, I have explained that the Lisbon Treaty envisages explicitly only the inter-institutional delegation and does not provide clear boundaries for delegation outside the institutional framework. On the other hand, transferring

[703] See the discussion of this matter in Chapter 4 of this thesis.

[704] Hofmann et al, 'Delegation and the European Union Constitutional Framework' (n 607), 239–41.

[705] A similar view is shared by Senden, 'The Constitutional Fit of European Standardization Put to the Test' (n 385), 350. She describes it as a case of sub-delegation in the shadow of Article 291 TFEU.

powers to agencies is a very common practice in the EU. Similarly, the delegation of rule-making power to the ESOs was suggested to be functionally close to the empowerment of the agencies. However, the institutional differences between agencies and the private ESOs were also noted. In light of this, I have argued that the transfer of rule-making power to the ESOs is a clear case of private delegation which is even further from the institutional reach than delegation to agencies. Such private delegation could also be seen as a form of sub-delegation.

5.5. The Lawfulness of Delegation of Powers to the ESOs under Articles 290 and 291 TFEU and Beyond

Projecting the cooperation between the Commission and the ESOs through the 'Delegation Framework' opens Pandora's Box in terms of further constitutional concerns related to the constraint and control of delegated powers. The constitutional doctrine of the delegation of powers in the EU has long been dominated by the *Meroni* case, which had manifestly prohibited delegation of discretionary powers. However, the recent *ESMA* case seems to mellow the *Meroni* doctrine and seeks to strike an appropriate balance between legitimate delegation of powers and proper functioning of the internal market.[706] In addition, the Lisbon Treaty, in introducing the dichotomy between delegated and implementing acts, has updated the constitutional doctrine of the delegation of powers. Hence, in what follows, the lawfulness of delegation in the context of European standardisation is discussed in light of the current developments and is contrasted with the old but gold *Meroni* doctrine.

5.5.1. The HESs in the Constitutional Hierarchy of EU Legal Acts: Delegated or Implementing Acts?

The formal legal status of an HES under the hierarchy of EU legal acts remains obscure despite the fact that in *James Elliott* the Court called a harmonised

[706] J. Pelkmans, 'Mellowing Meroni: How ESMA Can Help to Build Single Market' (2014) *CEPS Commentaries*, <https://www.ceps.eu/publications/mellowing-meroni-how-esma-can-help-build-single-market>

standard a measure which by its 'nature implement(s) an act of EU law'.[707] In this section, I describe the delegated and implementing acts, attempt to distinguish them so as to consider the place of the HESs in the constitutional hierarchy of non-legislative acts, and argue that functionally the HESs are close to implementing acts.[708]

The Lisbon Treaty introduced the distinction between '*legislative* and *executive* delegation'.[709] The former allows the adoption of delegated acts while the latter grants the power to develop implementing acts. Before the Lisbon Treaty, Article 202 EC did not distinguish between the power to implement legislative acts at the EU level and the power to adopt non-essential elements thereof.

It is also true that the EU executive rule-making is not confined solely to delegated and implementing acts, but also includes 'all non-legislative acts of general application…that concretize the content of the Treaty provisions or legislative acts, defining the criteria for the regulation of specific cases.'[710] Still, this section considers the HESs in light of delegated or implementing acts in order to delineate the delegation via standardisation in the context of Articles 290 and 291 TFEU. These Articles establish a new system of delegation under the Lisbon Treaty, though the Court has not yet had the opportunity to define the boundaries of these Articles in the context of delegation via standardisation.[711]

The crucial limitation of the delegated rule-making is that it should not go so far as to affect the essential parts of a legislative act. The rationale for forbidding the legislative delegation is the constitutional principle of democracy, which requires that legislative power is exercised by a parliament

[707] Case C-613/14, *James Elliott* (n 60), paras 34 and 43.

[708] A similar reasoning is shared by Senden, 'The Constitutional Fit of European Standardization Put to the Test' (n 385), as well as by Tovo, 'The Judicial Review of Harmonized Standards' (n 385), 1196–7.

[709] P. Ponzano, 'The Reform of Comitology and Delegated Acts. An Executive's View', in C.F. Bergström and D. Ritleng, *Rulemaking by the European Commission* (Oxford University Press 2016), 43.

[710] Mendes, 'Executive Rule-making: Procedures in between Constitutional Principles and Institutional Entrenchment' (n 601).

[711] Gestel and Micklitz, 'European Integration through Standardization' (n 63), 151.

composed of elected representatives.[712] Prohibition of legislative delegation is the well-established principle of EU law and originates from the *Köster* case,[713] where the Court made clear that 'the basic elements' of the matter should be regulated by and preserved in the main legislative act.[714] It is due to this principle that Article 290 TFEU allows only the amendment of non-essential parts, while the core of a legislative act belongs to the inalienable domain of the Parliament. According to the Court, the essential elements of a legislative act encompass 'political choices falling within the responsibilities of the European Union.'[715] As Mendes rightly notes, the Court's reasoning in the *Schengen Borders Code* case does not imply that all political choices are left to the legislator; rather it is the EU legislator who decides what political choices are essential and what falls under its domain.[716] In *Europol*, the Court explained further that as long as the EU legislator has defined the objective and principles to guide the decisions adopted on the basis of a legislative act, it would not imply the delegation of 'political choices falling within the responsibilities of the European Union legislature.'[717]

It is not just the distinction between 'essential parts' and 'detailed practical rules' that is important for the lawfulness of delegation; so too is the distinction between delegated and implementing acts. Firstly, because the extent to which an institution can delegate rule-making power depends on whether it (usually the Commission) is entrusted to adopt the delegated or implementing acts. Secondly, the qualification of acts as delegated or implementing influences the type and extent of control that should be exercised over the delegated powers.[718] In other words, the European Parliament and the Council monitor

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[712] D. Ritleng, 'The Reserved Domain of the Legislature: The Notion of Essential Elements of an Area', in C.F. Bergström and D. Ritleng (eds), *Rulemaking by the European Commission: The New System for Delegation of Powers* (Oxford University Press 2016), 133–4.

[713] Case 25/70, *Köster* (n 659).

[714] Ibid, para 6.

[715] Case C-355/10 *Parliament v Council* EU:C:2015:516, para 65.

[716] See Mendes, 'Executive Rule-making: Procedures in between Constitutional Principles and Institutional Entrenchment' (n 601).

[717] Case C-363/14 *Parliament v Council* EU:2015:579, para 50.

[718] Delegation under Article 290 is controlled by the legislative branch, with equal control from the Parliament and the Council. Meanwhile, exercise of implementing power under Article 291 TFEU is controlled by the Member States. The latter is exercised through comitology procedure prescribed by Regulation (EU) 182/2011 (n 475). The comitology procedure functions through the committees with State representatives and is chaired by the Commission. The legislative branch monitors it by way of the Commission, which provides

the powers leading to the adoption of delegated acts directly,[719] while the powers resulting in the adoption of implementing acts are controlled by the Member States.[720]

However, drawing the line between delegated and implementing acts has remained an unresolved conundrum since the adoption of the Lisbon Treaty.[721] Nor was the rapidly developing case law able to resolve this complex issue. Below, the case law on delegated and implementing acts is analysed with the aim of considering the HESs in this light, as well as assessing the lawfulness of delegation via standardisation.

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to the Parliament and the Council the agendas of the meetings of such committees, draft acts and opinions thereof.

[719] Mendes rightly states that the control exercised by the Parliament is rather weak. It can either revoke delegation or veto it, but does not enjoy the power to modify the delegated acts. Also, the exercise of the Parliament's control demands high voting majority (majority of its component members). Mendes summarises the weaknesses of the control over the delegated acts as follows: 'Timely access to information', lack of 'personal and technical resources' and 'short timeframes to exercise oversight' hinder the effective control over the delegated acts. See: J. Mendes, 'The Making of Delegated and Implementing Acts: Legitimacy beyond Inter-Institutional Balances', in C.F. Bergström and D. Ritleng (eds), *Rulemaking by the EU Commission: The New System for Delegation of Powers* (Oxford University Press 2015). See also T. Christiansen and M. Dobbels, 'Delegated Powers and Inter-Institutional Relations in the EU after Lisbon: A Normative Assessment' (2013) 36 (6) *West European Politics* 1159.

[720] The mechanism to oversee the Commission's implementing power is laid down by the European Parliament and Council Regulation (EU) 182/2011 (n 475). This regulation envisages two types of procedures to control the Commission's implementing powers. These are examination and advisory procedures. The type of procedure depends on the scope and the field to which the measures adopted pertain.

[721] A. Alemanno, 'The Biocides Judgment: In Search of a New Chemistry for the Principle of EU Institutional Balance' (2014) European Law blog <http://europeanlawblog.eu/?p=2336> accessed 15 May 2016. Mendes also distinguishes these two types of acts on the basis of three criteria: First is the nature of the act, meaning that the delegated acts regulate legislative matters and are 'quasi-legislative' (as the Commission calls them, see: Commission Communication, 'Implementation of Article 290 of the Treaty on the Functioning of the European Union, COM (2009)', 673, at 3), while the implementing acts concern non-legislative matters which are close to executive measures; Second is functional differentiation between delegated and implementing acts, the former supplements and/or amends a legislative act, while the latter provides the uniform conditions for the implementation of a legislative act; Third is the different mechanism of control exercised: a) powers leading to adoption of the delegated acts are monitored by the Parliament and the Council, and b) the implementing acts are controlled through the comitology procedure, i.e. by the representatives of the Member State. See J. Mendes, 'Delegated and Implementing Rulemaking: Proceduralisation and Constitutional Design' (2013) 19 (1) *European Law Journal* 22.

The Lisbon Treaty provides a rudimentary distinction between delegated and implementing acts. 'The treaty defines a delegated act in terms of its content (i.e. "acts that supplement and amend non-essential elements of legislative acts")[722] and an implementing act in terms of its rationale'[723]—laying down 'uniform conditions for implementing legally binding Union acts.'[724] Article 290 states that the Council and the Parliament may delegate to the Commission the adoption of delegated acts, which may amend or supplement the non-essential parts of the legislative act.[725] AG Mengozzi has further elaborated on the notions of amending and supplementing a legislative act. According to him, a delegated act *amends* the legislative act when it makes formal changes to it.[726] The Court in the *Parliament and Council v Commission* case clarified further that 'amend' authorises the Commission 'to modify and repeal non-essential elements laid down by the legislature.'[727] While 'supplement' according to the Court means 'to authorise the Commission to flesh out the act…To develop in detail non-essential elements of the legislation in question that the legislature has not specified.'[728] In other words, to supplement implies that a delegated act complements the normative content of the non-essential part of a legislative act.[729]

Unlike delegated acts, implementing acts neither amend nor modify a legislative act.[730] The purpose of an implementing act is to provide the measures for the implementation of the legislative act. The task of adopting an

[722] Article 290 TFEU.

[723] K. Bradly, 'Delegation of Powers in the European Union, Political Problems, Legal Solutions', in C.F. Bergström and D. Ritleng (eds), *Rulemaking by the European Commission: The New System for Delegation of Powers* (Oxford University Press 2016), 77. See also T. Christiansen and M. Dobbels, 'Comitology and Delegated Acts after Lisbon: How the European Parliament Lost the Implementation Game' (2012) 16 *European Integration Online Papers*.

[724] Article 291 TFEU.

[725] Article 290 TFEU, para 1.

[726] AG Mengozzi's opinion in the Case 88/14*, Commission v Parliament and Council* (n 608).

[727] Case C-286/14, *European Parliament and Council v European Commission*, ECLI:EU:C:2016:183, para 42.

[728] Ibid, para 41.

[729] AG opinion in Case C-88/14 (n 608).

[730] Joined Cases C-78/16 and C-79/16*, Giovanni Pesce and Others v Presidenza del Consiglio dei Ministri - Dipartimento della Protezione Civile and Others*, ECLI:EU:C:2016:428, para 46.

implementing act is delegated to the Commission when the uniform conditions for implementation of Union-binding acts are required.[731]

The Court made the first attempt to distinguish between delegated and implementing acts in the *Biocides* case.[732] In this case, the Commission requested the annulment of Article 80 of Regulation 528/2010, concerning the fees payable to the European Chemical Agency. This Article conferred upon the Commission the power to adopt those fees through an implementing act, instead of a delegated act. The Commission contested this choice. Whereas, the Court made clear that it is the EU legislator who has discretion to make a choice between delegated and implementing acts, and the Court will be deferential to this choice.[733]

At the outset, the Court noted that Article 291 TFEU does not provide the definition of an implementing act, which ought, therefore, to be defined in relation to the concept of the delegated act.[734] To do so, the Court contrasted two concepts—delegated and implementing acts—and their legal natures with one another. According to the Court, the purpose of a delegated act is 'to achieve the adoption of rules coming within the regulatory framework',[735] while the implementing act just provides further details to the legislative framework so as to ensure its uniform implementation.[736]

After examining the normative framework relevant to the case at hand, the Court came to the conclusion that deciding on the fee payable is an implementing act, since it does not supplement 'certain non-essential elements of that legislative act but provides further detail to the normative content of the act.'[737]

According to the Court, then, delegated and implementing acts are mutually exclusive types of non-legislative act. The distinguishing factor is whether an act supplements the non-essential parts of the legislative act or provides further details to it. However, this distinction seems problematic since it is difficult, perhaps even impossible, to distinguish sharply between situations in which

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[731] In duly justified specific cases and in the cases provided by Articles 24 and 26 of the TEU, the adoption of the implementing acts is entrusted to the Council. See: Article 291 TFEU.

[732] Case C-427/12, *Commission v Parliament & Council, (Biocides),* ECLI:EU:C:2014:170.

[733] Ibid, para 40.

[734] Ibid, para 33.

[735] Ibid, para 38.

[736] Ibid, para 39.

[737] Ibid, para 52.

further details are provided without supplementing and situations in which supplementing does not involve providing further details.[738]

The distinction between the delegated and implementing acts was further discussed in *Commission v European Parliament and the Council*.[739] In this case, the Court faced the task of defining the concept of a delegated act. The case concerned a specific Article of Regulation 1289/2013 on reciprocal measures against third-country nationals. That Article envisaged adoption of delegated acts by the Commission while amending Annex II to the Regulation by inserting a footnote suspending the visa exemption for third-country nationals. The Commission contested the choice of the legislator and argued that the powers delegated were to adopt the implementing act instead of the delegated act.

The Court ruled that the lawfulness of the legislators' choice to confer the delegated powers on the Commission rests on two criteria. The acts to be adopted on the basis of the conferral are a) of general application, and b) intended to amend or supplement the non-essential parts of a legislative act.[740] The Court explained further that 'amending' means having an effect on the normative content of the non-essential elements of the legislative act.[741] This was explained by AG Mengozzi in more detail. He opined that an amendment to the legislative act that does not affect an entire body of legal provisions does not appear 'to require legislative delegation since it does not alter the *legislative elements* of the act.'[742]

In light of the combined reading of the two cases above, the following conclusions can be drawn. The concept of an implementing act covers acts that provide further details to the legislative act, without modifying or affecting its normative content. A delegated act, by contrast, amends or supplements a legislative act by affecting the normative content of the non-essential parts of the legislative acts.

Following this qualification, it is obvious that deciding whether the HESs are delegated or implementing acts depends on whether an HES supplements and

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[738] See: Bergström, *Comitology: Delegation of Powers in the European Union and the Committee System* (n 662), 356–7, 359–60; Mendes, 'The Making of Delegated and Implementing Acts' (n 719).

[739] Case C-88/14, *Commission v European Parliament and the Council,* ECLI:EU:C:2015:499.

[740] Ibid, para 32.

[741] Ibid, para 42.

[742] AG opinion in Case C-88/14 (n 608), para 46.

amends or provides further details to a legislative act.[743] In the former case, an HES would have an impact on the normative content of a legislative act. In the latter case, an HES simply would provide further details to the legislative requirements for purposes of uniform application. Keeping in mind that HESs are used to harmonise technical requirements, i.e. 'give concrete form (to the legislative act) on a technical level'[744] and, by so doing, ensure the uniform application of the essential requirements, the HESs clearly fall under the category of implementing acts. Moreover, the power to adopt a technical standard for harmonisation of technical specifications is conferred on the ESOs by a mandate which is an implementing act of the Commission. A mandate is adopted in the form of an implementing act in accordance with the comitology procedure laid down by Regulation 182/2011 providing the Member State control over the Commission's implementing power.[745]

However, the formula derived from the case law requires an assessment of the relationship between an act adopted through delegation and the normative content of a legislative act. Consequently, conceiving the HESs as implementing acts would also require specifying the 'self-standingness' of the essential requirements of a directive, since the 'self-standingness' of the essential requirements decreases the chances that the HESs will affect or modify the normative content of a legislative act.

Can it be inferred, *a contrario*, that when HESs affect the normative content of the legislative act, they should be qualified as delegated acts? Not necessarily. The HESs are adopted to provide the technical means of enforcing the essential requirements and are connected to the essential parts of the legislation. However, according to Article 290 TFEU, delegated acts can only supplement or amend the non-essential elements of a legislative act. Even more, if the HESs were to affect the essential parts of the legislative act, this would amount to an unlawful delegation of legislative power. However, it is impossible to generalise an answer to this question, because the answer will depend on the distinction between the essential and non-essential parts of a

[743] One could also object that the HESs cannot be considered as delegated or implementing acts envisaged by Articles 290 and 291 TFEU, because they are not formally adopted by the Commission. As opposed to this view, the Commission's decision to publish references to the HESs and grant the status of the harmonised standards could be seen as a formal adoption of these standards. Especially so, given that the Commission's decisions to (not) publish the references are susceptible to judicial review. See the discussion of this in Chapter 7 of this thesis.

[744] Case C-613/14, *James Elliott* (n 60), para 36.

[745] See the detailed overview of the process of adopting a mandate in Chapter 4 of this thesis.

legislative act. This distinction will most likely be clarified over the course of political practice[746] and decided on a case-by-case basis.[747] In the Court's words, to establish what amounts to an essential part requires '[taking] account of the characteristics and particularities of the domain concerned.'[748] According to Mendes, these harmonised standards 'convey the distinction between the realms of law making, where essential requirements are set, and the realm of technical stipulations'.[749]

In brief, the relation of the HESs to legislative acts determines not only whether they should be regarded as implementing or delegated acts, but also whether transferring such a rule-making power to the ESOs amounts to an unlawful delegation. This is because where the HESs would affect the normative content of a legislative act, with a high probability, this effect would be on the essential parts of a legislative act. Consequently, it would amount to a conferral of legislative powers which is not permitted in the EU.[750] On the other hand, the HESs generally, by their very function, resemble the implementing acts, as they provide detailed technical rules for the uniform implementation of the legislative acts, as well as being developed pursuant to the Commission's mandate, which in its turn is an implementing act.

At the same time, it is equally possible to argue that the rule-making powers are conferred on the ESOs directly, and as such are not confined by Articles 290 and 291 TFEU.[751] The Court in the *ESMA* case[752] found that Articles 290 and 291 TFEU do not form the closed and single framework of the delegation

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[746] Craig argues that the Court should take the non-essential requirement of Article 290 TFEU more seriously in developing the non-delegation doctrine. However, he is very sceptical that the Court would be ready to do so. See: P. Craig, 'The Role of the European Parliament under the Lisbon Treaty', in S. Griller and J. Ziller (eds), *The Lisbon Treaty: EU Constitutionalism Without a Constitutional Treaty?* (Springer 2008), 109–34. See also: W. Voermans, 'The New EU Delegation System under the Treaty of Lisbon' (2011) 17 (2) *European Public Law* 313–30.

[747] Ritleng, 'The Reserved Domain of the Legislature: The Notion of 'Essential Elements of an Area' (n 712), 154.

[748] Case C-355/10 *European Parliament v Council* (n 715), para 68.

[749] Mendes, 'Executive Rule-making: Procedures in between Constitutional Principles and Institutional Entrenchment' (n 601).

[750] See: Case 25/70, *Köster* (n 659); Article 290 TFEU confers the powers to modify only *non-essential* parts of the legislative act.

[751] For instance, in the recent Case C-521/15, *Spain v Council* EU:C:2017:982, para 43, the Court found that '…acts of Secondary legislation may establish implementing powers outside the regime laid down in Article 291 TFEU'.

[752] Case C-270/12, *ESMA* (n 635), ECLI:EU:C:2014:18.

and that the systemic reading of the Treaties permits the delegation of powers outside the EU institutions. These issues are discussed below.

5.5.2. The Legislative Use of European Standardisation—A Lawful Delegation?

This section analyses the lawfulness of delegation of a rule-making power to the ESOs. In doing so, I contrast the doctrine derived from the *Meroni* and *Romano* cases with the recent *ESMA* case and the delegation framework provided by Articles 290 and 291 TFEU. Finally, I argue that the recent developments at the legislative level[753] and in the case law—particularly a new constitutional doctrine of delegation[754] derived from *ESMA*—have the potential to put the co-regulation via European standardisation at ease with the EU constitutional law requirements.[755]

The *Romano* case prohibits delegation of powers leading to the adoption of rules of general application outside the EU institutions. Consequently, the ESOs that adopt the HESs, whose application is general, and which have legal effects, are in conflict with the *Romano* doctrine. However, the latter case did not explain whether an act with legal force includes only legislative acts[756] or also legal acts of a quasi-legislative nature.

For its part, the *Meroni* case prohibited the delegation of discretionary powers and demanded the exercise of administrative and judicial control over delegated powers. This was based on the rationale that a delegation of wide discretionary power would upset the institutional balance.[757] However, the *Meroni* criteria have hardly ever been used for invalidating delegation, either because all cases challenged have satisfied these requirements[758] (which is

[753] The legislative development here refers to the adoption of Regulation (EU) 1025/2012 (n 14).

[754] See detailed analysis of the ESMA case in D. Adamski, 'The ESMA Doctrine: A Constitutional Revolution and the Economics of Delegation' (2014) 39 (6) *European Law Review* 812.

[755] Some parts of this section coincide with the prior publication of: Medzmariashvili, 'Delegation of Rulemaking Power to European Standards Organisations' (n 385).

[756] C.F. Bergström, 'Shaping the New System for Delegation of Powers to EU Agencies: United Kingdom v. European Parliament and Council (Short selling)' (2015) 52 (1) *Common Market Law Review* 219, 221.

[757] Case 9/56 and 10/56, *Meroni* (n 634), 173.

[758] See e.g. Case cases C-154/04 and C-154/04, *R (Alliance for Natural Health and Another) v Secretary of State for Health*, ECLI:EU:C:2005:449, paras 90–2. In this case, the delegation

highly unlikely), or because the Court's scrutiny was not strict enough. Nonetheless, the CJEU remained faithful to the *Meroni* doctrine prohibiting unequivocally delegation of wide discretionary powers. At the same time, the EU experienced a proliferation of the agencies typically exercising discretionary powers.

Some scholars have put forward arguments against strict constitutional boundaries of delegation established by *Meroni* and *Romano*,[759] as not corresponding to the changing economic and political reality, as well as undermining effective interaction between 'agencification' and the internal market.[760] Against this background, *ESMA* represents the process of mellowing *Meroni* doctrine and striking the appropriate balance between the legitimate delegation of powers and the proper functioning of the internal market.[761]

The *ESMA* case[762] concerned the annulment action brought by the UK against Regulation 236/2012. This regulation empowered the European Securities and Market Authority (ESMA), an agency created by EU secondary law, to adopt the legally binding measures under certain circumstances—namely when there is a threat to the orderly functioning or stability of the European financial market.[763] The UK argued that ESMA was vested with powers that could not be so delegated under EU constitutional law. Articles 290 and 291 TFEU permit only the delegation of powers to the Commission. Thus, the empowerment of ESMA to adopt measures of general application was alleged to be illegal. Furthermore, according to the UK, ESMA was entrusted with discretionary powers leading to the adoption of rules of general application, counter to the doctrine of the *Meroni* and *Romano* cases.

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was found to be lawful, since the powers delegated to the Commission were strictly limited by objective criteria.

[759] M. Chamon, 'EU Agencies: Does the Meroni Doctrine Make Sense?' (2010) 17 (3) *Maastricht Journal of European Comparative Law* 281; Yataganas, 'Delegation of Regulatory Authority in the European Union' (n 610); D. Geradin, 'The Development of European Regulatory Agencies: What the EU Should Learn from American Experience' (2004) 11 *Columbia Journal of European Law* 1; J.P. Schneider, 'A Common Framework for Decentralized EU Agencies and the Meroni Doctrine' (2009) 61 *Administrative Law Review* 29.

[760] Adamski, 'The ESMA Doctrine: A Constitutional Revolution and the Economics of Delegation' (n 754), 815.

[761] Pelkmans, 'Mellowing Meroni: How ESMA Can Help to Build Single Market' (n 706).

[762] Case C-270/12, *ESMA* (n 635).

[763] Ibid.

The Court disagreed with all the arguments put forward by the UK. Firstly, it started by recalling the *Meroni* case and emphasised a difference between these two cases stemming from the facts. This means that in *Meroni* delegated powers were conferred to the private bodies, governed by private law, while in the case at hand it was the EU agency. Although the ECJ did not explain the importance of this factual difference, one could argue that perhaps the lawfulness of delegation to the private bodies should be more strictly overseen as opposed to the EU agencies that are closer to the institutional framework of the EU.

Adjudicating in this case, the ECJ ruled that Articles 290 and 291 TFEU do not provide a closed system of delegation and that the Treaties recognise indirectly a right of delegation of powers outside EU institutions.[764] Since the contested Article delegated the power directly to the ESMA and not to the Commission, the Court found that this situation did not correspond to the regime established under Articles 290 and 291 TFEU. The legality of the delegation beyond the system of delegated and implementing acts was sought through the systematic interpretation of the Treaties, particularly of Articles 263, 265, 267 and 277 TFEU.[765]

The Court ruled that 'while the treaties do not contain any provision to the effect that powers may be conferred on a Union body, office or agency, a number of provisions in the FEU Treaty none the less presuppose that such a possibility exists.'[766] Firstly, the acts of bodies, offices, and agencies can be annulled (Article 263); secondly, these bodies, offices, and agencies can be sued for failure to act (Article 265); thirdly, the Court can give preliminary rulings on the interpretation and validity of the acts of such bodies (Article 267); and finally, these acts can be the object of a plea of illegality (Article 277).[767] In light of these findings, the Court reached the conclusion that delegation of powers to agencies resulting in the adoption of acts of general application is allowed since the Lisbon Treaty provides the mechanism of judicial control over these acts.

Moreover, although discretionary powers were conferred on ESMA, such delegation was regarded as lawful since it aimed to utilise the 'specific

[764] Ibid, paras 79–86.

[765] Ibid, paras 84–5.

[766] Ibid, para 79.

[767] Ibid, para 80.

technical and professional expertise' of this agency.[768] The European Parliament offered a similar argument, to the effect that conferral of powers 'which require specific technical expertise' and, moreover, 'are determined by professional, technical or scientific consideration', is allowed.[769] The rationale of the Court and the Parliament echoes the *Meroni II* case, where the Court stated that delegation to bodies and agencies outside the EU institutions is allowed, if it concerns technical aspects, does not include broad discretion, and is subject to the same control mechanisms as it would have been if exercised by the delegator.[770] A similar line of reasoning can easily be extended to the case of employing the ESOs for legislative purposes.

After analysing the legal framework at stake, the Court found that ESMA's powers, even if discretionary, were delineated by the legislation. In addition, the powers available to ESMA were amenable to judicial review. To demonstrate this, the Court stressed the fact that ESMA is an EU entity; thus, its acts are subject to judicial review.

Consequently, the *ESMA* case mellowed the *Meroni* doctrine, in the sense that the Court permitted the delegation of limited discretionary powers, on condition that it is subject to judicial review. By doing so, it tried to strike a balance between the benefits and drawbacks of delegation. Pertinently, the Court permitted delegation of discretionary powers as ESMA had specific technical expertise in the field,[771] and this expertise was necessary for the functioning of the internal market.[772] Finally, the Court's insistence on availability of judicial control could be seen as a way to mitigate the adverse effects of delegating the discretionary powers to the independent agencies. The limitation of delegated powers is usually rationalised as the means to constrain the losses of delegation, such as an agent defecting. However, it is clear that the Court in *ESMA* prefers legal accountability in the form of judicial review as a mechanism to mitigate the adverse sides of delegation, over the outright

[768] Ibid, paras 82, 102–5. The Court in *ESMA* recalled the Case C-66/04, *United Kingdom v Parliament and Council (Smoke Flavourings)* and Case C-217/04, *ENISA* (and stated that where 'the measures to be adopted are dependent on specific professional and technical expertise' and the body adopting a measure has 'ability to respond swiftly and appropriately'.

[769] Case C-270/12, *ESMA* (n 635), para 72.

[770] Case 10/56, *Meroni* II, ECLI:EU:C:1958:8.

[771] Case C-270/12, *ESMA* (n 635), para 105.

[772] Ibid, para 116.

limit of delegated powers.[773] Whether a judicial review could be an appropriate mechanism of accountability to mitigate such losses is another issue. But it is indisputable that control over the delegated powers followed with the principles of participation and transparency would be better '…to guarantee the fairness, consistency and impartiality of decision-making.'[774]

In light of the updated constitutional doctrine of delegation stemming from *ESMA*, delegated powers should be 'precisely delineated and amenable to judicial review.'[775] It follows then that for the co-regulation via European standardisation to remain within the frame of lawful delegation, two conditions must be satisfied: 1) The discretion left to the ESOs should be delineated by a legislative act or a Commission mandate; and 2) The acts of the ESOs (i.e. the HESs) should be subject to judicial review. The existence of judicial review over the delegated powers is a necessary component for the lawfulness of delegation of powers to the ESOs. However, unlike ESMA, which is an EU agency created by EU law, the ESOs are private bodies whose acts are not *per se* judicially reviewable. Counter to this, the present thesis argues, in the next chapter, that there is a possibility of judicial review of the European standardisation system, though it is not apparent at first glance.

To conclude, contrasting the *Meroni* and *Romano* doctrine with the more recent *ESMA* case, and applying these findings to the delegation via European standardisation, reveals that the existence of judicial control is the fundamental condition for the lawfulness of such delegation. As a result, the crux of the constitutionality of using private bodies—the ESOs—for regulating areas of public concern—such as health, safety, and environment—lies in legal accountability in the form of judicial review.

5.6. The Mechanism of Control and Accountability in the European Standardisation System

As discussed above, EU constitutional law sets the conditions and constraints of delegated rule-making. More precisely, the mechanism of control over delegated powers is a necessary condition for the lawfulness of delegation. As

[773] Adamski, 'The ESMA Doctrine: A Constitutional Revolution and the Economics of Delegation' (n 754), 818.

[774] Ibid.

[775] Case C-270/12, *ESMA* (n 635), para 53.

such, it is not surprising that the AG Sanchez-Bordona, in his opinion to the recent *James Elliott* case, qualified the relationship between the Commission and ESOs as 'controlled legislative delegation in favour of a private standardisation body.'[776] The AG chose these words consciously—'controlled delegation'—so as to make it appear that delegation of powers to the ESOs follows the constitutional requirements of administrative and judicial control.

Although the Court did not use the same wording, it still stressed the Commission's role in the development of the HESs in order to show that tasks exercised by the ESOs are delineated and controlled. According to the Court, the Commission plays an important role in the process of adopting the HESs. In particular, it issues a mandate, approves the ESOs' work programme adopted for the development of the HESs, decides on the compliance of the draft HES with the mandate, and finally confers the legal effects to an HES.[777]

In light of the foregoing, we need to examine whether the delegation of rule-making power to the ESOs is constrained by the mechanism of control and accountability. To begin with, it should be noted that the development of HESs is not monitored through the comitology procedure. In addition, the Court's jurisdiction to review the harmonised standards in an annulment action is open to discussion. However, this still does not mean that there is no control whatsoever over the powers exercised by the ESOs.

5.6.1. *Ex-ante* Control: Participation in and Transparency and Openness of the European Standardisation Process

In this section, application of the principles of participation and transparency to the European standardisation process is discussed, as the former are as *ex-ante* mechanisms of legal accountability, as well as essential elements of legitimate standardisation.

The Lisbon Treaty constitutionalised the principles on participation and transparency, applicable to the EU rule-making.[778] These principles serve as an 'overarching normative frame of reference that ought to shape both Union norms and practices.'[779] According to Mendes, they should be present not only

[776] AG Opinion in Case C-613/14, *James Elliott* (n 219), para 55.

[777] Case C-613/14, *James Elliott* (n 60).

[778] See Articles 10 and 11 TEU.

[779] Mendes, 'Delegated and Implementing Rulemaking: Proceduralisation and Constitutional Design' (n 721), 26.

in the legislative and administrative activities, but also in the context of regulatory activities, notwithstanding the locus of governance.[780] However, they do not, strictly speaking, constrain the rule-making in the private bodies such as the ESOs, but the application of these principles to European standardisation is provided via Regulation 1025/2012.[781] In addition, according to the 2003 Interinstitutional Agreement on Better Law-Making, both self- and co-regulation should meet the principles of transparency and participation.[782]

Under the heading of *ex-ante* control, the procedural principles constraining the EU executive rule-making are discussed, and their application to the standardisation by virtue of Regulation 1025/2012 is considered. Constraining the standard-setting procedure by the principles of participation, transparency, and openness has an impact on a substantive outcome of this process. As demonstrated by the Horizontal Guidelines in competition law, the standardisation, which follows these procedural principles, falls under the safe harbour rules and could be immune from the application of competition law.[783] Meaning that adherence to the principles of transparency, participation, and openness is a guarantor of delivering standards that do not harm competition in the market.[784]

Moreover, adherence to these procedural principles in the process of standard-setting is important since the latter type of private rule-making lacks direct electoral control; additionally, its *ex-post* accountability, in the form of judicial

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[780] Mendes, 'EU Law and Global Regulatory Regimes' (n 504), 1016.

[781] Regulation (EU) 1025/2012 (n 14), Recital 2, which announces that the 'ESOs are founded on the principles recognized by WTO in the field of standardisation, namely coherence, transparency, openness, consensus, voluntary application, independence from special interests and efficiency'.

[782] Interinstitutional Agreement on Better Law-Making (2003) (n 39), para 17. However, it is less likely that the principles of transparency and participation as enshrined in better lawmaking or better regulation packages could become a stand-alone ground on which to challenge the standardisation judicially. See on the better regulation as a sole ground for challenging judicially the regulatory tools the following contributions: W. Voermans and Y. Schuurmans, 'Better Regulation by Appeal' (2011) 17 (3) *European Public Law* 507; A. Alemanno, 'A Meeting of Minds on Impact Assessment' (2011) 17 (3) *European Public Law* 485.

[783] Commission, Communication (2011/C 11/01) from the Commission of 14 January 2011, Guidelines on the Application of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Co-operation Agreements, (Horizontal Guidelines), OJ C 11/1.

[784] See: Discussion on the adherence to these procedural principles in the standardisation process granting immunity from competition law in Chapter 6 of this thesis.

review, remains uncertain.[785] One of the many concerns over the use of standards to regulate areas of public concern—such as health, safety, and environment—is that these rules are not products of the democratic process. The common image of standard-setting is a process of rule-making dominated by engineers and experts, exercised behind the closed doors. Moreover, the standards organisations are 'result driven rather than created to protect various minority or societal interests, such as consumer protection'.[786] The dominant fear is that business interests can prevail over societal needs. Therefore, the increased use of and reliance on standards in the process of governance requires changes in the process of standard-setting itself.

To start with, let us consider the relevance of the participation principle for the European standardisation process. Participation is a prevalent principle in not only the EU formal lawmaking process, but also the governance process.[787] That said, there is no general EU legal provision that provides a participation requirement for all types of rule-making procedures.[788] Article 11 TEU, which sets out the participation principle, is concerned with the activities of the EU intuitions and does not impose this principle on all types of rule-making. As it stands now, the participation requirement is materialised by virtue of the specific legislative provisions of each sector. For instance, Regulation 1025/2012 encourages participation of small and medium-sized businesses, as well as stakeholder organisations in the process of standard-setting.[789] The importance of participation—especially of SMEs alongside stakeholder organisations—is reiterated in the *Joint Initiative on Standardisation*, set up under the Single Market Strategy.[790]

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[785] Mendes, 'EU Law and Global Regulatory Regimes' (n 504). See also on the need to proceduralise the Commission's soft post-legislative rule-making, as to counterbalance the lack of judicial review of such measures, in L. Senden, 'Soft Post-Legislative Rulemaking: A Time for More Stringent Control' (2013) 19 (1) *European Law Journal* 57, at 72.

[786] Lundqvist, 'The Governance and Institutional Structure', in *Standardization under EU Competition Rules and US Antitrust Laws* (n 146), 145.

[787] J. Mendes, 'Participation in Rule-making: European Union', in J-B. Auby (ed.), *Comparative Law of Administrative Procedure* (Bruylant 2016).

[788] Ibid.

[789] Regulation (EU) 1025/2012 (n 14), Article 5.

[790] Joint Initiative on Standardization under the Single Market Strategy (2016) <http://ec.europa.eu/growth/content/joint-initiative-standardisation-responding-changing-marketplace-0_en> accessed 1 March 2019. However, this document does not create any legal commitments and it sets out the frame for voluntary collaboration in the context of standardisation policy. This document does not enhance the participation principle in standardisation any more than as already provided in Regulation 102/2012.

Although, in general, the legal character of participation remains vague,[791] it is usually regarded as a prospect of taking part in the decision-making process and encompasses participation of both public entities and interest holders.[792] Participation itself cannot guarantee the best outcome in respect of a measure to be adopted, but it 'creates the conditions to avoid biased, possibly self-interested, acts that deny material justice.'[793]

Participation in the regulatory process might have two different aims that, while not mutually exclusive, entail different types of participatory rights. Participation could strive to either protect affected interests or promote participatory democracy.[794] Meaning that, in the former case, encouraging participation aims to ensure the consideration of affected interests, guarantee 'evidenced-based policy making', and uphold the rule of law.[795] This is especially true in light of technical complexities that regulatory process might face. By virtue of participation, the regulatees—who in most cases are better equipped with the information needed for the adequate decision—can assist evidence-based decision-making. By doing so, participation ensures responsive regulation, i.e. regulation that is in line with the needs of the regulated sector.[796]

The Interinstitutional Agreement from 2016 promotes such rationale of participation in the context of lawmaking: 'Public and stakeholder consultation

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[791] J. Mendes, 'Rule of Law and Participation: A Normative Analysis of Internationalized Rulemaking as Composite Procedure' (2014) 12 (2) *International Journal of Constitutional Law* 370, at 379.

[792] J. Mendes, 'Participation and Participation Rights in EU law and Governance', in H. Hofmann and A. Türk (eds), *Legal Challenges in EU Administrative Law* (Edward Elgar 2009), 257, at 258.

[793] Mendes, 'Rule of Law and Participation: A Normative Analysis of Internationalized Rulemaking as Composite Procedure' (n 791), 387.

[794] Mendes, 'Delegated and Implementing Rulemaking: Proceduralisation and Constitutional Design' (n 721). See also J. Mendes, 'Administrative Procedure, Administrative Democracy', in J-B. Auby (ed.), *Comparative Law of Administrative Procedure* (Bruylant 2016).

[795] Mendes, 'The Making of Delegated and Implementing Acts' (n 719). The Commission regards the stakeholder participation in the context of better regulation agenda as a way to ensure that policies are based on the best evidence available. See: The Commission Communication, 'Better regulation for better results: An EU Agenda' COM (2015) 215 final, at 4. On the link between rule of law and participation principle see: Mendes, 'Rule of Law and Participation: A Normative Analysis of Internationalized Rulemaking as Composite Procedure' (n 791).

[796] Mendes, 'Participation and Participation Rights in EU law and Governance' (n 792), 259.

is integral to well informed decision-making and to improving the quality of law-making…'.[797] Similarly, the better regulation guidelines on participation read as follows: parties consulted involve those 'who will be directly impacted by policy', and in doing so, it can 'avoid problems later and promote greater acceptance of the policy initiation/intervention.'[798] In their turn, through participation, the interest holders have the chance to influence the decision-making process and to protect and defend their respective interests.

Another element of participation is to enhance democracy in the rule-making process. Article 11 TEU, due to the link it establishes between participation and democracy, manifests the democratic feature of the participation principle.[799] In order to enhance participatory democracy, according to Mendes, the right to participation should be given in such a way as to enable access to the process to all interested parties ('giving them a voice').[800] Furthermore, equal opportunities to influence an outcome should be provided,[801] in order to compensate for any power imbalance between different groups that makes the equal realisation of participatory rights difficult in practice.

In the context of standard-setting, the participation requirement ought to be a double-edged sword—upholding the rule of law and addressing the lack of democratic legitimacy. However, the provisions of Regulation 1025/2012 concerning participation and inclusiveness seem to be driven by a rationale of responsive regulation. Meaning that participation of interest groups is regarded as the way to address the affected interests and ensure high acceptance of these standards, without much attention given to the democratic rationale behind participation.[802]

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[797] Interinstitutional Agreement on Better Law-Making of 13 April 2016, OJ L 123/1, para 19.

[798] Commission Staff Working Document, Better Regulation Guidelines COM (2015) 215 final, 63–4.

[799] J. Mendes, 'Participation and the Role of Law After Lisbon: A Legal View on Article 11 TEU' (2011) 48 (6) *Common Market Law Review* 1849. See also Mendes, 'Rule of Law and Participation: A Normative Analysis of Internationalized Rulemaking as Composite Procedure' (n 791). Here Mendes suggests that participation could provide democratic legitimation to regulatory regimes especially in the absence of traditional mechanisms of control.

[800] Mendes, 'Participation and the Role of Law After Lisbon' (n 799), 1863.

[801] Ibid, 1862.

[802] Regulation (EU) 1025/2012 (n 14), Recitals 20 and 21, as well as Articles 6 and 12, especially stress the importance of the participation of SMEs and stakeholder organisations throughout the standardisation process to develop market relevant standards. See: Joint

Regulation 1025/2012 tries to address the concerns about the inclusiveness of the standardisation process and requires stakeholder involvement in the standard-setting. However, this requirement is soft, as far as the language of Regulation is concerned. That is, it asks the European and national standards bodies to 'encourage' and 'facilitate' participation, and to guarantee that stakeholders have 'the opportunity' to submit comments.[803] Whereas, at the national level, the standard-setting bodies are asked to facilitate SMEs' participation by granting, for instance, free membership or free access to a draft of a standard. In addition, the national standard-setting bodies are required to send a report to their European counterparts about how successfully they have fulfilled this obligation.[804]

The need to hear the 'voice' of society in the process of standardisation, which in many different ways influences vital aspects of our daily life, is commonly accepted. The establishment of the European Association for the Co-ordination of Consumer Representations in Standardisation (ANEC)[805] in 1992 marked the shift towards a more inclusive and open standardisation process. ANEC is an independent body representing consumers' interests in the standard-setting. However, ANEC lacks any formal institutional status within the new approach strategy.

To aid the interest groups with access to the standardisation process, Regulation 1025/2012 envisages some financial support. Specifically, Annex III to this Regulation lays down the criteria for the European stakeholder organisations that can qualify for union financing. One such organisation is the European Environmental Citizen's Association for Standardisation (ECOS),[806] which mainly represents the environmental interests in the standardisation.

Although Regulation 1025/2012 indeed 'encourages' an inclusive and transparent standardisation process, as well as stakeholder involvement, the realisation of this remains in the hands of standards bodies. Without a clear mechanism through which to enforce the principles of openness, transparency, and participation in the standard-setting, the wording of Regulation 1025/2012

Initiative on Standardisation under the Single Market Strategy (2016), Annex, Action 6: Improve the exchange of information and dialogue with industry through the standards market relevance roundtable (SMARRT).

803 Regulation (EU) 1025/2012 (n 14), Articles 5 and 6.

804 Ibid, Article 6.

805 See ANEC functions and mission at <https://www.anec.eu/>

806 See ECOS functions and mission at <http://ecostandard.org/>

about more inclusive standardisation could remain as mere window-dressing.[807] Especially since Regulation 1025/2012 does not confer any strong legal status to the groups representing stakeholder interests in the standardisation process. The result is that these groups are not members of the ESOs, and as such, they cannot vote for a draft version of the standard nor can they object to its adoption.[808] The European Environmental Citizen's Organisation for Standardisation (ECOS), while commenting on the adoption of Regulation 102572012, expressed concerns that 'the system does not…guarantee such effective participation of societal stakeholders, neither at European nor national level' and urged for 'a truly inclusive and transparent standards setting process which delivers standards reflecting societal and environmental interests most appropriately.'[809]

The realisation of the participation requirement will remain impossible if the process of standard-setting is not transparent. The principle of transparency is a 'newcomer among general principles'[810] of EU law. However, according to Lenaerts, the status of transparency as being a general principle can no longer

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[807] The main Environmental stakeholder organisation participating in standardisation process (ECOS), reviewing the requirements concerning participation laid down by Regulation 1025/2012 remarks: 'ECOS regrets that the system does not currently guarantee such effective participation of societal stakeholders, neither at European nor national level. Supported by its 38-member organizations, ECOS advocates for a truly inclusive and transparent standards setting process which delivers standards reflecting societal and environmental interests most appropriately', <http://ecostandard.org/about-standards-2-2/> accessed 27 June 2017. The EU Parliament too urges the Commission to 'ensure the removal of the de facto obstacles [so as to guarantee the effective involvement of stakeholder organisations, namely Annex III organisations] in standardisation'. See: European Parliament, 'Resolutions of 4 July 2017 on European Standards for the 21st Century (2016/2274 (INI))', recommendations 11, 71–4.

[808] Regulation (EU) 1025/2012 (n 14), Recital 23. See: ECOS, 'The Future of European Standardization. ECOS Recommendation for a Transparent and Inclusive Standardisation System, that can Affectively Support EU Legislation and Policy', 6 July 2015. It is also notable that CEN and CENELEC have recently granted a 'right to opinion' to three organisations representing consumers, environment and trade unions, respectively: ANEC, ECOS and ETUC. These bodies can now, from 1 January 2017, express 'favourable' or 'not favourable' opinions during the standardisation process. However, an opinion does not equate to a voting right, but supposedly it should trigger reactions from the technical committee developing a pertinent standard. See information at: <http://ecostandard.org/right-of-opinion-a-major-step-towards-more-inclusiveness-in-standardisation/> accessed 20 August 2017.

[809] See: ECOS's website: <http://ecostandard.org/category/standardisation-and-policy/>.

[810] A. Ericsson, 'The Structural Guarantees: The Union's Last Best Hope against National Arbitrariness' (2010) *Europarättslig tids*, 247.

be denied.[811] Transparency—'a visible mark of democracy'[812]—entails the opportunity to observe the rule-making procedure. It follows then that transparency is a component of participation, the latter implying the possibility to participate in rule-making.[813] Both transparency and participation in their turn are crucial for the openness of administration[814] and similarly to an open standard-setting procedure.

The principles of transparency and openness are closely intertwined, since without transparency it is hard to imagine how one could achieve the goal of openness. At the same time, they both strive to promote good governance. Article 15(1) TFEU states: 'in order to promote good governance and ensure the participation of civil society, the Union institution, bodies, offices and agencies shall conduct their work as openly as possible.' Although this principle has a constitutional nature for EU rule-making, it cannot by virtue of the above-mentioned Article be extended to the process of standard-setting, since the ESOs are not EU entities. However, Regualtion1025/2012 lays down the requirement of transparency and openness for the ESOs and, thus, makes these principles applicable to the standard-setting process.

Due to the close link between transparency and participation, they are grouped together in Regulation 1025/2012, under section II—Transparency and Stakeholder Participation. Transparency, a component of participation, requires that parties interested in taking part in the standard-setting process have access to the relevant information, such as what is an agenda, what is standardised, when will it take place, access to a draft version of a standard, and so on. To this end, Regulation 1025/2012 requires the transparency and exchange of yearly standardisation programmes among the standard-setting bodies at both the EU and national level, and the same applies to the draft of a standard.[815] Although this requirement is mainly targeted at disseminating information among standardisation organisations, it also requires access to the draft of a standard for the relevant parties. But to claim that standardisation is an entirely open process, entailing access to standards, would be incorrect,

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[811] K. Lenaerts, 'In the Union We Trust: Trust-enhancing principles of Community Law' (2004) 41 *Common Market Law Review* 317, at 321f.

[812] Opinion of AG Bot in Cases C-203/08, *Betfair*, and C-258/08, *Ladbrokes*, ECLI:EU:C:2009:791, para 170.

[813] D. Curtin, H. Hofmann, and J. Mendes, 'Constitutionalising EU Executive Rule-Making Procedures: A Research Agenda' (2013) 19 (1) *European Law Journal* 1, at 6.

[814] Ibid, 10.

[815] Regulation (EU) 1025/2012 (n 14), Articles 3 and 4.

especially given that the standards are subject to copyright and only accessible for a fee.[816]

It is true that, nowadays, standardisation is no longer a closed activity; however, the representation of stakeholder interests remains weak, especially if one keeps in mind the fact that consumer and environmental organisations which want to steer the standardisation process have to cope with the expertise and resources of business operators of the relevant industry directed to the standardisation process.[817] There is still much to be improved in terms of the transparency, inclusiveness, and openness of the standardisation process. On the one hand, constraining private regulation-standardisation, through public law requirements, can ensure that European standardisers are committed to public goals.[818] In turn, a more open, transparent, and inclusive standardisation process is the price that private standardisers should pay for officially recognising their standards as tools for compliance with legislative requirements. On the other hand, in view of the current standardisation process that offers weak *ex-ante* remedies having a bearing on the input legitimacy of such rule-making, the need for legal accountability in the form of judicial review is even more apparent.

5.6.2. Administrative Control of the European Standardisation System

Regulation 1025/2012 codified the administrative control over the process of developing the HESs, as well as the legal effects of these standards. As it stands now, the Commission delineates and exercises control over delegated powers to the ESOs at different instances—namely during the process of preparing a mandate, and before and after the publication of a reference to an HES in the official journal.

The initial control of the content of an HES is exercised by the Commission in a form of a mandate. The latter circumscribes the content of the HES and prompts the exercise of delegated powers. The mandate in its turn is subject to

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[816] See the discussion on the copyright protection of standards in Chapter 4 of this thesis.

[817] This conclusion is not based on any empirical research conducted by the author, but is derived from looking at the wording of Regulation (EU) 1025/2012 (n 14) concerning the guarantees of participation and transparency provided therein.

[818] See J. Freeman, 'Extending Public Accountability Through Privatization: From Public Law to Publicization', in M.W. Bowdle (ed.), *Public Accountability: Designs, Dilemmas and Experiences* (Cambridge University Press 2006), 83–111.

a comitology control. According to Regulation 1025/2012, the Commission's mandate is an implementing act, which is adopted according to the procedure prescribed by Regulation 182/2011. More precisely, the Commission consults the Committee represented by the Member States before adopting a mandate. If the Committee gives a negative opinion, the Commission either appeals the decision to the Appeals Committee or submits a new version of the mandate within two months.

Upon acceptance of the mandate, the process of drafting the HES is overseen by the Commission with the help of New Approach consultants. They are independent experts appointed by CEN and CENELEC in consultation with the Commission and EFTA. Although they are not directly answerable to the Commission, these consultants provide information to the Commission on the preparation of a standard. The main task of the New Approach consultants is to ensure that the HESs comply with the essential requirements and the relevant mandate. However, the consultants do not decide what technical requirements should be included in the standard.[819]

The consultants are involved in the standardisation process from the very beginning and provide comments on the compatibility of a draft standard at each stage of the process, starting from establishing a work programme by the technical body, up until the formal voting on a draft of the HES. Negative comments from the consultants result in suspension of further proceedings. In that case, a new version of the draft standard must be prepared.[820] However, if a consultant and a technical body cannot agree on how to address the concerns, the technical board gets involved. It is important to stress that the consultants do not have a veto right. Moreover, the technical body is not obliged to adopt all suggestions provided by a consultant. To compensate for this, there is a second level of control to check the compatibility of a standard with the essential requirements.[821] In particular, before publishing a reference to an HES in the official journal, the Commission is entitled, together with the help of consultants, to check whether 'a harmonized standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation'.[822] However, in practice, the Commission hardly ever reviews the compliance of the HESs with the essential

[819] See CEN-CENELEC guide 15, 2014, section 3: Role and profile of consultants.

[820] Ibid.

[821] Ibid.

[822] Regulation (EU) 1025/2012 (n 14), Article 10(6).

requirements and usually rubber stamps these standards.[823] This fact itself highlights and stresses the need for judicial review over the process of standardisation.

At the stage of publication of a reference to the HESs, the European Parliament and the Member States can also get involved and object to it.[824] The control framework over the HESs, particularly its compatibility with essential requirements, does not stop at the point of publishing the reference to the harmonised standards in the official journal. Regulation 1025/2012 provides the mechanism of *ex-post* control that can be deployed by the Member States and the European Parliament. According to Article 11 of Regulation 1025/2012, the Commission can take a decision to withdraw a reference to the HESs and end presumption of compliance provided by the HES upon the application from a Member State. This *ex-post* control commonly known as a 'safeguard clause' was enshrined in each New Approach directive.[825]

Before Regulation 1025/2012 the safeguard clause was activated by either the Commission or a Member State, and the European Parliament was left outside this system. Following the objections from the Member State or the Commission, the so-called '98/34 Committee' would have been asked to intervene[826] which in turn would have consulted the relevant standardisation body (Article R9(1)(2) of Decision 768/2008)[827] and deliver the opinion about the compliance of the content of the HESs with the essential requirements. Consequently, it was the Commission that would decide on the basis of the above-mentioned opinion to maintain, to maintain with restriction, or to withdraw the references to the HESs concerned from the official journal of the European Union.[828]

With the introduction of Regulation 1025/2012 *ex-ante* and *ex-post* control mechanisms over the references to the HESs have been clearly distinguished.

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[823] See Schepel, *The Constitution of Private Governance* (n 111), 235. Commission, Guidelines of 6 April 2005 on the publication of references to standards in the official journal, which states that 'the Commission should not review the technical adequacy of the content of a standards' (D(2005) C2/MJE/IG –D (2005) 7049).

[824] Regulation (EU) 1025/2012 (n 14), Article 11.

[825] Decision 768/2008/EC (n 54), Annex I, Article R9. The latter Article requires from each New Approach directive to envisage such a safeguard clause.

[826] This was usually a Committee comprised of experts and advisers appointed by the Member States and chaired by the representative from the Commission.

[827] Decisions 768/2008/EC (n 54).

[828] Ibid, Annex I, Article R9(2).

The control prior to the publication of the reference is, firstly, in the hands of the Commission which assesses the compliance of the HESs with the essential requirements, and secondly, the Member States and the European Parliament which can object to its publication. After publication of the reference, the Commission is no longer entitled to challenge this reference. Instead the maintenance of the references to the HESs is subject to the objects from the European Parliament and the Member States. In addition, the *ex-ante* and *ex-post* control mechanisms entail different modes of comitology procedure[829] as prescribed by Comitology Regulation.[830]

It is clear that Regulation 1025/2012 introduced more comprehensive administrative control over the legal effects of the HESs, but whether it provides sufficient control remains an open question. This is especially the case since societal groups that are directly affected by the standards are excluded from this administrative procedure. For instance, neither business operators nor environmental or consumer associations can trigger the *ex-ante* or *ex-post* control mechanisms discussed above. The only avenue left open to them is to convince their Member States to initiate the objections to the HESs. Also, the ultimate decisions about publishing or not, maintaining or revoking the references to the HESs after assessing their compliance with the essential requirements is made by the Commission, which itself admits that it is in possession of limited resources and expertise on this matter.[831] In light of this, the importance of judicial review over the standardisation process in undeniable and it remains for us to discuss whether judicial review of the European standardisation system is available, such that it can satisfy the EU constitutional requirements of lawful delegation.

5.6.3. Judicial Review of the European Standardisation System

The case law on judicial review of the process or the products of European standardisation is sparse.[832] At first glance, the HESs are less likely to be subject to judicial control, since they are private, voluntary rules, while ESOs adopting these standards are not agencies or bodies of the EU. However, the

[829] See Article 11 in combination with Article 22 of Regulation 1025/2012 that in its turn refers to Articles 4 and 5 of Regulation (EU) 182/2011 (n 475).

[830] Regulation 182/2011 (n 475).

[831] Commission Communication enhancing the implementation of the New Approach directive, Com (2003) 240, 21.

[832] This is discussed in more detail in Chapter 7 of this thesis.

ECJ has accepted the acts for review, notwithstanding their formal legal status.[833] For instance, where they created substantial regulatory effects, the soft law instruments were admitted for judicial review so as to ensure the right to effective judicial protection.[834] What is more, the soft instruments are relevant during Article 267 TFEU procedure, and the validity of these instruments could be challenged while examining the validity of the secondary law.[835]

It is true that judicial control of European standardisation is not obviously apparent. However, the recent *James Elliott* case officially recognised for the first time that an HES, despite its private and voluntary nature, forms part of EU law. This creates an opportunity to subject the HESs to judicial control. The detailed discussion on the possibility of judicial review of the HESs and the process of standardisation will follow in the next chapter.

5.7. Conclusion

In this chapter, I examined the cooperation between the EU institutions and ESOs leading to the development of the HESs through the lens of EU constitutional law and regarded it as a delegation of rule-making power. Consequently, I positioned the HESs in the EU hierarchy of secondary norms in the light of Articles 290 and 291 TFEU and argued that the HESs are 'atypical' implementing acts.

Next, the EU constitutional law difficulties of involving private bodies in the regulation of the internal market were discussed. It was concluded that the judicial review of the powers delegated to the ESOs is crucial for ensuring the lawfulness of delegation via European standardisation. Chapter 7 of this thesis

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[833] Case C-354/04 P, *Gestoras Pro Amnistia v Council of European Union,* ECLI:EU:C:2007:115, paras 52–4; Case C-355/04 P, *Segi Araitz Zubimendi Izaga and Aritza Galarraga v Council of European Union*, ECLI:EU:C:2007:116, paras 53–4.

[834] The Court will ensure the effective judicial protection even against the soft law, when the latter has a substantive regulatory effect. See: Case C-355/10, *European Parliament v Council* (n 715), para 80. For a comment on this case, see: M. den Heijer and E. Tauschinsky, 'Where Human Rights Meet Administrative Law: Essential Elements and Limits to Delegation: European Court of Justice, Grand Chamber C-355/10: *European Parliament v Council of European Union*', (2013) 9 *European Constitutional Law Review* 513.

[835] M. Simoncini, 'The Erosion of the Meroni Doctrine: The Case of the European Aviation Safety Agency' (2015) 21 (2) *European Public Law* 309.

continues this discussion and explores the possibility of judicial review of the European standardisation system.

Although co-regulation via European standardisation is commonly regarded as a system of delegated rule-making, the EU institutions do not explicitly recognise it as such. However, the recent opinion of the AG in *James Elliott* officially regards it as a system of delegation in favour of private standards bodies. Nevertheless, the standards bodies are clearly against this vision of the cooperation between the Commission and the ESOs.[836]

One of the arguments usually offered against the delegation perspective is that, first, the power to develop the HESs is not delegated from the EU institutions. In order to delegate some authority, one must first possess said authority. However, the task of standards-setting belongs intrinsically to the ESOs and not to the EU institutions. Developing and setting a standard is the task of interested parties, thus the EU institutions do not delegate any authority that previously belonged to them. Rather, the EU institutions use private rule-making for public purposes—that is, they 'politically instrumentalise the private governance'[837]—without locking the HESs into the hierarchy of legal norms.

Secondly, the competence to set the requirements for safety, health, and environmental protection used to belong primarily to the Member States and drawing up the relevant technical standards was the task of NSBs. Therefore, establishing the ESOs—regional associations of NSBs—simply represents the elevation of national standardisation to the EU level, rather than the transfer of a rule-making power from the EU institutions to the ESOs.

Thirdly, the EU institutions simply employ the expertise of the ESOs and grant to the HESs presumption of conformity, for the purpose of achieving better harmonisation of technical rules throughout the Union. Moreover, the relationship between the Commission and ESOs has a contractual nature. The mandate from the Commission to draft an HES is not binding upon the ESOs. The latter retain the right to indicate within one month whether they accept the

[836] See for instance the blog post published by the head of legal affairs of CEN-CENELEC: B. Schettini Gherardini, 'Harmonised European Standards and the EU Court of Justice: Beware Not to Open Pandora's Box' (2016) *European Law blog*, <http://europeanlawblog.eu/?p=3212> accessed 27 May 2016.

[837] Schepel, *The Constitution of Private Governance* (n 111), 257.

Commission's mandate.[838] Therefore, it works like a contract—the Commission makes an offer and the ESOs either accept or reject this offer.

Furthermore, the new approach strategy did not intend to delegate public powers to the ESOs and allow them to produce law-like acts. On the contrary, it was decided that the law was not a suitable instrument to meet the challenges faced by the market. It was thought that experts with technical knowledge and the affected parties would be able to regulate themselves better.

The rationale behind the objections against the delegation perspective is to dodge the strict administrative and judicial control of the European standardisation system. This is because, following the 'Delegation Framework' as discussed, the accountability of delegated powers is to be guaranteed through hierarchical and formal means. Such a mechanism of control is feared, as it is seen to turn private regulators into public institutions and thereby undermine the benefits of privatisation.[839]

To translate this into the context of European standardisation, it is feared that subjecting the process of development of standards to the principles of public rule-making serves to undermine the efficiency of such private rule-making. In addition, for some, this would make standardisation susceptible to the Court's scrutiny and threaten the effectiveness of the new approach directives by creating an opportunity for each unhappy manufacturer to challenge the HESs before the Court(s).[840]

However, it is far less obvious how the requirement of public participation in the standardisation process, or judicial oversight thereof in some instances, could remove the benefits of using the HES in legislation and policy documents.[841] Regulation 1025/2012 already lays down the main principles to which the process of the development of standards should adhere, as well as stating that the standardisation can be subject to the requirements of competition law. But certainly, this Regulation did not turn the ESOs into EU institutions or agencies, nor did it undermine the efficiency of the European standardisation system.

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[838] Regulation (EU) 1025/2012 (n 14), Article 10(3).

[839] See the discussion on this matter in Freeman, 'Extending Public Accountability through Privatization' (n 818), 97–111.

[840] Schepel, 'The New Approach to the New Approach' (n 371).

[841] This thesis does not intend to provide any economic cost-benefit analysis of subjecting private regulators to the public law principles.

In light of these considerations, in the third part of this thesis, I discuss the judicial review of the co-regulation via European standardisation, highlight the role of the Court as a mechanism of legal accountability in the new forms of governance such as standardisation, and reflect on the Court's limited ability to deal with technical complexities.

6. The European Standardisation System under EU Economic Law—Functional and Deferential Approaches

6.1. Introduction

In this chapter I continue to explore the European standardisation system through the lens of EU economic law. In particular, I discuss how the free movement and competition law provisions could regard and regulate the European standardisation used in EU legislation and policy. This is undertaken so as to contemplate the legal framework offered by the EU Economic law, to juxtapose it with the previously described 'Separation' and 'Delegation Frameworks', and to reflect what it offers in respect of regulation and accountability of the European standardisation system by EU law and through the judiciary.

As a brief recap, I have previously presented the 'Official View' and the EU constitutional law perspective on the European standardisation used in EU legislation and policies. I argued that the co-regulation via European standardisation was devised 'officially' as operating on the strict separation between EU directives and the HESs. In contrast, following the EU constitutional law perspective, the HESs are acts of delegated rule-making and hence form part of EU Law.

In short, these two perspectives operate on the basis of a public-private divide, place the European standardisation system *ex-ante*, in the public or the private domain and view it, respectively, either as private or delegated rule-making used for public purposes. Consequently, the 'Official View' offers the 'Separation Framework' for the operation of the European standardisation system, entailing that the latter is a private activity falling within the scope of private law. In this case, the legitimacy of such private rule-making is

underpinned by the expertise of the standardisers, as well as the need for public accountability in the form of administrative and judicial control disappears.

In contrast, the 'Delegation Framework' assumes that the HESs are public rules, since they regulate important aspects of public life such as safety, health, and environment, as well as supplementing legislation in this respect, and are adopted on the basis of the Commission's mandate. Following the 'Delegation Framework', the European standardisation system should have certain features: it should be organised according to the principles of public rule-making; it should be controlled by the EU institutions; and the HESs should be the subject of judicial review. In other words, the 'Delegation Framework' requires a strict legal and judicial scrutiny with the mechanisms of accountability for the system's overall legitimacy.

More generally, the above-described perspectives on the European standardisation system can be viewed as providing either a private or a public law framework thereon. However, preferring one over the other would be wrong, because in the co-regulation via European standardisation, the public and private elements are closely intertwined and the HESs are part of a continuum that runs between public and private spheres.[842] This invites fluidity between these two frameworks.

Investigating the European standardisation system under the EU economic law shows that it is potentially subject to the application of both the internal market and the competition law provisions, because of the public-private intertwinement in the European standardisation. In other words, the EU economic law accepts both public and private aspects of the European standardisation system and offers a 'Hybrid (flexible) Framework', with potential application to both free movement and competition law provisions.

The EU legislator has made clear that actions of the European standards organisations are within the reach of the EU competition rules.[843] The cooperation among competitors in the standardisation process is a classical subject matter of competition law. By contrast, regulatory effects of the HESs that could restrict market access, for instance, to certain goods, leads to a

[842] See: F. Cafaggi, 'Private Regulation in European Private Law' (n 68); P. Glenn, 'Transnational Legal Thought: Plato, Europe and Beyond' (n 68), 76. Although these sources mainly discuss the standards as a continuum running between non-law and law, similarly the standards can be described as a continuum running between private and public spheres.

[843] Under the condition that the ESOs qualify as undertakings or associations of undertakings; Regulation (EU) 1025/2012 (n 14), Recital 13.

possible application of the free movement rules. The *Fra.bo* case[844] suggests that even a purely private standardisation and certification that is capable of restricting trade falls under the scope of the free movement provisions.

Consequently, I argue that the free movement and competition laws could regulate the European standardisation system which is a mixture of public/private efforts, employing the functional approach. The latter approach encompasses functional criteria or an effect-based assessment in the process of applying the free movement provisions against private actions.[845] Under the functional approach, two scenarios can be distinguished: 1) where the free movement provisions apply to private bodies exercising the regulatory functions; 2) the so-called effect-based assessment, whereby the free movement rules stretch to include the actions of private bodies that do not perform regulatory functions, but whose measures have an effect on the EU's four freedoms. In this thesis, the functional approach refers to the second type of scenario, where the effect of a measure on the internal market is decisive for the application of the free movement provisions. As a result, I suggest that the EU economic law, by employing the functional approach, can focus on the effects of the HESs, rather than their abstract legal nature.

On the other hand, I note that the application of the EU economic law to the European standardisation system is limited. The officially recognised HESs are less likely to be seen as restrictions to trade as the use of European standardisation in EU legislation has become official EU policy.[846] This means that the EU economic law would have a mild impact on, and exhibit a high deference to, the European standardisation system. In other words, the EU competition and internal market provisions, while applying to the European standardisation system, will show significant deference to the substance of a standard and instead will focus on the procedural rules that govern the development of standards within the ESOs.[847] A clear manifestation of this approach is the EU competition law that establishes safe harbour for standardisation operating on the basis of principles of openness, transparency, and non-discrimination.

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[844] Case C-171/11, *Fra.bo* (n 60).

[845] See: B. Van Leeuwen, 'Private Regulation and Public Responsibility in the Internal Market' (2014) 33 (1) *Yearbook of European Law Review* 277.

[846] Mataija, *Private Regulation and the Internal Market* (n 22), 253.

[847] Ibid, 252. See also: I. Lianos, 'In Memoriam Keck: The Reformation of the EU Law on the Free Movement of Goods' (2015) 40 (2) *European Law Review* 225.

In light of the foregoing, the remainder of this chapter is divided into the following sections. In section 2, the fading of the public-private distinction is discussed, as are the scope of application of free movement and competition rules and their overlapping effects. In doing so, I will show that the European standardisation system could be a subject of the overlapping application of the free movement and competition rules, but that this does not mean a full convergence of these provisions. In other words, if European standards are found to violate the free movement rules, this does not automatically mean the infringement of competition provisions too, or vice versa.

In section 3, the horizontal application of the free movement rules is discussed so as to prepare the ground for an analysis of the application of the free movement provisions to the European standardisation system. In section 4, I consider the application of the free movement rules to the European standardisation used in EU legislation and policy. In section 5, I begin the discussion about the relation between the competition rules and the European standardisation system, as well as outlining the application of competition law provisions to private regulation. Section 6 contemplates the application of the EU competition rules to the European standardisation system. In section 7, I project the EU competition law as a private administrative law for the co-regulation via European standardisation. More specifically, I argue that the EU competition law can facilitate the adherence to the public law principles—such as openness, transparency, and non-discrimination—in the process of standard-setting in the name of safe harbour. Section 8 concludes the chapter.

6.2. The EU Economic Law in Response to the Fading Public-Private Distinction

Distinguishing between the public and private spheres has never been an easy task. This is partly because public and private realms are becoming ever more intertwined, and partly a result of the ongoing debate about the theoretical and conceptual connotations entailed by the public and the private. The public-private divide is often assumed to imply a separation 'between *Imperium* (political power) and *Dominium* (economic power).'[848] The protection of

[848] J.W. van de Gronden, 'The Internal Market, the State and Private Initiative: A Legal Assessment of National Mixed Public-Private Arrangements in the Light of European Law' (2006) 33 (2) *Legal Issues of European Economic Integration* 105, at 106.

general interests is reserved for the former, while the latter is driven by the profit-making desire.[849] In a similar manner, in this thesis the term 'public sphere' includes binding public rules and public authorities serving the public interest. By contrast, the term 'private sphere' encompasses private actors and non-binding rules adopted by private bodies that are dominated by self-serving interests.

The interaction of the public and private spheres—in other words, State and market—is not a new phenomenon. States have always used the potential of private parties. But reliance on private regulators is even more prevalent nowadays.[850] Public tasks are often entrusted to private regulators through contracts or different forms of public-private partnership.[851] Moreover, the State is no longer the sole regulator[852] and also assumes the role of a market player.[853] According to Freeman, this has led to a 'mixed zone' of interaction between public and private activities.[854] And many forms of mixed public-private cooperation tend to manifest quasi-public and quasi-private features and in so doing they blur or fade the line between the public and the private.[855]

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[849] L. Bergkamp, 'Corporate Governance and Social Responsibility: A New Sustainability Paradigm?' (2002) 11 *European Environmental Law Review* 136, at 50.

[850] See: M. Taggart, 'From "Parliamentary Powers" to Privatization: The Chequered History of Delegated Legislation in the Twentieth Century' (2005) 55 (3) *University of Toronto Law Journal* 575.

[851] J-B. Auby, 'Contracting Out and "Public Values": A Theoretical and Comparative Approach', in S.R. Ackerman and P.L. Lindseth (eds), *Comparative Administrative Law* (Edward Elgar 2010). The discussion about contracting out public functions to private bodies concerns not only a fading public-private distinction, but also the issues of how to ensure that the public tasks are performed in a manner that respects public interests, as well as how to ensure legal accountability of private actors performing public tasks. There are numerous research papers on this matter, including: C. Michler, 'Government by Contract-Who is Accountable?', (1999) 15 *QUT Law Journal* 135; A.L. Dickinson, 'Public Law Values in a Privatized World' (2006) 31 *Yale Journal of International Law* 383; J-B. Auby, 'Comparative Approach to the Rise of Contract in the Public Sphere' (2007) *Public Law* 40.

[852] W. Sauter and H. Schepel, *State and Market in European Union Law*: *The Public and Private Spheres of the Internal Market before the EU Courts* (Cambridge University Press 2009).

[853] H. Micklitz and D. Patterson, 'From the Nation State to the Market: The Evolution of EU Private Law as Regulation of the Economy Beyond the Boundaries of the Union', in B. Van Voore, S. Blockmans, and J. Wouters (eds), *The EU's Role in Global Governance* (Oxford University Press 2013), 59–78.

[854] Freeman, 'Private Parties, Public Functions and the New Administrative Law' (n 24).

[855] See: J. Weintraub, 'The Theory and Politics of the Public/Private Distinction', in J. Weintraub and K. Kumar (eds), *Public and Private in Thought and Practice: Perspectives on a Grand Dichotomy* (University of Chicago Press 1997), 38. He puts forward four different models underpinning the public-private distinction: i) a liberal-economic model,

The spheres of State and market are no longer so neatly separated.[856] As such, the public-private divide has been declared 'dead'[857] and is thought to be a mere legal fiction.

The public-private divide is actually not central to the EU legal order. The terms public and private are used only rarely in the EU Treaties,[858] and the public-private distinction did not prove pivotal for the ECJ when dealing with the infringement of the fundamental principle of non-discrimination,[859] as seen in the *Mangold*[860] and *Kücükdeveci* cases.[861] These cases serve as examples of

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that distinguishes between public-state administration and private-market economy; ii) a Republican (classical) model, which considers political community under the public sphere, and citizenship under private market and administrative state; iii) a model inspired by work of Aries, which sees the public as a fluid sphere and for its understanding employs cultural and dramatic conventions that are important for making it; iv) a feminist model that distinguishes between the private-family sphere and a larger public sphere that includes the economy and political order.

856 P.M. Schoenhard, 'A Three-Dimensional Approach to the Public-Private Distinction', (2008) *Utah Law Review* 635, at 638.

857 D. Kennedy, 'The Stages of the Decline of the Public/Private Distinction', cited in Schoenhard, 'A Three-Dimensional Approach to the Public-Private Distinction' (Ibid), 636.

858 Article 36 TFEU sets out: 'Public morality, public policy or public security' as justifications for the obstacles to free movement of goods. Similarly, Article 45 TFEU provides justifications to the restrictions to free movement of persons on the basis of public policy, public security, public health. Article 272 TFEU states that '[t]he Court of Justice of the European Union shall have jurisdiction to give judgments pursuant to any arbitration clause contained in a contract concluded by or on behalf of the Union, whether that contract is governed by public or private law'.

859 The opinion of AG Kokkot in Case C-157/15, *Samira Achbita*, ECLI:EU:C:2016:382, is also relevant for the discussion of the public-private distinction. The case concerned a private organisation banning its employee from wearing a headscarf at the office. Kokkot did not find it necessary to distinguish between public and private employers when it comes to an obligation to respect religious freedom and not to discriminate on the basis of religion. She states: 'Even though an employee may not rely directly on the freedom of religion as against his private employer (Article 10 of the Charter of Fundamental Rights) because that freedom is binding only on the EU institutions and—in the implementation of EU law—the Member States (Article 51(1) of the Charter), that fundamental right is nevertheless one of the foundations of a democratic society and an expression of the system of values on which the European Union is founded (see also, in that regard, Article 2 TEU). Accordingly, the values expressed by the freedom of religion also have repercussions, at least indirectly, on private employment relations. Within the scope of Directive 2000/78, it is important to take due account of those values, from the point of view of the principle of equal treatment, when seeking to strike a fair balance between the interests of employers and employees' (para 113).

860 Case C-144/04, *Werner Mangold v Rüdiger Helm*, ECLI:EU:C:2005:709.

861 Case C-555/07, *Seda Kücükdeveci v Swedex GmbH & Co. KG*, ECLI:EU:C:2010:21. It is interesting to note the recent developments regarding the horizontal direct effect of the

the horizontal application of a general principle, i.e. restraining the private action of an employer-private body, by the general principle of non-discrimination. That said, this is not to overlook the fact that the public-private distinction played an important role in limiting the horizontal direct effect of directives in *Marshall*.[862] However, the Court did not strictly adhere to the prohibition of the horizontal direct effect of directives in the subsequent case law.[863] The ECJ gradually expanded the notion of the State starting from *Foster*[864] and allowed the reliance on directives in horizontal cases via the back door of indirect effect[865] and harmonious interpretation.[866]

A dogmatic public-private distinction becomes even less relevant where it is on the way to a 'guiding paradigm'[867] of economic integration. The private law status of a body is not a shield from the application of the free movement rules. The CJEU treats the barriers to trade stemming from the private regulators similarly to State barriers. Consequently, this entails the horizontal application of the free movement provisions, which is viewed as 'constitutionalisation' of the market and market obligations for private parties.[868]

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general principle of non-discrimination at the national level. The Danish Supreme Court made a preliminary ruling request on the similar matters in C-441/14, *Ajos.* The ruling from the ECJ required from the Danish Supreme Court to either interpret the national law in light of the directive or disapply the conflicting national law. However, the Danish Court did neither; rather, it set aside the judgment from the ECJ. See on this S. Klinge, 'Dialogue or Disobedience between the European Court of Justice and the Danish Constitutional Court? The Danish Supreme Court Challenges the Mangold-Principle' (2016) <http://eulawanalysis.blogspot.se/2016/12/dialogue-or-disobedience-between.html> accessed 20 March 2017.

862 Case 152/84, *M. H. Marshall v Southampton and South-West Hampshire Area Health Authority (Teaching)*, ECLI:EU:C:1986:84.

863 See Cases: C-194/94, *CIA* (n 303); Case C-443/98, *Unilever* (n 304); C-106/89, *Marleasing SA v La Comercial Internacional de Alimentacion SA* ECLI:EU:C:1990:395.

864 Case C-188/89, *A. Foster and others v British Gas plc*., ECLI:EU:C:1990:313; On the concept of 'emanation of state' see the opinion of AG Sharpston in the Case C-413/15, *Farell*, ECLI:EU:C:2017:492.

865 See for instance: Case C-194/94, *CIA* (n 303); Case C-443/98, *Unilever* (n 304).

866 Case 14/83, *Sabine von Colson and Elisabeth Kamann v Land Nordrhein-Westfalen*, ECLI:EU:C:1984:153; Case C-106/89, *Marleasing SA* (n 863).

867 C. Semmelmann, 'The Public-Private Divide in European Union Law or an Overkill of Functionalism', *Maastricht European Private Law Institute, Working Paper No 2012/12*, 3.

868 See: H. Schepel, 'Constitutionalising the Market, Marketising the Constitution and to Tell the Difference: On the Horizontal Application of the Free Movement Provisions in EU Law' (2012) 18 *European Law Journal* 177.

The effectiveness of EU law demands that private restraints that have a similar effect on trade as public measures should not slip through the application of the free movement provisions due to their private status. Likewise, the market behaviour of public entities should be constrained by the competition rules, entailing 'publicisation' of competition provisions.[869] To do so, the Court gives preference to a functional approach founded on the effect-based assessment. The EU economic law does not tend to operate on an *ex-ante* public/private distinction; rather it is inclined to take a case-by-case approach entailing a three-dimensional assessment.[870]

Neither the legal form of a body or measure nor the purpose of the activity alone is a decisive factor for three-dimensional assessment. Instead the question asked is whether X is public or private with respect to Y?[871] Using the three-dimensional assessment in the context of the co-regulation via European standardisation would firstly entail a case-by-case treatment. In every case, it would require answering the question of whether a European (harmonised) standard is a public or private rule, with respect to a company participating in standardisation or using this standard, or to a Member State, or to a conformity assessment body, and so on, depending on the facts of the case. In this way, the functional approach avoids giving a general answer on the abstract legal nature of the European (harmonised) standards and treats their effects.[872]

To simply suggest that a State-recognised standardisation falls under the free movement provisions and a purely market-based one falls under the competition law would be incorrect, especially in light of *Fra.bo* reasoning (discussed later on). In addition, it suffices to note that the formal recognition of European standardisation by the EU institutions does not render such standardisation *per se* immune from the application of competition law.[873]

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869 R. Lane, 'The Internal Market and Individual', in N. Nic Shuibhne (ed.), *Regulating the Internal Market* (Edward Elgar 2006).

870 The idea of the three-dimensional approach is taken from Schoenhard, 'A Three-Dimensional Approach to the Public-Private Distinction' (n 856).

871 Ibid.

872 Ibid, 656–9.

873 Case T-432/05, *EMC Development AB v European Commission*, ECLI:EU:T:2010:189.

6.2.1. The Overlap between the Free Movement and Competition Laws apropos of European Standardisation

The 'economic constitution'[874] of the EU comprises the free movement and competition laws. These provisions, at first blush, have the distinct scope of application. Although both sets of rules address the restraints of cross-border competition, the free movement provisions apply to public actions/restraints while the competition law applies to private ones. The Court makes such a distinction, reiterating occasionally that the competition law covers the actions of undertakings and the free movement provisions address State measures.[875] Notwithstanding this formal separation, the Court usually focuses on the effects of an action, rather than on the public or private status of a regulator while scrutinising a measure under the competition or free movement rules.[876]

Both sets of rules have a converging aim. Already in *Consten and Grundig*,[877] the Court made clear that the EU competition rules were not simply ensuring a competitive market, but also had an objective of market integration. To achieve this goal, the competition rules prevent the fragmentation of markets.

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[874] The term is borrowed from J. Baquero Cruz, *Between Competition and Free Movement: The Economic Constitutional Law of the European Community* (Bloomsbury 2002). See also Sauter and Schepel, *State and Market in European Union Law* (n 852), 11: '…[the t]erm "European Economic constitution" has enjoyed wide currency in European legal thought since the earliest days if European Integration…'.

[875] Case 65/86, *Bayer AG and Maschinenfabrik Hennecke GmbH v Heinz Süllhöfer*, ECLI:EU:C:1988:448, para 11; Joined cases 177 and 178/82, *Criminal proceedings against Jan van de Haar and Kaveka de Meern BV*, ECLI:EU:C:1984:144, paras 11–12, 14.

[876] The functional definition of the concept of undertaking in competition law entailed the application of competition law provisions to hybrid regulatory strategies. The competition rules were applied in the functionalist manner, meaning that it is the nature of a measure that matters and not its formal legal classification. See for instance Case C-364/92, *SAT Fluggesellschaft mbH v Eurocontrol*, ECLI:EU:C:1994:7, para 19. Also, if a body is not an undertaking in certain aspects of its activity, the competition law will still apply to its other activities for which it could qualify as an undertaking. When it comes to the actions of private bodies that could still fall under the free movement provisions, it suffices here to mention the Cases C-341/05, *Laval un Partneri Ltd v Svenska Byggnadsarbetareförbundet, Svenska Byggnadsarbetareförbundets avdelning 1, Byggettan and Svenska Elektrikerförbundet*, ECLI:EU:C:2007:809 and C-438/05, *International Transport Workers' Federation and Finnish Seamen's Union v Viking Line ABP and OÜ Viking Line Eesti*, ECLI:EU:C:2007:772.

[877] The Court in this case, while finding an agreement anti-competitive, paid particular attention to whether an agreement was capable of restricting trade between Member States directly or indirectly, actually or potentially. See: Joined cases 56 and 58–64*, Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community*, ECLI:EU:C:1966:41.

Moreover, in *Leclerc*,[878] the Court explained that the establishment of the internal market is secured by prohibiting trade constraints through the free movement rules, as well as through the application of the competition law provisions.[879] The convergence of these two sets of rules was facilitated by borrowing the concepts from one and applying them in the context of the other. The concept of 'effect on trade between member states', not just actual but also potential, was borrowed from *Consten and Grundig* and was inserted in *Dassonville*,[880] so as to define measures having an effect equivalent to the quantitative restriction on the free movement of goods.

The convergence between the competition and free movement provisions is, to some extent, a result of pursuing an overarching goal of market integration based on free competition.[881]

> …[f]ree movement rules are more than a ban on discriminatory or protectionist measures. They also protect market access 'under conditions of effective competition'882 and thus, to some extent, overlap with the function of competition law. On the other hand, the competition rules are strongly influenced by the ideal of market integration, disciplining restriction on parallel trade. Thus, they overlap with the function of free movement.883

It is true that the competition and free movement rules are closely connected, and both form the 'normative [foundations] of European economic constitution.'[884] The scope of application of internal market and competition rules also overlap, especially in the context of the fading public-private divide. The overlap occurs when both of these sets of rules apply equally to the same facts. However, this does not mean the complete convergence between the two sets of rules. The Court admits that the competition and free movement rules

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878 Case 231/83, *Henri Cullet and Chambre syndicale des reparateurs automobiles et detaillants de produits petroliers v Centre Leclerc a Toulouse and Centre Leclerc a Saint-Orens-de Gameville*, ECLI:EU:C:1985:29.

879 Ibid, para 11.

880 Case 8-74, *Procureur du Roi v Benoît and Gustave Dassonville*, ECLI:EU:C:1974:82, para 5.

881 See: Mataija, *Private Regulation and the Internal Market* (n 22), 116–18.

882 See: Case C-565/08, *European Commission v Italian Republic*, ECLI:EU:C:2011:188, para 51.

883 Mataija, *Private Regulation and the Internal Market* (n 22), 19.

884 E. Szyszczak, 'Competition and the Liberalised Market', in N. Nic Shuibhne (ed.), *Regulating the Internal Market* (Edward Elgar 2006), 101–2.

have a somewhat distinct scope of application.[885] In the *Viking* case, the Court stated that

> …the fact that an agreement or an activity are excluded from the scope of the provisions of the Treaty on competition does not mean that that agreement or activity also falls outside the scope of the Treaty provisions on the free movement of persons or services since those two sets of provisions are to be applied in different circumstances.[886]

Keeping somewhat incomplete the separation between the competition and free movement rules does not rule out scenarios in which both sets of provisions are applied simultaneously. However, in those cases, the Court usually takes an easier way out, meaning that after finding a violation of one set of rules, the Court does not proceed with the scrutiny under the second set of rules.[887] Such an approach does not necessarily mean that these two sets of rules converge and that finding an infringement under one implies infringement of another. Nor does it mean that these two sets of rules are based on the same legal test. The reasons for resorting to such a shortcut could simply be judicial economy or the result of posing the preliminary questions in an alternative manner.[888]

In short, the competition and free movement rules are interlinked due to the aim they pursue. Also, the complexity of the regulatory landscape and intertwinement of public and private spheres bring these rules even closer together. However, this is not to suggest full convergence.[889] Consequently,

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[885] Joined Cases 177 and 178/82, *van de Haar* (n 875). The Court here distinguished between the scope of competition and free movement rules on the basis of three criteria: addressees, aim, and the measures to which they are applied.

[886] Case C-438/05 *Viking Line* (n 876), para 53. Similar reasoning is found in C-519/04P, *David Meca-Medina*, ECLI:EU:C:2006:492, para 31.

[887] Case C-415/93, *Union royale belge des sociétés de football association ASBL v Jean-Marc Bosman, Royal club liégeois SA v Jean-Marc Bosman and others and Union des associations européennes de football (UEFA) v Jean-Marc Bosman*, ECLI:EU:C:1995:463, para 138. See for instance Case C-171/11, *Fra.bo* (n 60).

[888] Case C-171/11, *Fra.bo* (n 60).

[889] These two sets of rules are still distinct. There is a fundamental distinction—for instance, economic analysis is more detailed and akin to competition law, as opposed to free movement rules. Also, the free movement and competition rules are distinguished on the basis of how they define restrictions, and what justifications the treaties provide to the restrictions. Moreover, there are different types of remedies in the cases of infringement of competition rules as opposed to free movement provisions. See the discussion of this in Mataija, *Private Regulation and the Internal Market* (n 22), 132–54.

assuming that these two sets of rules could apply to the European standardisation system does not mean that violation of the free movement rules would automatically entail also the infringement of the competition rules. It is possible that the European standardisation used for regulatory purposes could be found to infringe the free movement rules but not the competition provisions, or vice versa. In addition, in some cases, the co-regulation via European standardisation could fall under both sets of rules at the same time or neither of them at all.

6.3. The *Effet Utile* of Free Movement Rules

In this section, I discuss the application of the free movement provisions to private bodies and regulators, and demonstrate that the free movement law constrains private measures that have similar effects on the internal market as State ones. By doing so, this section provides the framework to consider whether the standardisation—a form of private regulation[890]—can fall under the scope of application of the free movement provisions. This will also pave the way for us to contemplate the interplay between the free movement rules and the European standardisation system.

The internal market provisions are 'principle elements of the economic Constitution of the [Union]'.[891] These rules of the Treaty protect the free

[890] See the discussion on seeing the standardisation process as a private regulation in Chapter 4 of this thesis.

[891] Gerkrath, *L'émergence d'un droit constitutionnel pour l'Europe* (Université de Bruxelles 1997), 315, cited in P. Oliver and W.H. Roth, 'The Internal Market and the Court Freedoms' (2004) 41 *Common Market Law Review* 407, at 410. See also P. Maduro, *We the Court: The European Court of Justice and the European Economic Constitution* (Hart 1998), 166–8. Maduro argues that the provision on free movement of goods is a 'fundamental political right' and 'fundamental economic freedom'; Cruz suggests that four freedoms are 'constitutional rights, but not fundamental constitutional rights'; see: Cruz, *Between Competition and Free Movement* (n 874), 81. The Court describes free movement rules as 'fundamental community provisions'; see: Case C-49/89, *Corsica Ferries France v Direction générale des douanes françaises*, ECLI:EU:C:1989:649, para 8; 'one of the foundations of the Community'; see: Case C-194/94, *CIA* (n 303), para 40; Case C-443/98, *Unilever Italia* (n 304), para 40. These cases concern free movement of goods; 'fundamental freedoms'; see: Case C-390/99, *Canal Satélite Digital SL v Adminstración General del Estado, and Distribuidora de Televisión Digital SA (DTS)*, ECLI:EU:C:2002:34, paras 28–30; Case C-112/00, *Eugen Schmidberger, Internationale Transporte und Planzüge v Republik Österreich*, ECLI:EU:C:2003:333, paras 62 and 67; 'one of the fundamental

movement of goods, services/establishment, capital, and workers. The primary addressees of these four freedoms are restrictive State measures[892] that hinder 'directly or indirectly, actually or potentially, intra-Community trade.' However, the potential application of the free movement rules to actions of private bodies is not excluded. Nothing in the text of the free movement provisions indicates that these freedoms only cover State measures.[893]

It is perhaps more accurate to say that the free movement rules cover a spectrum of measures ranging from the State to private actions.[894] At one end of the spectrum are State measures or private measures attributable to a State.[895] This also includes private regulation connected to a State by virtue of delegation or *ex-post* recognition.[896] At the other end of the spectrum are measures stemming from private bodies, without any connection to a State, exercising regulatory functions. For instance, in *Bosman*,[897] the Court found that the transfer rules of a football association impeding a club's hiring of football players, from another Member State, fell under the scope of the free movement of workers. Similarly, in *Walrave*,[898] the rules of an international cyclist union that required a pacemaker and stayer to be of the same nationality were regarded as potential restrictions to the free movement of workers.

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principles of the treaty'; see: Case C-265/95, *Commission of the European Communities v French Republic*, ECLI:EU:C:1997:595, para 27.

892 For instance, the *Dassonville* formula states that the prohibition on restriction to free movement of goods refers to 'all trading rules enacted by Member States'; Case 8-74, *Dassonville* (n 880), para 5.

893 J. Krzeminska-Vamvaka, 'Horizontal Effect of Fundamental Rights and Freedoms: Much Ado about nothing? German, Polish and EU Theories Compared after Viking Line', *Jean Monnet Working Paper 11/09*. See also: G.R. Milner-Moore, 'Accountability of Private Parties under the Free Movement of Goods Principle' (1995) *Jean Monnet Working Paper 09*.

894 This spectrum does not follow the chronological order though. See also: L. Azoulai, 'The Court of Justice and the Social Market Economy: The Emergence of an Ideal and the Conditions for its Realization' (2008) 45 *Common Market Review* 1335.

895 Case C-325/00, *Commission of the European Communities v Federal Republic of Germany*, ECLI:EU:C:2002:633; Case C-249/81, *Commission v Ireland* (n 270).

896 Mataija*, Private Regulation and the Internal Market* (n 22), 22. See for instance: Case C-249/81, *Commission v Ireland* (n 270); Case C-325/00, *Commission of the European Communities v Federal Republic of Germany* (n 895).

897 Case C-415/93, *Bosman* (n 887).

898 Case 36-74, *B.N.O. Walrave and L.J.N. Koch v Association Union cycliste internationale, Koninklijke Nederlandsche Wielren Unie and Federación Española Ciclismo (Walrave),* ECLI:EU:C:1974:140.

The institutional authorship or the legal form—whether private or rooted in private law—is not an impediment to the application of the free movement provisions.[899] Meaning that similar measures of private and public bodies should be treated similarly notwithstanding the legal status of a body.[900] The general justification of constraining private bodies by the free movement provisions is the effectiveness of EU law, so-called *effet utile* doctrine. Restrictions stemming from the actions of private actors, if not disciplined by the free movement rules, can circumvent the effectiveness of EU law. In the Court's words:

> [t]he abolition, as between Member States, of obstacles to freedom of movement for persons and freedom to provide services would be compromised if the abolition of State barriers could be neutralised by obstacles resulting from the exercise, by associations or organisations not governed by pubic law, of their legal autonomy.[901]

AG Maduro admits that the free movement provisions address primarily the State measures, and the competition law disciplines private actions, but, according to him, this situation does not validate the argument against the horizontal direct effect of the free movement provisions. Quite the contrary, the horizontal effect of the free movement provisions is required to ensure the equal opportunities for market participants to gain access to any part of the internal market.

> …in order effectively to ensure the rights of market participants, the rules on competition have horizontal effect, while the rules on freedom of movement have vertical effect. However, this does not validate the argument *a contrario* that the Treaty precludes horizontal effect of the provisions on freedom of movement. On the contrary, such horizontal effect would follow logically from the Treaty where it would be necessary in order to enable market participants

[899] For instance, in the Case C-249/81, *Commission v Ireland* (n 270), the Court took a functional approach and ruled that the free movement provisions applied to the measure adopted by a private body, because the latter body had links to the State (control, financing, and so on).

[900] Case 36-74, *Walrave* (n 898), para 19; Case C-415/93, Bosman (n 887), para 83; Case C-281/98, *Roman Angonese v Cassa di Risparmio di Bolzano SpA,* ECLI:EU:C:2000:296, para 84.

[901] Case C-415/93, *Bosman* (n 887), para 83; Case C-281/98, *Roman Angonese* (n 900), para 32.

> throughout the Community to have equal opportunities to gain access to any part of the common market.[902]

This is especially true since the competition rules address only certain types of private impediments to trade, while internal market provisions target barriers that disturb the free movement of goods, services/establishment, persons, and capital.[903]

Horizontal application of fundamental freedoms is prevalent in the services,[904] establishments,[905] and workers[906] fields. Meanwhile, the application of the provisions on free movement of goods to private bodies has remained restricted until recently, due to the wording of the *Sapod Audic* case.[907] In the latter case, the Court stated that an obligation to affix the Green logo on packaging stemmed from a private contract. Hence, '…such a contractual provision [could not] be regarded as a barrier to trade…since it was not imposed by a Member State but agreed between individuals.'[908] *Sapod Audic* was relied upon for a long time to deny the horizontal application of the free movement rules in the case of goods. However, the *Fra.bo* case has changed the well-established *status quo*.

Although the horizontal application of fundamental freedoms aims to ensure the effectiveness of market freedoms, not everybody considers it to be the Court's 'proudest achievement'.[909] One of the main arguments against horizontal application of the free movement rules is that individuals should not

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[902] Opinion of AG Maduro in the Case C-438/05, *Viking Line,* ECLI:EU:C:2007:292, paras 34–5.

[903] See also: Krzeminska-Vamvaka, 'Horizontal Effect of Fundamental Rights and Freedoms: Much Ado about Nothing?' (n 893), 35; Milner-Moore, 'Accountability of Private Parties under the Free Movement of Goods Principle' (n 893).

[904] See for instance: Case C-341/05, *Laval* (n 876).

[905] Case C-438/05, *Viking Line* (n 876).

[906] Case C-281/98, *Roman Angonese* (n 900); Case C-415/93, *Bosman* (n 887).

[907] Case C-159/00, *Sapod Audic v Eco-Emballages SA*, ECLI:EU:C:2002:343.

[908] Ibid, para 74.

[909] According to Schepel, the Court's case law on the horizontal application of free movement rules is rather obscure. Consequently, '…the total market may be a lot more fearsome than the total constitution, but the scariest position of all is to find ourselves unable to tell the difference'. See: H. Schepel, 'Who is Afraid of the Total Market? On the Horizontal Application of the Free Movement Provisions in EU Law', in I. Lianos and O. Odudu (eds), *Regulation Trade in Services in the EU and the WTO: Trust, Distrust and Economic Integration* (Cambridge University Press 2012), 301–16.

be subject to vague obligations.[910] However, it is difficult to argue that the free movement provisions impose unclear and imprecise obligations, for if it were so, then they should not have any direct effect at all, even against Member States.

Another claim against the horizontal effect of fundamental freedoms is based on private autonomy. It is commonly argued that private bodies should not be subject to the same obligations as States,[911] because this would amount to an unjustified interference with private autonomy.

According to Leczykiewicz, private autonomy in the EU legal order is protected under 'the rubric freedom to conduct a business'[912]—the right enshrined in the EU Charter. Does this mean that Article 16 of the Charter (freedom to conduct a business) should be taken into consideration when constraining the actions of private standards bodies by free movement rules? Such a possibility cannot *per se* be ruled out, but the prospect of, for instance, the ESOs being able to justify restrictions of free movement simply by referring to its private autonomy enshrined in Article 16 is not promising. The *Fra.bo* case was a perfect occasion to test the limits of Article 16 for protecting the private autonomy of a standardisation body vis-à-vis the free movement rules. However, the German standardisation and certification organisation had not invoked Article 16, and thus the issue was not raised in the questions submitted for a preliminary ruling. That said, AG Trstenjak noted the possibility of using Article 16 to counterbalance the restrictions stemming from the market freedoms. On this point, she opined:

> DVGW might, furthermore, refer to its private-law nature and rely on the protection of the fundamental rights guaranteed in the Charter of Fundamental Rights, such as the freedom to conduct a business guaranteed in Article 16 of the Charter of Fundamental Rights, and endeavour to demonstrate a collision between the free movement of goods and one or more fundamental rights,

[910] Krzeminska-Vamvaka, 'Horizontal Effect of Fundamental Rights and Freedoms: Much Ado about Nothing?' (n 893).

[911] See on this matter P. Oliver and W.H. Roth, 'The Internal Market and Four Freedoms' (2004) 41 *Common Market Law Review* 407.

[912] D. Leczykiewic, 'Horizontal Effect of Fundamental Rights: In Search of Social Justice or Private Autonomy in EU Law?', in U. Bernitz, X. Groussot, and F. Shulyok (eds), *General Principles of EU Law and European Private Law* (Kluwer Law International 2013); also available at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2257818> 172.

between which a fair balance would have to be struck in application of the principle of proportionality.[913]

It follows that, according to the AG, where the free movement rules are invoked against the private standardisation body, the latter can invoke Article 16 of the Charter. When this happens, the AG argues that the balance between the free movement provisions and private autonomy should be struck on the basis of the principle of proportionality. However, justifying the private restrictive measures on the basis of merely private autonomy is less viable, especially where these measures interfere with other parties' private autonomy.

6.3.1. Functional Approach of the Free Movement Provisions against Private Measures

As mentioned above, the EU Economic law tends to disregard the dogmatic public-private divide and adopts the so-called 'functional' approach.[914] Under the umbrella term of the functional approach, two scenarios can be distinguished.[915] Firstly, in a narrow sense the functional approach entails the application of the free movement provisions to private bodies exercising regulatory function,[916] as well as to private bodies that assume 'legal autonomy from the public law.'[917] The *Walrave* case demonstrates that the quasi-legislative nature of a cyclist association was a decisive factor in the application of the free movement rules to that body.

Secondly, the EU economic law employs the functional approach in a broader sense so as to reach private bodies, which neither exercise regulatory functions nor are quasi-public bodies. In *Viking Line*, the Court made clear that fundamental freedoms were applicable not only to the actions of quasi-public organisations exercising regulatory powers, but also to private bodies.[918] The functional approach in its broader sense is not confined to establishing the

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[913] AG Trsternjak in the Case C-171/11 *Fra.bo,* ECLI:EU:C:2012:176, para 56.

[914] The functional approach focuses on the functions of a body and the effects of the measures produced by that body.

[915] See: Van Leeuwen, 'Private Regulation and Public Responsibility in the Internal Market' (n 845), 1–21.

[916] Case 36/74, *Walrave* (n 898), para 17.

[917] See: Schepel, 'Constitutionalising the Market, Marketising the Constitution and to Tell the Difference' (n 868).

[918] Case C-438/05, *Viking Line* (n 876), para 64.

regulatory function or legal autonomy of a private body, but rather focuses on the effect of a measure on the four freedoms.

The effect-based test is three-dimensional. It pays attention to the effect of a measure with respect to a certain market player in the context of particular facts.[919] The main drawback of this approach is that it can be rather abstract, since in one way or another, all actions of private bodies could have market-restricting effects for other private bodies. Therefore, under this test

> …it should be necessary to make the additional effort of showing why this particular measure produces restrictive effects of the sort normally contemplated by the free movement rules. This should be done on a case-by-case basis and the evidentiary burden should be higher than in the case of clearly public restraints.[920]

To tame the overreaching effects of the broad functional approach, AG Maduro suggested distinguishing between private operators with and without significant market power. The former, according to Maduro, have sufficient strength to possibly restrict trade, while the latter cannot do so.[921] To illustrate this, he gave an example of an individual shopkeeper who refuses to purchase the goods from another Member State that definitely has restricting effect for foreign private operators. However, the effect is not of such extent to be a barrier to market access. This is because, according to Maduro, foreign operators are still able to contact other shop owners and sell their goods in the same country and as a result the initial shop operator might even fail to withstand competition.

Maduro's approach is similar to the *de minimis* test that has been widely used in competition law cases.[922] It follows that the free movement rules should

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[919] Case C-171/11, *Fra.bo* (n 60) is a manifestation of the three-dimensional approach, as discussed in the next section in more detail.

[920] Mataija, *Private Regulation and the Internal Market* (n 22), 58.

[921] Opinion of AG Maduro in Case C-438/05, *Viking Line*, ECLI:EU:C:2007:292, para 42; D. Wyatt, 'Horizontal Effect of Fundamental Freedoms and the Right to Equality after Viking and Mangold, and the Implications for Community Competence' (2008) *University of Oxford Legal Research Paper Series, No 20/2008*; Krzeminska-Vamvaka, 'Horizontal Effect of Fundamental Rights and Freedoms: Much Ado About Nothing?' (n 893). According to Vamvaka, this test seems to introduce into the free movement field the de minimis principle that is well used in matters of competition law.

[922] However, the Court has never officially recognised de minimis in free movement of goods case law. See for instance joined Cases 177 and 178/82 *Van de Haar* (n 875), para 13; Case 269/83, *Commission v France*, ECLI:EU:C:1985:115, para 10; Case 103/84, *Commission v*

constrain only private actions, which, due to their power, economic strength or regulatory framework have similar market restricting effects as public measures. Other private actions that have an insignificant effect on trade should be beyond the reach of the free movement rules. In those cases, the competition in the market can remedy the situation and judicial involvement is not necessary.

Scrutinising private actions under the free movement rules requires reflection on the possible justifications available to private parties. Whether private bodies can rely on the Treaty justifications which are intended primarily for State measures, such as public policy, public security, health, and so on, has been a topic of much discussion.[923] However, the Court has a clear position on this matter.

> There is nothing to preclude individuals from relying on justifications on grounds of public policy, public security or public health. Neither the scope nor the content of those grounds of justification is in any way affected by the public or private nature of the rules in question.[924]

Another relevant point to be addressed is how private autonomy could be incorporated into the justifications put forward by the private parties.[925] It is not uncommon for private parties to be able to invoke private autonomy alongside the substantive justifications.[926] However, the prospect of private autonomy as being a separate and independent justification for private actors is arguable. Just as purely economic interests cannot justify restrictive State measures, so the stand-alone private autonomy is not sufficient justification for

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Italy, ECLI:EU:C:1986:229. See: L.W. Gormley, 'Inconsistencies and Misconception in the Free Movement of Goods' (2015) 40 (6) *European Law Review* 925, at 931.

[923] K. Mortelmans, 'Towards Convergence in the Application of the Rules on Free Movement and on Competition?' (2001) 38 *Common Market Law Review* 613. He suggests that a private party's ability to justify restrictive measures should be limited; Schepel, 'Who is Afraid of Total Market? On the Horizontal Application of the Free Movement Provisions in EU Law' (n 909); Schepel argues that broad justifications availed to private parties will be detrimental to 'coherence of justification regime'.

[924] Case C-415/93, *Bosman* (n 887), para 86.

[925] Opinion of AG Tstenjak in the Case C-171/11, *Fra.bo* (n 219), para 56. See also: Leczykiewicz, 'Horizontal Effect of Fundamental Rights: In Search of Social Justice or Private Autonomy in EU Law?' (n 912).

[926] For instance, in Case C-438/05, *Viking Line* (n 876), the justifications put forward could be seen as protecting trade unions' right to negotiate, as well as ensuring the public interest and social protection of workers.

private restrictions.[927] Where the measures of private bodies affect persons beyond ones adopting them, invoking private autonomy would not succeed, because such actions are no longer self-regulation and covered by private autonomy. The same is true for the standardisation used in legislation and policy documents.

6.4. Free Movement Rules and Standardisation

A standard is a technical rule that prescribes the specifications of products or the process of manufacturing. Such technical rules that vary from one Member State to another create technical barriers and are capable of hindering trade. This is especially true when it comes to binding technical rules, in other words, technical regulations.[928] In *Cassis de Dijon*, the Court found that a German binding rule laying down the minimum content of alcohol for specified categories of liqueurs was a 'measure having an effect equivalent to quantitative restriction on imports contrary to Article 30 [34 of the TFEU]'.[929]

Unlike technical regulations, standards are not mandatory rules; however, whether a standard is purely private or State-sanctioned, it still entails exclusionary effects. Meaning that a business operator needs to incur expenses to comply with a relevant standard in order to access a market easily.

In this section, I discuss the application of provisions on the free movement of goods to standardisation in general and focus on the European standardisation system. In so doing, I distinguish two scenarios: 1) standardisation linked to a State by delegation or *ex-post* recognition; and 2) purely private standardisation without an apparent link to a State. The latter is a controversial issue and is analysed in the light of the *Fra.bo* case. The final part of this section considers the application of the free movement rules to the European standardisation used in the EU legislation and policy documents.

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[927] Without substantive justification, it is difficult to ascribe weight to private autonomy claim. Opinion of AG Lenz in the Case C-415/93, *Bosman*, ECLI:EU:C:1995:293, para 126. He suggests that although a sporting association can rely on the right to association, the focus in balancing exercise should be on the 'imperative reasons in the general interest'.

[928] The technical regulations, unlike standards, are mandatory de jure or de facto technical specifications: Directive (EU) 2015/1535 (n 153), Article 1(F).

[929] Case 120/78, *Rewe-Zentral AG* (n 276), para 15.

6.4.1. Free Movement Provisions and Standardisation with a Link to State

A voluntary standard can become mandatory technical regulation where a national legislator references it in a legislative material or confers compulsory status. A technical regulation that promotes national products and discriminates against foreign products unjustifiably easily falls under the scope of application of the free movement provisions. In these scenarios, a Member State's action turns a technical standard into the 'measures having an effect equivalent to quantitative restriction.'[930]

For instance, in *Commission v Ireland* from 1988, a Member State was found to be in breach of the provision on the free movement of goods, because it organised a public tender in a manner that goods complying only with a national standard could participate.[931] Such organisation of the tender was aimed to favour a national producer, which happened to be the only company complying with the national standard. In other words, the tender rules did not allow participation of goods which had similar qualities as goods complying with the Irish standard. In a sense, it could be argued that the tender rules disregarded the mutual recognition principle. Consequently, the Court found that Ireland, using the national standard as a condition for identifying the successful tenderer and failing to accept equivalent goods, restricted the free movement of goods.

Even non-mandatory standards produced under the co-regulatory mechanisms were found to be capable of restricting the free movement of goods. Member States commonly resort to co-regulatory arrangements with national private bodies within which two situations can be distinguished—namely a delegation of State powers to private bodies[932] and *ex-post* recognition of a private measure by a State.

The restrictive private measures resulting from delegation fall under the scope of free movement provisions. This is because such private measures are linked or attributed to a State. The *Buy Irish* case manifests a similar situation. In that case, the Irish government was seen to be behind private measures, because it

[930] Article 34 TFEU.

[931] Case 45/87, *Commission v Ireland*, ECLI:EU:C:1988:435.

[932] Case C-249/81, *Commission v Ireland* (n 270).

was the government, which had established the private body, subsidised its actions, and appointed the members of a management board.[933]

Ex-post recognition of a private measure by a State[934] is another form of co-regulatory arrangements capable of falling under the free movement provisions. In the *Commission v Germany* case,[935] the activities of a private body, composed of private producers, was subject to the free movement provisions, because Germany recognised and promoted the standardisation and research activities of that body. Among several factors indicating a strong private nature of a measure was the private law form of the company. In addition, this body issued a certificate of 'German quality product' to private producers based on the leasing contract. Notwithstanding these facts, activities of that private body were found to fall under the free movement provisions because

> …[s]uch a body, which is set up by a national law of a Member State and which is financed by a contribution imposed on producers, cannot, under Community law, enjoy the same freedom as regards the promotion of national production as that enjoyed by producers themselves or producers' associations of a voluntary character.[936]

It follows that some State activities that are carried out by private standard bodies under the authorisation of a State are capable of falling under the scope of the free movement rules. However, the case law does not provide a homogenous test on State involvement. Instead, the Court merely identifies several elements indicating State involvement.[937]

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[933] Ibid, paras 11, 12, 15, 23–5 and 30. See also Case 222/82, *Apple and Pear Development Council v K.J. Lewis Ltd and others*, ECLI:EU:C:1983:370, para 35.

[934] See for instance: Case C-171/11, *Fra.bo* (n 60).

[935] Case C-325/00, *Commission of the European Communities v Federal Republic of Germany* (n 895).

[936] Ibid, para 18.

[937] See the rather elaborative test provided by AG Capotori in the Case C-249/81, *Commission v Ireland*, ECLI:EU:C:1982:293. The Irish Goods Council has the same appearance as a public institution with auxiliary functions in the economic field; more precisely, it constitutes an instrument which: a) pursues objectives which correspond or are parallel to certain objectives of the Irish Government, with regard to the development of national economic activity, and b) maybe used or influenced by that Government.

Falke et al give five scenarios of State involvement in private activities that are equally relevant to the standardisation discussion too.[938] These include State involvement in: a) the creation or dissolution of the body;[939] b) setting the rules governing the body; c) the management of the body;[940] d) financing the body;[941] and finally e) directing the activities of the body.[942]

Extending the scope of the free movement provisions to private regulation based on a link to a State is uncontroversial and seems logical. However, one must be cautious about it, because a State action can be traced in almost all cases. On the other hand, suggesting that 'the state action is always present'[943] rules out the possibility of a purely private action.[944]

6.4.2. Free Movement Provisions and Standardisation without an Apparent Link to a State: The *Fra.bo* case

Can a purely private standardisation without the elements of State involvement be constrained by the free movement provisions? The answer to this question is considered below. As discussed in section 6.3.1., the Court using the functional approach has applied free movement rules horizontally, against private bodies, in certain cases.[945] However, horizontal application of free movement provisions had been restricted in the sector of goods until *Fra.bo*. The latter case suggests that private standardisation without an apparent link to the State might fall under the scope of the free movement provisions.

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938 Schepel and Falke, 'Legal Aspects of Standardisation in the Member States of EC and EFTA' (n 343), 58–9.

939 See for instance: Case 222/82, *Apple and Pear Development Council* (n 933).

940 Case 302/88, *Hennen Olie BV v Stichting Interim Centraal Orgaan Voorraadvorming Aardolieprodukten and State of the Netherlands*, ECLI:EU:C:1990:455, para 15.

941 Case C-249/81, *Commission v Ireland* (n 270).

942 Ibid.

943 C. Sunstein, 'State Action is Always Present' (2002) 3 *Chicago Journal of International Law* 465.

944 Although similarly one could argue that 'no function is inherently governmental and almost everything can be performed by private actors'. See: M. Elliott, 'Judicial Review's Scope, Foundations and Purposes: Joining the Dots' (2012) *New Zealand Law Review* 75, at 97.

945 See inter alia: Case 36/74, *Walrave* (n 898), paras 17, 23 and 24; Case C-415/93, *Bosman* (n 887), paras 83 and 84; Case C-309/99, *Wouters,* ECLI:EU:C:2002:98, para 120; Case C-281/98, *Roman Angonese* (n 900); Case C-171/11, *Fra.bo* (n 60).

The case concerned a dispute between Fra.bo SpA, an Italian company, specialised in the production and distribution of copper fittings, and the German standardisation and certification body (hereafter DVGW). In particular, the actions of DVGW were challenged under free movement of goods provision. These actions included the refusal to accept the test of the Italian laboratories for certification purposes and request for the 3,000-hour water submersion test demanded by DVGW standard.

The German Court was interested in receiving an answer from the ECJ to the question of whether Article 34 TFEU[946] must be interpreted as applying to standardisation and certification activities of private-law bodies. In short, the ECJ found that the DVGW's activities were capable of restricting the free movement of goods. To come to this conclusion, the Court did not use the usual mantra that 'activities of regulating collectively…trade fall within the scope of application of free movement rules.' This is because the Court did not regard standardisation *per se* as regulatory activity, or the activity which inherently belongs to the State.

Rather the ECJ used an effect-based, three-dimensional approach and asked whether the action of DVGW, in this particular case, with respect to Fra.bo, could be capable of restricting free movement of goods.

> It must, therefore, be determined whether, in the light of inter alia the legislative and regulatory context in which it operates, the activities of a private-law body such as the DVGW has the effect of giving rise to restrictions on the free movement of goods in the same manner as do measures imposed by the State.[947]

It found that compliance with a DVGW standard was the only way for Fra.bo to penetrate the German market. The DVGW's certificate was carrying such significance because of the 'legal and regulatory context' that granted products certified by DVGW a presumption of conformity with the rules on general sales conditions for the water sector. The alternative ways of compliance were also recognised; however, such possibility was left purely on paper. This meant that Fra.bo could, in theory, appoint an independent expert to certify its products' compliance with legislative requirements, although this route was costly and unclear. In addition, DVGW, 'in reality', assumed the power '…to

[946] The Article reads as follows: 'Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States'.

[947] Case C-171/11, *Fra.bo* (n 60), para 26.

regulate the entry into the German market.'[948] This is because most consumers in Germany preferred the goods certified by DVGW.

> Although the ABVWasserV (German Regulation on General Conditions of Water Supply) merely lays down the general sales conditions as between water supply undertakings and their customers, from which the parties are free to depart, it is apparent from the case-file that, *in practice, almost all German consumers purchase copper fittings certified by the DVGW*.[949]

Fra.bo is a remarkable example of a broad functional approach focusing on the effect of a measure at hand. Here the ECJ did not resort to the formal public-private distinction, based on the status of the body or the nature of the activities. Rather it explored whether the activities of a private standardisation body, in respect of the pertinent facts, were capable of restricting trade, that is to say, their effects were similar to those of State measures. For the Court, it was not important whether the standardisation and certification activities were linked to the State, or whether the standardisation was an inherently public function, or whether DVGW could be qualified as public law body. Rather the fact that DVGW 'in reality' regulated access to the market was sufficient to trigger the provision on the free movement of goods.

However, the ECJ's reasoning in *Fra.bo* is still limited. On the one hand, the Court found that activities of a standardisation body fall under the free moment provisions, but it did not consider whether these activities restricted the free movement of goods and could have been justified or not.

If the Court were to find that refusal to recognise an Italian laboratories' test was a restriction to the free movement of goods, as the German Court did, after receiving the Court's ruling, this would strike at the very sensitive issue of mutual recognition among the national standard bodies in the absence of a common harmonised standard.[950] As Mataija has rightly noted, 'the whole standard-setting exercise could lose value, leading to a "race to bottom" where undertakings would have an incentive to satisfy the least demanding quality standard.'[951]

The second aspect of the DVGW's action, namely requiring a 3,000-hour submersion test, could infringe free movement of goods if it were proved to be

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[948] Ibid, para 31.

[949] Ibid, para 30, emphasis added.

[950] Mataija, *Private Regulation and the Internal Market* (n 22), 247–8.

[951] Ibid, 248.

unnecessary. However, to reach this conclusion the Court would have needed to enter into the assessment of the technical standard itself. In particular, the Court would have been forced to rule on whether copper fitting needs to satisfy and endure the 3,000-hour submersion test, which would go beyond the competence and the knowledge of the Court. Therefore, the only plausible review the Court could exercise in similar cases is procedural, that is, to assess whether a standardisation process satisfies the principles of good governance—such as openness, non-discrimination, and transparency. In the next chapter I continue this thread of reasoning and argue that the Court should act as a catalyst in reviewing cases concerning standardisation. Specifically, the Court should focus on the adherence of the standard-setting process to the principles of good governance, so as facilitate deliverance of legitimate standards, not restricting trade.

On another note, it is worth reflecting on the relationship between DVGW and Germany. The *Fra.bo* case could have developed in a different way given that the preliminary ruling had concerned the issue of whether Germany was infringing the free movement provisions. In that case, the free movement rules would have constrained a State measure legislation, for not providing any viable alternatives to the DVGW's certificate, such as explicit recognition of certificates from the standards bodies from other Member States. It follows that Germany alongside DVGW could have been found to be restricting the free movement provisions. Germany would have been liable under the free movement provisions due to its regulations. Meanwhile, DVGW would have been infringing the free movement provisions for either discriminating undertakings or test laboratories on the ground of nationality, or failing to conduct standardisation in an open, transparent, non-discriminatory, and inclusive manner.[952]

6.4.3. Free Movement Provisions and the Co-regulation via European Standardisation

The somewhat forgotten issue is the application of the EU free movement provisions to co-regulatory arrangements involving EU institutions and private bodies, as in the case of the European standardisation system. In principle, nothing restricts the application of the free movement rules to private regulators at the EU level. However, in the event of a conflict between the free movement provisions and the European standardisation used in EU legislation,

[952] Ibid, 249.

it is expected that the Court would have high deference to such standardisation, especially since the HESs are used as a tool to remove trade barriers and ensure free movement of goods.

Would the European standardisation used in support of EU legislation and policy, although on a voluntary basis, fall under the scope of the free movement provisions? The answers to this question cannot be resolved through the formal public-private divide. One cannot put the European standardisation system into purely private or public boxes; rather it includes many shades of public-private features.

The elements of the EU institutions' involvement in the European standardisation process are not strong enough to trigger unequivocally the application of the free movement rules. The ESOs are neither created nor can be dissolved by the EU institutions or Member States. The EU only pays for the work carried out in response to a Commission's mandate.[953] The rules governing the ESOs are internal guidelines and articles of association. At the same time, Regulation on European standardisation urges these bodies to arrange the procedure in an open, transparent, and non-discriminatory manner.[954] These are principles of good governance if observed by standards bodies, providing the assumption that the standards developed are 'trustable' and can be used for regulatory purposes.

In the wake of uncertainty, the *Fra.bo* case provides helpful guidance. The co-regulation via European standardisation displays similar features as the regulatory arrangements in *Fra.bo.* The ESOs, like DVGW, are private bodies that draft standards, compliance with which is also strictly speaking voluntary and yet de facto mandatory, given the presumption of conformity granted to products complying with these standards. Likewise, European consumers prefer to buy goods carrying the CE mark, which adds to the pressure for companies to conform to the ESOs' standards.

Consequently, in the light of *Fra.bo*, the ESOs' action to write an HES potentially falls under the scope of the free movement rules for two reasons. Firstly, the legislative framework grants legal effects to the HESs, and although compliance with the HESs is voluntary, alternative ways of compliance only really exist on paper. Secondly, the ESOs 'in reality' hold power to regulate entry into the internal market of products covered by the New Approach directives. This is because the HESs are de facto mandatory for business

[953] Regulation 1025/2012 (n 14), Article 15.

[954] Ibid, Chapter II.

operators wishing to engage in cross-border trade and they affect market access. It follows that the harmonised standards written by the ESOs and the regulatory arrangements of the New Approach could fall under the scope of Article 34 TFEU.[955] To continue with this logic, at the end of the day, the national standards-setting organisations might be found impinging the rules on the free movement of goods, due to the market-hindering effects of national standards simply transposing the HESs.[956] What this means is that the EU free movement provisions most certainly would intersect with European standardisation at the national level, since all the HESs are transposed by national standard bodies and business operators buy the national transpositions of the HESs. This could be quite an absurd situation whereby national standard bodies would be held responsible for the automatic transposition of the HESs.

It is true that usually the free movement rules apply to the measures of the Member States, but according to the Court's case law, it equally applies to the Institutions of the EU in a similar manner.[957] Meaning that the New Approach directives providing regulatory framework under which the HESs acquire de facto mandatory nature could potentially impinge on the free movement of goods. It would not matter that certification to the HESs is formally voluntary if it is established that alternative ways of compliance remain only possible on paper. What is more, the ESOs' activities concerning the writing of the HESs could trigger the application of free movement provisions, since the HESs which are acts of the ESOs 'in reality' regulate entry into the internal market.

In the light of *Fra.bo* one has to conclude that the European standardisation system is potentially subject to the free movement of goods provision. However, it is difficult to imagine that the Court would find that the HESs

[955] Schepel, 'Between Standards and Regulation' (n 600), 206. See also the Court's joined cases C-154/04 and C-155/04, *Alliance for Natural Health* (n 758), para 49. This case demonstrates that Article 34 TFEU applies to the actions of the EU institutions likewise as to the Member States.

[956] Schepel, 'Between Standards and Regulation' (n 600), 207.

[957] See: Joined Cases C-154/04 and C-155/04, *Alliance for Natural Health* (n 758), paras 47 and 49: 'It must be observed that by virtue of settled case-law the prohibition of quantitative restrictions and of all measures having equivalent effect, laid down in Article 28 EC, applies not only to national measures but also to measures adopted by the Community institutions'; Case 15/83, *Denkavit Nederland*, ECLI:EU:C:1984:183, para 15; also K. Mortelmans, 'The Relationship Between the Treaty Rules and Community Measures for the Establishment and Functioning of the Internal Market: Towards a Concordance Rule' (2002) 39 *Common Market Law Review* 1303.

restrict trade given that the whole point of adopting these standards is to ensure the free movement of goods.

Moreover, the co-regulation via European standardisation, even if it were to be found to restrict the free movement provisions, could most probably be justified. The HESs provide technical means for implementation of essential requirements of the New Approach directives. Those essential requirements usually concern safety, health, and environmental protection, and hence fall under the scope of mandatory requirements enshrined in the Treaties and objective justifications provided by the case law.

This means that the Commission will be requested to demonstrate how the HESs satisfy essential requirements, while the ESOs perhaps would need to prove that the developed HESs are necessary and appropriate means to ensure the compliance with the essential requirements.[958]

In addition to the mandatory requirements and objective justifications, according to AG Trstenjak, a private autonomy embodied in Article 16 of the Charter could be a legitimate ground of justification invoked by the standards bodies. However, such a proposal is debatable.[959] It is true that the ESOs are independent in their activity, i.e. in the process of development of standards even in response to a mandate. However, the ESOs trade off their private autonomy for a 'regulatory autonomy' by accepting cooperation with the Commission and allowing their standards to be used for regulatory purposes.

6.4.4. Section Conclusion

In this section, I have argued that the EU economic law and the free movement provisions in particular are capable of applying to and disciplining private actions. In doing so, the internal market provisions tend to abandon the formal public-private distinction and instead employ the functional approach that focuses on the effects of private measures. The *Fra.bo* case continues this line of reasoning in the sector of goods and indicates that private standardisation can also fall under the free movement rules.

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[958] Schepel, 'The New Approach to the New Approach' (n 371), 528.

[959] Mataija, *Private Regulation and the Internal Market* (n 22), Chapter 4. Mataija argues that private autonomy should give way to a regulatory autonomy. According to him, since the Courts usually would give greater deference to these bodies, in terms of the substance of their measure, in return these private bodies should sacrifice their private autonomy to openness.

In light of this, I suggested that the co-regulation via European standardisation can also be potentially subject to the free movement provisions. However, this does not mean that the HESs or their national transpositions, if falling under the scope of the free movement provisions, would be found to restrict trade unequivocally. Using the existing case law as a springboard, I noted that it is more likely that the Court would pursue a deferential approach to the European standardisation system. The rationale for this is that European standardisation is used as a technical harmonisation tool to ensure the free movement of goods and to harmonise product requirements throughout the Union. In addition, in considering whether standardisation restricts the free movement of goods, the Court would most probably refrain from assessing the content of a standard and exercise only procedural review.

6.5. Competition Rules and European Standardisation

The focus in this section is on the interplay between the EU competition law and the formal European standardisation at the EU level. More precisely, I discuss how the EU competition rules regard and regulate the European standardisation used in legislation and policy documents. This is done to investigate the legal framework offered by the EU economic law for regulating the European standardisation system, as well as to contemplate the accountability thereof through the EU economic law.

The competition law can apply to a broad range of practices within the standard-setting process, as well as to the actions of the ESOs. It is worth remarking, though, that certain anti-competitive actions of undertakings participating in standard-setting will not be discussed here. Rather I consider the application of the EU competition rules to the standardisation in general, as a form of private regulation, and to the process of standard-setting in particular.

Nobody disputes the economic incentives of standardisation for business operators. Among the many benefits, it suffices to mention 'first-mover advantage'[960] and revenues for licensing the technologies incorporated in a

[960] Delimatsis, 'Standardisation in Services: European Ambitions and Sectoral Realities' (n 594), 514.

standard.[961] Although an important element for economic growth,[962] standardisation can also entail certain pitfalls—such as creating barriers to trade and excluding or foreclosing some technologies from the market. As such, the exercise of private powers by the ESOs might encroach upon individuals' or legal persons' interest or impinge wider Union interests—such as the protection of competition in the internal market. This naturally calls for the application of the EU competition rules to the standard-setting.

The use of the competition rules in the case of de facto standards, set by the private undertakings, is less controversial.[963] The EU competition rules have the potential to deal with the standardisation agreements or discipline the actions of certain business operators participating in the standardisation process. However, the application of the EU competition rules is anything but clear to the standardisation bodies themselves and standards produced by the ESOs in response to a Commission's mandate. The controversy owes in part to the uncertainty over whether the ESOs[964] can qualify as undertakings or associations of undertakings especially when they act upon the Commission's mandate.

The development of the HESs that are later used for regulatory purposes is not immune from the competition law provisions, save that the ESOs qualify to be undertakings or associations of undertakings.[965] Already in 1986, the Commission stated that standards—irrespective of whether they are set by national associations or by the ESOs—fall within the reach of the competition rules.[966] Furthermore, recently the horizontal guidelines deemed standardisation agreements to be subject to competition rules.

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[961] See for instance: D. Spulber, 'Innovation Economics: The Interplay among Technology Standards, Competitive Conduct, and Economic Performance' (2013) 9 (4) *Journal of Competition Law and Economics* 777. See about the benefits of standards: Commission, Horizontal Guidelines (n 783), para 263.

[962] See: K. Blind and A. Jungmittag, 'The Impact of Patents and Standards on Macroeconomic Growth: A Panel Approach Covering Four Countries and 12 Sectors' (2008) 29 (1) *Journal of Productivity Analysis* 51.

[963] Schepel, *The Constitution of Private Governance* (n 111), 309.

[964] In this thesis ESOs refer only to CEN and CENELEC, excluding ETSI, if not otherwise specified.

[965] Regulation 1025/2012 (n 14), Recital 13.

[966] See the Commission notice concerning agreement, decision, and concerted practices in the field of co-operation between enterprises (1968) OJ C 75/3.

At the same time, the guidelines recognise that the standardisation may also benefit competition, and they stipulate requirements that provide safe harbour for the standardisation agreements. The EU's approach to standards can be summarised as follows. By their very nature, standards grant an economic advantage to some parties at the expense of others, thus falling squarely under the competition law restrictions. In its turn, competition law grants immunity to the standard-setting that follows the principles of good governance and is 'public-regarding'.[967]

In light of the foregoing, this chapter aims to demonstrate that the European standardisation in principle is not exempted from the competition rules. However, the EU competition law adopts a deferential approach to a formal standardisation. In particular, the European standardisation process can become immune from the application of the competition law on the basis of two pillars. Firstly, the ESOs might not always be regarded as undertakings or associations of undertakings; this is especially true for CEN-CENELEC, where business operators do not participate directly. In addition, CEN-CENELEC's action to develop the HESs in response to the Commission's mandate could qualify as an exercise of a public task.

Secondly, the EU competition law grants immunity to the European standardisation process that adheres to the pre-defined procedural principles. Consequently, the examination of the EU formal standards under the competition law starts with the assessment of the compliance of the standard-setting process with the procedural criteria of good governance. Although the EU competition law is deferential towards the formal standardisation, at the same time it could have a role of private administrative law promoting an open, non-discriminatory, and transparent process for standard-setting.

This topic is unpacked in the following manner. Firstly, the application of the competition rules to private regulation is addressed. Private regulation here denotes activities of private bodies that have regulatory impact or purpose and excludes pure self-regulation. Next, I discuss whether the ESOs can qualify as undertakings or associations of undertakings to allow the competition law scrutiny. Later, the application of the competition law provisions to the standard-setting procedure and the co-regulation via European standardisation is scrutinised. In conclusion, it is suggested that the competition law 'disciplining' the European standardisation system would most probably be

[967] See: Schepel, *The Constitution of Private Governance* (n 111), 257. See discussion about this in section 6.5.3.

concerned with the process of standard-setting. Hence, the EU economic law in general and the competition provisions in particular have the potential to promote procedural principles of good governance in the standardisation process, rendering the latter more accountable and improving the standards-making process.

6.5.1. Competition Law and Private Regulation: The Case of the European Standard-setting

The EU competition provisions are directly effective and serve to constrain primarily private power.[968] Limiting private regulation with the EU competition law is not uncommon. Indeed, competition law provisions have been applied against the rules of, for instance, bar associations,[969] air-traffic control,[970] and sporting associations.[971] Private regulation, in many different ways, could entail anti-competitive actions falling under the scope of Articles 101 and 102 TFEU.

In this section, I provide a general outline of the competition law constraining private regulation, and specifically European standardisation, with the caveat that there is no specific test as to how the competition law provisions address private regulation. Assuming that the reader is familiar with the well-established steps under Articles 101 and 102 TFEU, I do not revisit them here. Nor do I discuss or give examples of specific actions of the standardisation bodies, which could be constrained by the competition rules.

Applicability of the competition rules to entirely private standardisation without any co-regulatory schemes is not disputable. It is worth noting that the co-regulatory arrangements are sometimes exempted from the competition law reach, as to protect Member States' political choices.[972] In the rest of the cases, the competition law can apply to both private regulators, as well as Member States within a co-regulatory strategy. The focus of this thesis is the cooperation between the Commission and the ESOs—in other words,

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[968] See for instance joined Cases 177 and 178/82, v*an de Haar* (n 875), para 24, which suggests that the competition provisions apply to private undertakings.

[969] Case C-309/99, *Wouters* (n 945).

[970] Case C-113/07P *SELEX Sistemi Integrati SpA v Commission* (Eurocontrol), ECLI:EU:C:2009:191; Case C-364/92, *SAT Fluggesellschaft mbH v Eurocontrol* (n 876).

[971] Case C-519/04P, *David Meca-Medina* (n 886).

[972] Mataja, *Private Regulation and the Internal Market* (n 22), 84.

cooperation between the EU institutions and the standards bodies at the EU level. Therefore, discussion on the application of competition law to the co-regulation involving standardisation and Member States does not follow. However, the presence of the link between the standardisation and EU institutions is to be incorporated into the competition law analysis. At the same time, it does not automatically amount to an *ex-ante* exemption of such standardisation from the application of the competition law.

Standardisation as a form of private regulation enables different kinds of horizontal cooperation, where, for instance, competitors can exchange information within the standard-setting process. Such practice is a potential subject matter of Article 101 TFEU. The application of 101 is more common to private regulators than is Article 102 TFEU. This is because Article 102 encompasses actions of a private regulator which is a dominant undertaking[973] and does not apply to an association of undertakings or industry association that do not compete in the relevant market.[974]

In addition, the ESOs would not qualify as a group of undertakings for the purpose of Article 102 TFEU if their members are not linked to the extent that they limit competition by adopting the same conduct.[975] In contrast, competitors participating in private regulation, if forming collective dominance, are potential subject matters of Article 102 TFEU. In the context of standardisation, an undertaking or undertakings can be regarded to hold a dominant position, which they can abuse through the rules of the ESOs. Hence, to avoid one of the most common abuses in the standard-setting context that is patent hold-ups, competition law imposes on the ESOs requirements to develop intellectual property policy based on Fair, Reasonable, and Non-Discriminatory terms (FRAND).

[973] Dominance is generally defined as '…a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers'. See: Case 27/76, *United Brands Company and United Brands Continentaal BV v Commission of the European Communities*, ECLI:EU:C:1978:22, para 65.

[974] See Article 102 TFEU. See also: R. Whish and D. Bailey, *Competition Law* (8th edn, Oxford University Press 2015), Chapter 3, Article 101(1), 85.

[975] See the same reasoning in Case C-309/99, *Wouters* (n 945), para 114.

6.5.2. Limited Reach of the EU Competition Law to the European Standardisation System: Are the ESOs Undertakings or Associations of Undertakings?

The concept of undertaking is central in competition law, and only the agreements or concerted practices between undertakings fall under Article 101. Similarly, Article 102 applies only to the abuses of dominant undertakings. In other words, competition law disciplines anti-competitive actions, which are the responsibility of an undertaking.[976]

According to Regulation 1025/2012, the ESOs[977] could be subject to EU competition rules if they qualify as undertakings or associations of undertakings.[978] Hence, below I will discuss the concept of undertaking and its constituent parts. By doing so, I analyse whether the ESOs could be regarded as undertakings or associations of undertakings.

The EU Treaties do not define the meaning of the term 'undertaking' and leave it to the ECJ. In its turn, the ECJ has adopted a functional approach to the concept of undertaking so as to ensure the effectiveness of the EU competition rules.[979] An 'undertaking' is an EU law concept that 'encompasses every entity engaged in economic activity, regardless of the legal status of the entity and the way it is financed.'[980] It follows that an undertaking in EU law is a relative term.[981] For instance, public bodies could be seen as undertakings while exercising commercial activities, but when they act in a public capacity they would not qualify as undertakings.[982] The core element of the concept of undertaking is economic activity. In its turn, the economic activity

[976] See Article 102 TFEU. See also: Whish and Bailey, *Competition Law* (n 973), Chapter 3, Article 101(1), 85.

[977] As mentioned in Chapter 1, this thesis concerns standards developed in response to the Commission's mandate excluding the Telecommunication and ICT standards, hence the ESOs which fall under the scope of this thesis are CEN and CENELEC, excluding ETSI.

[978] Regulation 1025/2012 (n 14), Recital 13.

[979] A. Ezrachi, 'The Concept of Undertaking in EU Competition Law', in *An Analytical Guide to the Leading Cases* (Hart Publishing 2014).

[980] Schepel, *The Constitution of Private Governance* (n 111), 315. See also Case C-41/90, *Höfner*, ECLI:EU:C:1991:161, and Case 118/85, *Commission v Italy*, ECLI:EU:C:1987:283.

[981] Ezrachi, 'The Concept of Undertaking in EU Competition Law' (n 979).

[982] 'The Classification as an activity falling within the exercise of public powers or as an economic activity must be carried out separately for each activity exercised by a given entity'; Case C-49/07, *Motosykletistiki Omospondia Ellados NPID (MOTOE) v Elliniko Dimosio*, ECLI:EU:C:2008:376, para 25.

encompasses offering goods or services.[983] The fact of whether an undertaking has an economic purpose[984] or profit motive[985] is not crucial to qualify an activity as economic.[986] In *Höfner*, the employment agency was regarded as an undertaking, because its activity incorporated supplying services, notwithstanding the fact that this service was provided free of charge.[987]

The Court also held that even an organisation established as private and profit-making, but which exercises tasks belonging to the domain of public power, is not an undertaking for the purposes of competition law. In the *Diego Cali* case,[988] a corporation that verified compliance with environmental laws and charged retribution for it was not considered to qualify as an undertaking. This is because, according to the Court, '[s]uch surveillance is connected by its nature…with the exercise of powers relating to the protection of the environment which are typically those of a public authority.'[989]

In short, the concept of an undertaking is subject to two limitations—namely, the non-economic nature of the activity and the exercise of public power. A body will not qualify as an undertaking if one of these two conditions is present. Therefore, the discussion about whether the ESOs are undertakings or associations of undertakings evolves around these two criteria.

The ESOs are non-profit, regional, standard-setting bodies officially recognised by Regulation 1025/2012. As explained above, a body can be considered as an undertaking if it pursues an economic activity, notwithstanding its non-profit purpose. Delimatsis suggests that the ESOs could be regarded as pursuing economic activities even in the system of the

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983 See Case C-41/90, *Höfner* (n 980), where German federal employment agency was seen providing services and hence qualified as an undertaking; Case C-475/99, *Firma Ambulanz Glöckner v Landkreis Südwestpfalz*, ECLI:EU:C:2001:577. In the latter case, the medical aid organisation was regarded as an undertaking because providing ambulance services for remuneration was an aspect of economic activity.

984 Whish and Bailey, *Competition Law* (n 974), Chapter 3, Article 101(1).

985 Case C-244/94, *Fédération Française des Sociétés d'Assurance*, ECLI:EU:C:1995:392, para 21.

986 In the Court's case law, certain activities were qualified as non-economic. See on this matter: Whish and Bailey, *Competition Law* (n 974), Chapter 3, Article 101. Three activities have been held to be non-economic: those provided on the basis of 'solidarity'; the exercise of public powers; and procurement pursuant to a non-economic activity.

987 See Case C-41/90, *Höfner* (n 980).

988 Case C-343/95, *Diego Calì*, ECLI:EU:C:1997:160.

989 Ibid, para 23.

co-regulation that produces the HESs used in legislation.[990] Such conclusion is correct only if the ESOs engage in economic activity, which consists of offering goods and services. The European standards developed by the ESOs are sold not by these bodies, but rather by national standard bodies. As a result, it is less doubtful that national standard bodies could qualify as undertakings, since they are engaged in selling access to their standards.[991] However, when it comes to ESOs, they receive financing from the EU for setting the HESs. Could this be qualified as offering 'goods'—i.e. the HESs—to the Commission? The HESs are intended to be used by the undertakings. Therefore, the economic activity includes offering these standards to the interested undertakings, which takes places through the national standards bodies. It follows then that the ESOs do not themselves supply goods—the HESs—in the market. Hence, the ESOs do not pursue an economic activity and cannot be regarded as undertakings.

The second limit of the concept of an undertaking is closely linked to the exercise of public power. The horizontal guidelines state that the competition rules are not applicable in cases that concern the 'preparation and production of technical standards as part of the execution of public powers'.[992] The *SELEX*[993] is the judicial support of this point. The case concerned a complaint against the European Organisation for the Safety of Air Navigation (Eurocontrol) established by contracting States. The latter had set standards in the area of air navigation that were used by participating States to create a uniform system for air traffic management and control. The applicant, SELEX, complained about Eurocontrol's regime of intellectual property rights in relation to the prototypes purchased under research contracts from undertakings. Access to these rights were vital for competing undertakings, should prototypes lead to enactment of a standard. According to SELEX, Eurocontrol's regime of intellectual property rights created a factual monopoly, whereas the firms providing prototypes were in an advantageous position compared to their competitors. The applicant's claim was based on Article 102 TFEU, alleging an abuse of a dominant position by Eurocontrol.

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[990] Delimatsis, 'Standardisation in Services: European Ambitions and Sectoral Realities' (n 594), at footnote 62.

[991] Gestel and Micklitz, 'European Integration through Standardisation' (n 63), 147.

[992] Commission, Horizontal Guidelines (n 783), para 258.

[993] T-155/04, *SELEX Sistemi Integrati v Commisison*, ECLI:EU:T:2006:387 and Case C-113/07P, *SELEX* (n 970).

The General Court (GC) distinguished between the Eurocontrol's activities to adopt, and to prepare and develop standards. Adoption of standards was not seen as economic activity, but rather was regarded as an exercise of public power. According to the GC, there was no market for standards, because the only purchasers of these standards would be States and the States would not use this service in economic activity. Neither research nor development activities of Eurocontrol were regarded as economic activity. The GC found that acquisition of prototypes did not include offering goods or services in the given market. An additional indicator of the non-economic nature of the activity was the fact that intellectual property rights were made available, free of charge to anyone.[994]

The ECJ, too, excluded Eurocontrol from the application of competition law, albeit with a somewhat different line of reasoning. The ECJ did not distinguish between the different functions of Eurocontrol. Rather, according to the ECJ, adoption of standards could not be separated from the preparation and development thereof. All these actions together were linked to the public task of managing air space and developing air safety.[995] Consequently, Eurocontrol was found to be immune from the competition rules.[996]

The ECJ's judgment in *SELEX* clearly sets the boundaries to the concept of an undertaking, leaving the exercise of public power outside this concept. *SELEX* creates the possibility to put the ESOs beyond the reach of competition law if they are regarded as performing a public task. Developing the HESs for the purposes of harmonisation of the product requirements throughout the Union might be seen as an exercise of a public task. The HESs perform an important role in harmonising product requirements and provide technical means to ensure safety, health, and environmental protections. However, in the *EMC* case, which concerned an HES, the Court did not even discuss whether the development of the said standard fell under the ambit of a public task.

As for whether the ESOs could be regarded as associations of undertakings, it should be kept in mind that the members of the ESOs are national standard-

994 Ibid.

995 Case C-113/07 P, *SELEX* (n 970), para 89 et seq.

996 T-155/04, *SELEX* (n 993), and Case *SELEX* (n 970). See the commentary on the latter case, J. Nowag, 'Case C-113/07P, Selex Sistemi Integrati SpA. V Commission [2009] ECT I-2207: Redefining the Boundaries between Undertaking and the Exercise of Public Authority', (2010) <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1891720> accessed 3 March 2015.

setting bodies[997] and not undertakings themselves, unlike in the European Telecommunications Standards Institute (ETSI). The national standard bodies are themselves associations of undertakings. Following this reasoning, it is difficult to argue that the ESOs, with the exception of ETSI, are associations of undertakings.

However, the national delegations in the ESOs consist of the representatives of undertakings. In particular, the technical committees responsible for the development of European standards, including harmonised ones, consist of the representatives of experts from pertinent industries. The working groups responsible for these technical committees are comprised of representatives of undertakings, which are appointed by the national standard bodies.[998]

The Commission in *EMC* did not address whether a challenged harmonised standard was a decision of an association of undertakings or an agreement between undertakings. The Commission stressed the fact that the national delegations to CEN consisted of representatives mainly from the relevant industry, which suggested perhaps that these members 'still conduct an "economic activity", and do not lose their standing as undertakings under the EU competition law.'[999] This invited an application of Article 101 and made an HES subject to the competition rules. It follows that the anti-competitive actions among undertakings participating in standardisation are subject to the competition law restrictions, save that the standardisation is not an exercise of public power.

The difficulties in regarding the European standards bodies as undertakings or associations of undertakings seem to limit the reach of competition law to the ESOs directly. However, the competition law grasps the ESOs through undertakings involved in the working groups, and in doing so, it influences the process of standard-setting. The competition rules require the ESOs to structure their internal policies in a manner so as to minimise the risk of anti-competitive actions by undertakings. In other words, the competition law reaches these standard bodies through undertakings participating in the standardisation process and 'disciplines' the standards-making process. In the

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997 Case C-367/10P, *EMC* (n 415).

998 Lundqvist, *Standardization under EU Competition Rules and US Antitrust Laws* (n 146), 126. See also: Commission Decision Rejecting a Complaint, Case COMP/F-2/38.401 EN 197-1 Standard. EMC/European Cement Producers, Brussels, 28 IX 2005, paras 73–5.

999 Lundqvist, *Standardization under EU Competition Rules and US Antitrust Laws* (n 146), 193.

process, it aims to avoid the restrictions of competition by undertakings involved in standards development.

In sum, the application of the competition rules to the standardisation system encompasses two scenarios. The first type includes cases where the competition law is concerned with standard-setting and the use of standardisations as a forum for anti-competitive activities. The second scenario concerns unilateral action that abuses the standard-setting process, for instance, cases related to patent ambush. These two scenarios of the intersection between the standardisation and competition law are addressed briefly below.

6.5.3. The European Standardisation System and Article 101 TFEU: The Safe Harbour

Application of the competition law to companies engaged in the standardisation activity is not an unheard-of practice. However, it is a rather controversial issue as to whether the formal ESOs could be susceptible to the competition law constraints as discussed above. Whether or not the ESOs could be regarded as undertakings or associations of undertakings,[1000] competition law has the potential to influence the process of standard-setting, through participating undertakings. In turn, the ESOs become responsible for protecting competition in the process of standards development. The main concern with the standardisation process is that it enables collusion between the companies and provides an opportunity to reduce or eliminate competition. Such collusive actions are usually covered by Article 101 TFEU.

The competition law regulating standardisation faces a tension—namely to tackle anti-competitive actions and, at the same time, avoid stifling pro-competitive effects of the standardisation. The Commission has long been aware of the benefits of standardisation.[1001] The standards have positive effects on the economy, as they promote economic interpenetration in the internal market, encourage the development of new products, increase competition, and

[1000] According to the Commission in *EMC*, CEN is a standard body recognised under Directive 98/34/EC entrusted with the general economic interest (after modification of the legal framework surrounding standardisation, now European Standard body, CEN is recognised by Regulation 1025/2012).

[1001] Commission Communication on 'Intellectual Property Rights and Standardisation' COM (1992) 0445, section 4.2.10.

lower output and sales costs.[1002] These benefits are attained through standards, which provide interoperability, enhance quality, and provide information.[1003] Notwithstanding its positive effects on the economy, standard-setting can, in specific circumstances, have restrictive effects on competition[1004]

> …by potentially restricting price competition and limiting or controlling production, markets, innovation or technical development. This can occur through three main channels, namely reduction in price competition, foreclosure of innovative technologies and exclusion of, or discrimination against, certain companies by prevention of effective access to the standard.[1005]

In short, competition law concerns can be caused either by the process of standard-setting or by the content of a standard. The Commission's revised guidelines on horizontal cooperation from 2011 seek to strike a balance between the benefits of standardisation and the possible competition law restrictions. To do so, it sets out detailed guidance on how to design the process of standard-setting. In its turn, respecting the procedural principles provides safe harbour for the standardisation agreements. Before exploring the content of these guidelines, a few comments on their legal nature are in order.

It is a common practice of the Commission to issue a variety of guidelines and notices. The formal legal status of these documents is non-binding. The ECJ has found that these documents may bind the Commission but not the EU Courts. That said, it is true that the Courts cannot simply disregard these documents, as they are a 'useful point of reference'.[1006] The most important function of these guidelines and notices is that they provide interpretative

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[1002] R. Schellingerhout, 'Standard-setting from a Competition Law Perspective', competition policy newsletter, 1 November 2011. See also: the Commission, Horizontal Guidelines (n 783), para 263.

[1003] Commission Communication, 'On the Role of European Standardisation in the Framework of the European Policies and Legislation', COM (2004) 674 Final.

[1004] The Commission, Horizontal Guidelines (n 783), para 264; for more detailed explanation of these anti-competitive effects, read paras 265–9. Also, guidelines make clear that standardisation agreements may have an effect on four markets: First, to product or service markets to which the standard(s) relate; second, on the relevant technology market; third, standard-setting may be affected in the case of different standard-setting bodies or agreements; fourth, also where relevant, a distinct testing and certification market could also be affected. See: Horizontal Guidelines, para 261.

[1005] The Commission, Horizontal Guidelines (n 783), para 264.

[1006] C-310/99, *Italy v Commission*, ECLI:EU:C:2002:143, para 52.

clarification and legal certainty to undertakings.[1007] For instance, it creates legal certainty to companies by giving detailed outlines as to what kind of actions would fall under the safe harbour of competition rules.[1008] Baileys has eloquently captured the legal nature of the Commission's guidelines, as to be setting the rules of practice, rather than rules of law.[1009] These rules of practice tell us how the competition law will regard and control certain actions.

The Commission's guidelines from 2011 on the application of Article 101 in the context of standardisation aim to outline the instances in which the standardisation normally will not be creating competition law problems. In a nutshell, the horizontal guidelines stipulate procedural guarantees which, if observed, put the standardisation process under a safe harbour, making it immune from scrutiny under the competition rules. However, the standardisation agreements that restrict competition by object—i.e. where standards are used as part of a broader restrictive agreement to exclude competitors—do not fall under the safe harbour.[1010]

The standardisation agreements that do not restrict competition by object or risk creating market power will not normally restrict competition if the following conditions are satisfied:

> 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).[1011]

[1007] J. Pierce, *The Antitrust Dilemma: Balancing Market Power, Innovation and Standardisation* (Lund University 2016), 235.

[1008] Ibid.

[1009] Lecture given by David Bailey at King's College, London, on 24 September 2013, a copy can be found at <www.kcl.ac.uk/law/research/centres/european/research/bailey-lecture-slides.pdf>.

[1010] The Commission, Horizontal Guidelines (n 783), para 273. The Commission in these guidelines gives an example of restriction of competition by object in the context of standardisation agreement referring to its own decision in Case IV/35.691, *Pre-insulated pipes*, where the use of standards sought to prevent or delay the introduction of new technology that would lead to a price reduction. See: Whish and Bailey, 'Horizontal Agreements (3): Cooperation Agreements', in *Competition Law* (n 974).

[1011] The Commission, Horizontal Guidelines (n 783), para 280.

These procedural principles can be seen as criteria of good governance,[1012] which are also reflected in the standardisation Regulation[1013] and incorporated in the by-laws of the ESOs. The principle of unrestricted participation requires the ESOs to ensure an objective and non-discriminatory right of participation to all competitors. This requirement is, to some extent, reflected in Regulation 1025/2012 which demands facilitation of the participation of SMEs in the standard-setting.[1014] The Commission states in the guidelines that if membership to standard bodies is restricted for competitors and stakeholders, and only certain firms are allowed to be members, then safe harbour will not apply.[1015]

Next, the transparency of the procedure demands that all stakeholders are informed about the upcoming event, ongoing or finalised works. To this end, the Regulation puts in order transparency provisions, obliging the exchange of information about planned standardisation work for the next year, between the national and European standards organisations.[1016] In addition, the ESOs' internal rules require publication of a prepared draft standard for public enquiry through the national standards bodies. The aim of such public enquiry is to receive comments and suggestions about the draft standard. In addition, the participation of consumer and environmental interest groups is promoted at the EU level, and the EU grants financial assistance to such groups.[1017] However, these interest groups participate without voting rights. The participation of public authorities is also encouraged.[1018]

Moreover, the non-binding nature of standards is a necessary requirement imposed by horizontal guidelines to qualify for the safe harbour. The members of the ESOs should be free to develop alternative standards for products. This is given effect by the status of an HES which is formally voluntary. Finally, the effective access to standards should be granted on fair, reasonable, and non-

[1012] Mataja, *Private Regulation and the Internal Market* (n 22), 237.

[1013] Regulation on European Standardisation 1025/2012 (n 14).

[1014] Ibid, Articles 5 and 6.

[1015] The Commission, Horizontal Guidelines (n 783), para 295. The guidelines refer to the Commission Decision in Case IV/31.458, *X/Open Group*, OJ L 35, 6.2.1987, 36, where the Commission stated that even if the standards adopted were made public, the restricted membership policy had the effect of preventing non-members from influencing the results of the work.

[1016] Regulation 1025/2012 (n 14), Articles 3 and 4.

[1017] Ibid, Articles 5 and 16.

[1018] Ibid, Article 7.

discriminatory terms. This becomes especially important where IPR of certain companies reads on standards and hence the danger of foreclosure of third parties willing to use standards can be realised by the IPR owner refusing to license intellectual property or requesting excessive royalties for licensing.

Although it should be stressed that deviation from these principles does not automatically indicate a breach of Article 101 TFEU. In the latter case, an effect-based assessment under 101 will be required. This means that the standardisation agreements that depart from the above-mentioned principles will fall under 101(1).[1019] However, such agreements can still be exempted given that the conditions under Article 101(3) TFEU are met.[1020]

The application of the horizontal guidelines to the standardisation agreements was tested in the *EMC* case.[1021] The case concerned a complaint brought by EMC 'attacking' the process of standard-setting, as well as the content of a standard. EMC argued that in the process of standard-setting, CEN and the European Cement Association had created a cartel. Specifically, EMC claimed that these bodies, with their collusive actions created a barrier to enter the European cement market by means of an industrial standard. The complaint concerned the development of the EN 197-1 Standard, by the technical committee of CEN, which acted in response to the Commission's mandate and for the purposes of Directive 89/106 on construction products. The mandate outlined the scope of application of the standard, as well as stated that the standards should have been expressed in product performance terms.[1022] The adopted standard grouped common cement products into five cement categories according to the proportions in which the main constituents were mixed. Each cement category was composed of a certain percentage of Portland cement mixed with different levels of constituents. EMC produced

[1019] The Commission, Horizontal Guidelines (n 783), paras 279 and 292–9; Whish and Bailey, 'Horizontal Agreements (3): Cooperation Agreements', in *Competition Law* (n 974); see the Commission decision of 14 October 2009 in the *Ship Classification* case. Here the Commission was concerned that rules of the International Association of Classification Societies prevented and foreclosed third parties. The case was closed based on commitments undertaken by parties that guaranteed the access of third parties to the standard-setting process.

[1020] It seems that criteria establishing whether efficiencies under 101(3) balance competition restrictions is largely similar to the procedural principles laid down by these guidelines. For example, it matters whether participation was open to all competitors, whether the standard is binding and so on. For more detailed analysis about it, see the Commission, Horizontal Guidelines (n 783), paras 308–11.

[1021] Case C-367/10P, *EMC* (n 415).

[1022] Case T-432/05 *EMC* (n 873), para 12.

energetically modified cement by activation of Portland cement with different materials such as fly ash, blast furnace, and so on. According to EMC, such cement did not fit the standard and thus was excluded from the market.

Moreover, EMC argued that the standard reflected the result of the cartel. Particularly, EMC claimed that the standard-setting procedure was discriminatory since it was designed to favour major cement producers on the market. It further argued that the procedure was in fact controlled and influenced by the Cement Association and the chairman of the technical committee working on a particular standard. That chairman held a senior executive position in the cement company, which was well-established on the market. It is interesting to note that the Commission did not deny the fact that standard-setting was influenced by the Cement Association and the chairman of CEN's technical committee. However, according to the Commission, such influence did not go beyond normal lobbying activities.

EMC also argued that the procedure was neither transparent nor open, and the standard adopted was de facto mandatory. EMC gave two reasons for the mandatory nature of the standard. Firstly, the products covered by the standard dominated the market and therefore the standard itself dominated the market. Secondly, cement was usually purchased under public procurement procedures, which commonly relied on standards.[1023]

Interestingly, neither the Commission nor the Courts addressed the complaint with respect to the content of a standard and instead focused on the procedural requirements. The Commission and the Court refused to assess the content of the standard, as it was not a question of competition law,[1024] but required the assessment with respect to the Construction Products Directive.[1025] In doing so, the Court refused to converge the requirements of competition law and the internal market directive. Perhaps, in this case, it would have been more helpful for the applicant to challenge the publication of a reference to this standard due to its non-compliance with the directive.[1026]

[1023] Ibid, para 107.

[1024] Ibid, para 136.

[1025] Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations, and administrative provisions of the Member States relating to construction products [1988] OJ L40/12, Article 7/2. The latter was replaced by Regulation (EU) 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC.

[1026] See: Chapter 6 of this thesis.

Overall, the case was dismissed because EMC failed to provide necessary evidence about the infringement of the competition law. The Commission and the Court did not in fact analyse whether a cartel was present behind the adoption of the standard—in other words, whether standardisation was used to shut out competitors. Instead, the case was decided by looking at whether the standardisation process satisfied the procedural requirements provided in horizontal guidelines.

Clearly, in *EMC,* the Court took a deferential approach to the officially recognised European standardisation. It presumed that the standard-setting procedure was 'non-discriminatory, open and transparent' since it was not proved otherwise. In fact, the Court found that EMC did not provide evidence of the infringement of these principles, nor did it '…indicate in what respect the situation in the present case represented a special case with regard to CEN's operating rules'.[1027] It follows that unless an applicant shows that the standard-setting fails to adhere to the principles of good governance, the European standardisation system would be presumed to be in compliance with these procedural requirements.

In short, according to the *EMC* case, the following conclusions can be drawn. Firstly*,* European standard-setting, even in response to the Commission's mandate, could be susceptible to competition law scrutiny, without resolving the issue of whether the ESOs qualify as undertakings or associations of undertakings. Secondly, the competition law most probably would take a deferential approach towards the officially recognised European standardisation, that is, it would refrain from interfering with the standardisation process that follows the principles of transparency, openness, non-discrimination, and that provides non-binding standards.

6.5.4. The European Standardisation System and Article 102 TFEU

The use of the standardisation by an undertaking as a tool to abuse a dominant position could be an action scrutinised under Article 102 TFEU. It is important to note that in that case it is not the standardisation that entails anti-competitive effects; rather the anti-competitive use of the intellectual property undermines the effectiveness of standardisation. Such cases are beyond the scope of this thesis, because my principal focus is on the ways in which competition law

[1027] Case T-432/05 *EMC* (n 873), para 91.

disciplines the ESOs. Below, I will only consider how these types of abuses have affected the practices of the standardisation bodies and demanded the modification of the policies and by-laws of the ESOs.

The EU competition law was applied in cases of patent wars and abuse of IP rights taking place during the standard-setting in high technology fields. To mention just a few among many, one can refer to the Commission's decisions in *Rambus*[1028] and *Qualcomm*.[1029]

Although horizontal guidelines deal with the application of Article 101 TFEU, they also recognises that Article 102 TFEU could be an appropriate mechanism to constrain patent hold-ups in the standardisation context. This encompasses the cases where a holder of Standard Essential Patents (SEP), after the adoption of a standard, restricts other companies' access to standards by refusing to license the necessary SEP or by demanding excessive royalties.[1030] This kind of action can occur not only in informal standardisation, but also during the formal standardisation system.[1031]

In order to avoid patent ambush or patent hold-ups by undertakings, the standard bodies have to design IPR policy accordingly.[1032] The Commission's anti-trust investigation involving ETSI and Sun demonstrates this point. In this case, the Commission decided also to investigate whether ETSI's IP policy made it possible for companies to conduct a patent ambush.[1033] It made a preliminary observation that ETSI rules did not provide sufficient protection from patent ambush.[1034] ETSI reacted to this accusation promptly and changed its internal rules so as to allow *ex-ante* licensing.[1035] Consequently, the

[1028] Commission Decision SG-Greffe (2010) D/275 C (2010) in Case COMP/C-3/38 636, *Rambus.*

[1029] Press release 'Antitrust: Commission closes formal proceedings against Qualcomm', 24 November 2009, MEMO/09/516.

[1030] See: The Commission, Horizontal Guidelines (n 783), para 269. See also: J. Pierce, 'Standards and Competition Law: Debunking the Myth of Business Freedom', October 2013, SRC 12.

[1031] Commission Decision C (2012) 1068 in Case No COMP/M.6381, *Google-Motorola Mobility.* The Commission assessing Google's acquisition of Motorola under the Merger Regulation also discussed Motorola's patents, essential for ETSI Standards.

[1032] Pierce, *The Antitrust Dilemma: Balancing Market Power, Innovation and Standardisation* (n 1057), 349. See also: The Investigation of ETSI in the Sun investigation by the Commission, press release 12 December 2005, IP/05/1565.

[1033] The Investigation of ETSI (Ibid).

[1034] Schellingerhout, 'Standard-setting from a Competition Law Perspective' (n 1002), 5.

[1035] Ibid.

Commission did not pursue the case, as it considered the *ex-ante* licensing, where royalties are set or disclosed before a standard is agreed, to be pro-competitive.[1036] This reasoning is now reflected in the horizontal guidelines:

> …It is important that parties involved in the selection of a standard be fully informed not only as to the available technical options and the associated IPR but also as to the likely cost of that IPR. Therefore, should a standard-setting organisation's IPR policy choose to provide for IPR holders to individually disclose their most restrictive licensing terms, including the maximum royalty rates they would charge, prior to the adoption of the standard, this will normally not lead to a restriction of competition within the meaning of Article 101(1). Such unilateral ex ante disclosures of most restrictive licensing terms would be one way to enable the standard-setting organisation to take an informed decision based on the disadvantages and advantages of different alternative technologies, not only from a technical perspective but also from a pricing perspective.[1037]

According to the horizontal guidelines, the policies of the ESOs must ensure that companies offering their IPR to be read onto a standard commit to the obligation to license these rights. The access to IPR should be fair, reasonable, and non-discriminatory (FRAND)[1038] and it must be disclosed in good faith.[1039] The above discussed is a manifestation of how the competition rules influence and trigger the perfection of the standards-making process. That is, the possible abuses of Article 102 by undertakings participating in standardisation process 'forces' the ESOs to modify the policies and rules governing the standards-setting process.

6.5.5. Competition Law and the EU-wide Co-regulation via European Standardisation

The European standardisation that is used as a co-regulatory tool will not *per se* be outside the reach of competition law, as was demonstrated above. Meaning that private actions under the co-regulatory regimes would not escape

[1036] Ibid.

[1037] The Commission, Horizontal Guidelines (n 783), para 299.

[1038] Ibid, para 280.

[1039] Ibid.

the application of competition law.[1040] However, whether the competition law applies to the EU co-regulatory regimes is unclear.

The liability of EU institutions under competition rules is a complex and uncertain issue. The EU institutions can facilitate anti-competitive regimes in a similar way to Member States. It is not unheard-of to prohibit Member States from adopting measures or regulatory regimes that conflict with the competition law. By virtue of Article 4(3) TEU, Member States must 'refrain from any measure which could jeopardise the attainment of the Union's objectives.' The use of the obligation of sincere cooperation in conjunction with the competition rules prohibits Member States from adopting measures depriving effectiveness to the competition rules, facilitating anti-competitive actions or enabling undertakings to escape the competition law constraints.[1041] Arguably, there will be greater deference to the actions of the EU institutions conflicting with the competition laws, than in the case of the Member States. This is especially so in the case of a regulatory use of the European standardisation that aims to remove technical barriers, promote competition, and ensure easy access to the EU market. However, this does not rule out the non-contractual liability of the EU institutions under Article 340(2) TFEU for facilitating 'potential' anti-competitive conduct if such cases arise.[1042]

6.5.6. Section Conclusion: Competition Rules as a Private Administrative Law of the European Standardisation System

Viewing the EU competition law as a regulation mechanism of private regulators is not novel.[1043] Article 101 TFEU has a peculiar role in constraining private regulation. The measures of private regulators are caught under 101 because they are excessive or unfair and not because they benefit regulators.[1044]

[1040] See: Mataija, *Private Regulation and the Internal Market* (n 22), 111.

[1041] See Case 13/77, *SA G.B.-INNO-B.M. v Association des détaillants en tabac (ATAB),* ECLI:EU:C:1977:185, paras 28–31; Case 267/86, *Pascal Van Eycke v ASPA NV*., ECLI:EU:C:1988:427, para 16.

[1042] See on this, N. Petit and M. Rato, 'The Commission's Non-contractual Liability in the field of Merger Control: Don't Use a Hammer When You Need a Screwdriver' (2007) 1 *Global Competition Policy*. See also: Mataija, *Private Regulation and the Internal Market* (n 22), 111.

[1043] See: J. Temple Lang, 'European Competition Policy and Regulation: Differences, Overlaps and Constraints', in F. Lévêque and H. Shelanski (eds), *Antitrust and Regulation in the EU and US* (Edward Elgar 2009), Chapter 2.

[1044] Mataija, *Private Regulation and the Internal Market* (n 22), 92.

In *Meca-Medina*, the Court considered anti-doping rules under 101, to decide whether they were unnecessarily restrictive for sportsmen.

Although private regulation could be a prima facie restriction of competition rules, it could be justified on the basis of an inherent restrictions test.[1045] This test was first laid down in *Wouters*. The inherent restrictions test is not constrained within narrow economic efficiency as justifications under Article 101(3).[1046] Under the inherent restrictions test, there is no consideration of the balance between harm and benefit. Rather the Court assesses whether the measure under scrutiny is necessary to achieve the regulatory objective. And if so, the Court concludes that although a measure is restricting competition, such restriction is inherent to the measure which is necessary to achieve a regulatory objective.

There is ongoing discussion as to whether the competition law should have such broad function, i.e. accept wider justifications,[1047] as opposed to focusing on economic efficiency.[1048] It is beyond the scope of the present project to discuss whether the broad regulatory justifications can be incorporated into the competition law analysis.[1049] It is true that the EU competition rules have not

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[1045] Ibid, 93.

[1046] It needs to be remarked that the General Court has more recently seemed to interpret the *Wouters* exception as only applying within the strict confines of outright legislative delegation, see: Case T-90/11, *Ordre national des pharmaciens (ONP) and Others v European Commission*, ECLI:EU:T:2014:1049, paras 343–8.

[1047] Mataija, *Private Regulation and the Internal Market* (n 22), 75.

[1048] Opponents of a broad approach have several arguments on their side. Firstly, that the goal of competition law is economic efficiency in the form of consumer or total welfare. See: O. Odudu, 'The Wider Concerns of Competition' (2010) 30 (3) *Oxford Journal of Legal Studies* 599. Secondly, the public interest should not be addressed by competition authorities in the context of competition law application and competition law cannot take into account other goals except economic efficiency, and 'correcting flaws in political process is not an antitrust task'; see: H. Hovenkamp, *Antitrust Enterprise Principle and Execution* (Harvard University Press 2009), 231. The proponents of a broader approach argue for incorporation of wider policy arguments, such as environmental protection in the competition law analysis. See for instance: H.H.B. Vedder, 'Voluntary Agreements and Competition law' (2000) 79 *Nota di Lavoro, Fondazione Eni Enrico Mattei*. For example, manufacturers' agreement on a binding energy-efficient standard for washing machines that, although it increased the price, did not fall foul of competition law: CECEK (Case IV.F. 1/36.718) Commission Decision 2000/475/EC [1999] OJ L187/47.

[1049] This strikes at the heart of the objectives of competition law. If we agree that competition law is concerned not with everything but strictly with consumer welfare, which is translated as economic efficiency then including wider justifications under Article 101(3) is not possible. However, the group of scholars arguing for a wider concern of competition law, suggest that, especially in the context of the EU, competition law is not simply aimed at

introduced public policy justification in the cases concerning standardisation, as opposed to the *Wouters* or *Meca-Medina* cases. For instance, in the *IAZ* case, the fact that a certification scheme for washing machines was pursuing the aims of public health did not alter the finding that such scheme was anti-competitive.[1050] Contrast this with the Commission's decision in *CECED*, where the agreement setting standards that precluded manufacturers from producing less environmentally efficient washing machines was seen as justified under Article 101(3). Although a public policy argument, i.e. protection of environment, played a role in the assessment, the decision was primarily based on an economic efficiency analysis.[1051]

The EU competition law does not incorporate public interest justification in the cases of distortion of competition by the standardisation agreements. Instead, it grants immunity to the standardisation, which follows the procedural principles guaranteeing the public interest. In doing so, the competition law performs an administrative law function, focusing on the principles of good governance and subjecting the standardisation process to 'a procedural public interest test.'[1052] Focus on the process by the competition law in the context of standardisation 'transforms antitrust into a kind of administrative law for private regulation.'[1053] According to Schweitzer, the EU competition law has a 'strong concern with open, transparent standard-setting procedure' and requires 'fair and non-discriminatory access to all competitors to a standard once agreed.'[1054]

These procedural guarantees of public interest do not simply try to protect economic interest and avoid collusion; they also seek to positively promote

protecting economic efficiency, but protects EU objectives, such as market integration. For a proponent of the wide justification test see: C. Townley, *Article 81 EC and Public Policy* (Hart Publishing 2009). For the support of strict efficiency justification see: Odudu, 'The Wider Concerns of Competition Law' (n 1048).

[1050] Joined Cases 96-102,104,105,108 and 110/82 *NV IAZ International Belgium and Others v Commission*, ECLI:EU:C:1983:310.

[1051] CECED (Case IV.F. 1/36.718) Commission Decision 2000/475/EC [1999] OJ L187/47.

[1052] Schepel, *The Constitution of Private Governance* (n 111), 323.

[1053] H. Schepel, 'Delegation of Regulatory Powers to Private Parties under EC Competition Law: Towards a Procedural Public Interest Test' (2002) 39 *Common Market Law Review* 31, at 46.

[1054] H. Schweitzer, 'European Standard-setting Policy and the Role of Competition Law', in C. Baundendacher (ed.), *Current Developments in European and International Competition Law: 15th St Gallen International Competition Law Forum* (ICF) 2008 (Helbing & Lichtenhahn 2009), 30–1.

non-discriminatory, motivated, transparent, and open decision-making. In other words, by focusing on the procedural requirements to guard public interest, competition law introduces a 'procedural public interest' test.[1055] And procedural requirements ensure that standardisers serve the public interests and not simply self-interest. More precisely, '…what antitrust protects here is not a competitive market [but] democratic legitimacy.'[1056]

It seems that the principles of transparency, openness, and non-discrimination have been transplanted from administrative law into competition law. In turn, the EU competition law uses these principles as the basis for a procedural public interest test to regulate informal rule-making, i.e. standardisation. In particular, the EU competition law shapes the process of standard-setting in the formal and non-formal standards bodies by requiring them to follow the procedural principles and develop intellectual property policies.[1057] When it comes to the European standardisation system that is formally recognised, the competition law's deferential approach is clearly noticeable. The European standardisation system would be presumed as complying with procedural principles unless proved otherwise. The rationale behind such deferential approach, as explained by the Commission, is to 'facilitate market integration and allow companies to market their goods and services' so as to improve consumer choice and reduce prices.[1058] In sum, although the competition law offers rather deferential treatment to the officially recognised European standardisation system, in offering the procedural public interest test it also provides the 'Hybrid (Flexible) Framework' to regulate the European standardisation. It is flexible since the procedural public interest test avoids scrutiny of the substance of a standard, but 'forces' the ESOs to organise the process of standard-setting according to the principles of good governance, which in turn facilitates production of legitimate standards.

6.6. Conclusion

The co-regulation via European standardisation involves both public and private actors and as such it is difficult to place it entirely within either the

[1055] Schepel, *The Constitution of Private Governance* (n 111), 320.

[1056] Mataija, *Private Regulation and the Internal Market* (n 22), 75 (footnote 40).

[1057] Ibid, 83.

[1058] The Commission, Horizontal Guidelines (n 783), para 308.

public or the private realm. The standard itself is a private rule; it is agreed on by experts and business operators, addresses important aspects of public life, and is used for legislative purposes. Consequently, the European standardisation system has a hybrid public-private nature. This mixed public-private nature of the European standardisation system does not shield it from the application of EU economic law, as argued above. Quite the contrary, the EU economic law is applicable to the European standardisation system without *ex-ante* placing it under public or private framework.

I suggested that the EU economic law most probably would adopt an effect-based approach to deal with mixed public-private European standardisation system. Such an approach ensures that European standardisation which could easily escape the reach of free movement law, appealing to its private nature while exercising publicly important tasks, does not happen. The *Fra.bo* case demonstrates that the free movement rules are applicable even to purely private standardisation if the latter is capable of effectively hindering market access. In such cases, the Court should take into account the economic and legal context of the standardisation and analysis should be more complex and thorough compared to the cases where the free movement rules are applied against State measures.[1059]

Moreover, the competition law can also influence the European standardisation used in EU legislation and policy. Nevertheless, European standardisation could be exempted from the application of the competition rules if the standard-setting organisations observe the certain procedural principles, creating safe harbour to such standardisation. Therefore, the assessment of standardisation under competition law is concerned with the process of standard-setting and is deferential to the content of a standard.[1060] This means that the Court is not and will not be concerned with the substance of a standard as long as the procedure for adopting such a standard is appropriate.

The Court's deferential approach to the substance of a technical standard may be seen as a reflection of the Court's limited expertise to deal with complex technical and scientific issues (as discussed in Chapter 7 of this thesis). Moreover, since the European standardisation is an integral part of the EU's industrial policy, there is less danger that the European standards, and especially harmonised ones, will restrict competition or trade, because they are developed to promote both. However, the deferential approach does not mean

[1059] Mataija, *Private Regulation and the Internal Market* (n 22), 256.

[1060] As demonstrated by the Case C-367/10P, *EMC* (n 415).

toothless application of the EU economic rules. On the contrary, it has the potential to 'mould' the standardisation process by imposing the principles of good governance.

It is true that the chief aim of the functional approach of EU economic law is to ensure proper functioning of the EU's internal market, i.e. eliminate trade barriers and establish free competition. However, by finding that the European standardisation is contrary to the internal market rules, the Court's judgment can be a catalyst, forcing the standard-setting organisations to change the rules on participation, access, and transparency. This is because the scrutiny under EU economic law would be based on the procedural principles of good governance. In this manner, the EU economic law could ensure an accountable 'public-regarding' standardisation process.

Interestingly, the strict constitutional and administrative control of the European standardisation is feared to undermine the effectiveness of this co-regulatory strategy. However, it is possible to still enforce the constitutional values of transparency, openness, and non-discrimination but through the mild approach of EU economic law. Specifically, by reintroducing the procedural principles of good governance, the EU economic law can facilitate the adoption of safe, non-discriminatory, and legitimate standards.

In sum, I suggest that the EU economic law has an important role in disciplining the European standardisation that is used in EU legislation and policy, focusing on the process of standardisation and promoting the principles of good governance such as transparency, openness, and non-discrimination. In this way, the EU economic law could be a back door through which the catalyst Court[1061] can introduce constitutional principles of good governance and ensure deliverance of legitimate and well-developed standards.

[1061] The role of the EU Court in reviewing standardisation is discussed in detail in Chapter 7. Therein the Court's role is projected to be that of a catalyst, i.e. focusing on the process of standardisation and promoting adherence to the principles of openness, transparency, participation and so on.

Part III

Accountability of European Standardisation by Means of Judicial Review

7. Judicial Review of Harmonised European Standards as a Mechanism of Accountability: Perfecting the Process of European Standardisation through EU Judiciary

7.1. Introduction

Having explored different perspectives on the understanding and regulation of the European standardisation system under EU law, I now turn to investigate the legal accountability thereof by means of judicial review at the EU level. The objectives of this exercise are two-fold. Firstly, it responds to the discussion on the lawfulness of delegation of rule-making power to the ESOs. As previously explained, the EU constitutional law requires the judicial supervision of the delegated powers—in our case, judicial control of the co-regulation via standardisation—to regard it as lawful. Secondly, and primarily, this chapter directly addresses the main aim of this thesis, i.e. holding the European standardisation accountable through EU judiciary. More precisely, as explained in Chapter 1, the legal accountability is understood as overseeing the standardisation system by EU law and primarily within the context of judicial review at the EU level. In this sense, judicial review is a mechanism for holding the standardisation system accountable by means of law.

Ergo, I focus here exclusively on the judicial review, conceptualise it as a mechanism of legal accountability, discuss its operation in the context of European standardisation, and reflect on its limitations. In doing so, three intertwined themes are unfolded and addressed. Firstly, I revisit the

foundations of judicial review and reckon it as a form of legal accountability, as well as explain the role of judicial review in new governance regimes in general and in the co-regulation via European standardisation[1062] in particular.

Secondly, I investigate whether the Harmonised European Standards (HESs) and the Commission's decisions[1063] conferring legal effects thereto can be subject to judicial review at the EU level, in the context of direct or indirect actions, provided by Articles 263 and 267 TFEU. Due to the private and non-binding nature of the HESs and private law status of the ESOs, the judicial review of European standardisation cannot be taken for granted. As it stands now, the case law on judicial review of the process or products of European standardisation is sparse.[1064]

Thirdly, I discuss the scope of judicial review of the European standardisation system and stress that although judicial review is a well-established form of legal accountability, it is constrained by the Court's 'limited' ability to deal with technical complexities. Hence, I argue for the Court's catalyst function to facilitate more accountable standardisation and trigger the 'perfection' of the standards-making process.

The discussion on the judicial review of European standardisation at the EU level has been recently reinvigorated[1065] and is a topic of controversy. It is feared that the judicial review of standardisation undermines the flexibility in

[1062] The phrase 'judicial review of the co-regulation via European Standardisation' is used to cover both review of the HESs and the Commission's decision concerning the publication of references thereto.

[1063] Decisions refer collectively to the Commission's communications/decisions on publishing references to HESs in the official journal, as well as the Commission decisions on withdrawing or maintaining a reference to an HES following the Parliament's or a Member State's *ex-ante or ex-post* objections.

[1064] There are only a few cases concerning the Harmonised European Standards. See: T-264/03 *Jürgen Schmoldt and Others v Commission*, ECLI:EU:T:2004:157; Case T-474/15*, GGP Italy* (n 481); Case C-613/14, *James Elliott* (n 60); Case C- 367/10P *EMC* (n 415); C-630/16, *Anstar Oy*, ECLI:EU:C:2017:971; and finally currently pending case T-229/17, *Germany v Commission.*

[1065] See for instance: Gestel and Micklitz, 'European Integration through Standardisation' (n 63); Eliantonio, 'Judicial Control of the EU Harmonized Standards' (n 385); Tovo, 'Judicial Review of Harmonized Standards: Changing the Paradigms of Legality and Legitimacy of Private Rule-making under EU Law' (n 385), 1187–216; A.v. Waeyenberge and D.R. Amariles, 'James Elliott Construction: A "New(ish) Approach" to Judicial Review of Standardisation' (2017) 42 (6) *European Law Review* 882–93.

regulation brought by using non-legal instruments such as standards,[1066] and in this regard it has been seen as opening up 'Pandora's box.'[1067]

As discussed in Chapter 1, the reliance on private and non-binding technical standards in EU legislation and policy documents represents a shift towards new forms of governance.[1068] Characteristic of these new forms of governance is that they move 'away from the idea of specific rights elaborated by formal legal bodies and enforced by judicially imposed sanctions.'[1069] Following this, the involvement of Courts in the forms of new governance, with their traditional role as norm enforcers and elaborators, is viewed as undermining the premises of new governance, and signalling 'a return to traditional top-down regulation.'[1070]

On the one hand, flexibility and technical complexity is at the heart of the argument against judicial review of the new forms of governance in general and the European standardisation system in particular. On the other, accountability and legitimacy of European standardisation demands the judicial control and underpins the argument for judicial supervision. I side with scholars arguing that judicial review of the new forms of governance 'remains indispensable to that accountability', and hence, 'to the system's overall legitimacy.'[1071] Similarly, an absolute denial of judicial review of the European standardisation system is not viable; 'no critic of the judicial review…goes so far as to say that we can do without it.'[1072] The Courts get involved in the forms of new governance more often and 'cannot shy away from technical matters'[1073] for long. This is true also of standardisation that is no longer

[1066] Schepel, *The Constitution of Private Governance* (n 111), 249–54.

[1067] There is an apparent fear of judicial review of European standardisation in the standardisation society. See: Gherardini, 'Harmonised European Standards and the EU Court of Justice' (n 836).

[1068] See: Chapter 1 of this thesis.

[1069] J. Scott and S. Sturm, 'Court as Catalysts: Re-thinking the Judicial Role in New Governance' (2006) 13 *Columbia Journal of European Law* 565, at 566.

[1070] Ibid. Similar concerns were raised in the context of independent agencies. It has been argued that accountability mechanisms are counter-productive in the context of independent agencies, as they would prevent agencies from performing their tasks effectively.

[1071] W.D. Araiza, 'Reinventing Regulation/Reinventing Accountability: Judicial Review in New Governance Regimes' (2010) 28 *Windsor Yearbook of Access to Justice* 361.

[1072] King, 'The Instrumental Value of Legal Accountability' (n 99).

[1073] AG Jacob's Opinion to the Case C-269/90 *Technische Universitat Munchen*, ECLI:EU:C:1991:438, para 13.

conducted 'behind closed doors'[1074] nor is it immune from judicial intervention.[1075]

Consequently, I argue that the question to be asked is how the Courts can ensure legal accountability and not undermine the effectiveness of the co-regulation via European standardisation. At the same time, the effectiveness cannot be used as a 'trump card' against judicial review, nor can the judicial review be seen as an absolute panacea for the lack of legitimacy. However, a carefully elaborated role of the Courts in reviewing the process of European standardisation can ensure accountability of this regulatory system and contribute to its overall legitimacy. Therefore, I suggest rethinking the Court's role in European standardisation and, in doing so, build on Scott and Sturm's vision of the Court as a 'catalyst'. According to Scott et al, the Court's catalyst role encompasses three main functions: facilitating 'full and fair participation, enhancing the epistemic or information basis for decision-making and ensuring principle decision-making through transparency and accountability.'[1076]

Similarly, I argue that the Court dealing with the European standardisation system should be deferential to substance but active procedurally—promoting participation, enhancing technical expertise, and urging for a transparent and accountable standardisation process. In other words, the Court reviewing European standardisation system should perform a catalyst role, stimulating a transparent, inclusive, and better-informed standard-setting process. To do so, the Court should focus on the process of standardisation.

The conception of the Court's role as catalyst entails a reciprocal relationship between the Courts and the standardisation process. In particular, on the one hand, the Courts construct criteria applicable to their judgments on the basis of the practices of the standardisation system. And, on the other, these criteria directly or indirectly shape the deliberative process within the standardisation process.[1077]

[1074] Gestel and Micklitz, 'European Integration through Standardisation' (n 63), 150.

[1075] See cases: Case C-185/08, *Latchways*, ECLI:EU:C:2010:619; Case C-171/11, *Fra.bo* (n 60); and Case C-613/14, *James Elliott* (n 60).

[1076] Scott and Sturm, 'Court as Catalysts: Re-thinking the Judicial Role in New Governance' (n 1069), 575.

[1077] Scott and Sturm, 'Court as Catalysts: Re-thinking the Judicial Role in New Governance' (n 1069), 567. Here the authors speak about the relationship between the Courts and generally new forms of governance.

Now, the structure of this chapter will be as follows. In section 2, I explain the foundations of judicial review and present it as a form and forum of legal accountability. In section 3, I discuss whether the European standardisation system can be a subject of direct and indirect actions before the CJEU. Section 4 analyses the scope of judicial review of the standardisation system and its limitations. In the sub-sections, I also argue for the Court's role to catalyse the betterment of the standardisation process and in this manner serve the purpose of making the standardisation process more accountable. Section 5 concludes the chapter.

7.2. Legal Accountability in the Form of Judicial Review

In this section, I conceptualise judicial review as a mechanism of legal accountability and discuss why and how the judiciary should control the standardisation process. The question entails reflecting on the role of the Court and the scope of judicial review in the context of the European standardisation system.

The concept of accountability is well-ploughed terrain. Much ink has been spilt over explaining what it means.[1078] Yet, despite painstaking efforts to define accountability, it remains a somewhat elusive and 'ever-expanding concept.'[1079] As stated before,[1080] accountability in this thesis is understood as 'a relationship between an actor and a forum, in which the actor has an obligation to explain and to justify his or her conduct, the forum can pose questions and pass judgments, and the actor may face consequences'.[1081] In light of this understanding, the judicial review is regarded as a mechanism of

[1078] Bovens, 'Analysing and Assessing Accountability: A Conceptual Framework' (n 94). See also: R. Mulgan, *Holding Power to Account: Accountability in Modern Democracies* (Palgrave 2003).

[1079] R. Mulgan, 'Accountability: An Ever-Expanding Concept' (2000) 78 (3) *Public Administration* 555.

[1080] In Chapter 1.

[1081] Bovens, 'Analysing and Assessing Accountability: A Conceptual Framework' (n 94), 450. See also: J. Black, 'Calling Regulators to Account: Challenges, Capacities and Prospects' (2012) *LSE Legal Studies Economy Working Paper No. 15/2012*, 356.

legal accountability,[1082] where the CJEU is a forum before which the HESs, and the Commission's decisions conferring legal effects thereto, could be challenged.

Judicial review is indeed a keystone of the legal accountability system in modern democracies.[1083] According to Harlow and Rawlings, the Courts, on the one hand, are the machinery and the forum for accountability, and on the other, contribute to public accountability, 'by buttressing transparency.'[1084] To do so, the Courts hold vested governmental powers accountable, as well as oversee the legality of governmental and administrative decisions.[1085] It follows that judicial review is a form of legal accountability that prevents abuse of powers[1086] and, by doing so, guards the rule of law, protects the rights of individuals,[1087] and secures public interest in the process of governance.[1088]

As in any legal system based on the rule of law, the principle of judicial protection is a backbone of the EU legal order too,[1089] guarding individuals' rights, preventing abuse of powers, and safeguarding institutional balance, as

[1082] See analysis of the concept of accountability in Bovens, 'Analysing and Assessing Accountability: A Conceptual Framework' (n 94).

[1083] J.L. Mashaw, 'Judicial Review of Administrative Action: Reflections on Balancing Political, Managerial and Legal Accountability' (2005) *Especial 1 Direito GV Law Review* 153. See also: P.L. Strauss, *An Introduction to Administrative Justice in the United States* (1989), cited in C. Tobler, 'The Standards of Judicial Review of Administrative Agencies in the US and EU' (n 52), footnote 31.

[1084] Harlow and Rawlings, 'Promoting Accountability in Multilevel Governance' (n 52), 547. It should be stressed that, as Craig explains, judicial review is just 'one method of securing accountability'; see P. Craig, 'Accountability and Judicial Review in the UK and EU: Central Precepts', in N. Bamforth and P. Leyland, *Accountability in the Contemporary Constitution* (Oxford Scholarship Online 2014).

[1085] Tobler, 'The Standards of Judicial Review of Administrative Agencies in the US and EU' (n 52).

[1086] Perhaps it is more precise to say that the primary aim of the judicial review is to prevent abuse of governmental powers. See discussion on this in Elliott, 'Judicial Review's Scope, Foundations and Purposes: Joining the Dots' (n 944), 76–8.

[1087] King, 'The Instrumental Value of Legal Accountability' (n 99).

[1088] Elliott, 'Judicial Review's Scope, Foundations and Purposes: Joining the Dots' (n 944), 80.

[1089] Case 294/83, *Les Verts v Parliament*, ECLI:EU:C:1986:166, para 23. The right to an effective judicial protection enshrined in Article 47 of the Charter is a general principle of EU law. See for instance cases: Case C-279/09, *DEB,* ECLI:EU:C:2010:811, paras 30–1; Case C-457/09, *Chartry,* ECLI:EU:C:2011:101, para 25; Case C-69/10, *Samba Diouf,* ECLI:EU:C:2011:524, para 49; C-386/10, *Chalkor v Commission*, ECLI:EU:C:2011:815, para 52.

well as securing public interest and overseeing the lawfulness of delegation of powers within or beyond the EU institutions.

Notwithstanding all of these functions, the proposal to extend the domain of adjudication to European standardisation inevitably prompts the question: Why? Firstly, as judicial review functions to secure the public interest, this inevitably requires judicial control of governmental functions regardless of whether they are exercised by public authorities or by other actors. Protection of public interest justifies the extension of judicial review to the new forms of governance or to private regulation that performs tasks affecting the public at large. '…[A]t whichever level it is exercised, public power stands in need of legitimation and limitation.'[1090]

Secondly, HESs are the centrepieces in achieving the safety goals of the New Approach Directives. Moreover, the General Product Safety Directive[1091] regards products as safe if they comply with European standards references which have been published in the official journal.[1092] It follows that the HESs 'regulate' important aspects of public life such as safety, health, and environment. At the same time, market players who participate in the development of standards might be willing to standardise less costly technologies and overlook safety or environmental concerns. The vulnerability of privately developed HESs exacerbates the need for judicial control, especially since they are used in EU legislation. In other words, since the standardisation bodies perform important functions, albeit in the 'shadows', they should not escape judicial review.

However, uncertainty concerning the legal status of the European standards and the private nature of the ESOs has kept standardisation at arm's length from judicial reach. The only apparent way of holding European standardisation accountable by law, although indirectly, is via private law. The

[1090] D. Grimm, 'The Achievement of Constitutionalism and its Prospects in a Changed World', cited in Mendes, 'Rule of Law and Participation: A Normative Analysis of Internationalized Rulemaking as Composite Procedure' (n 791), 381.

[1091] Directive 2001/95/EC on General Product Safety (n 18). This Directive applies in the absence of specific EU regulation on the safety of a certain category of products and complements the sectoral legislation.

[1092] Ibid, Article 3(2). The 2013 Commission's Proposal to Regulation on Consumer Product Safety which aims to repeal General Product Safety Directive, similarly considers products to be safe if they comply with European Standards, references to which have been published in the official journal, Article 5(b).

legal basis of such private litigation is the Product Liability Directive,[1093] which imposes liability on a producer for damage caused by his/her defective product.[1094] Although harm caused could be the result of a product's compliance with a 'defective' European standard, this does not discharge a producer from liability.[1095] Plausible indirect effect of product liability litigation is that manufacturers would be interested in better standards so as to avoid product liability claims in the future. Hence, they would urge the ESOs to organise the process of standard-setting in a manner that ensures the development of better standards.

The product liability law is a long shot to ensure the legal accountability of the European standardisation process. This is because it is just an indirect route to induce more responsible standards-setting, but does not replace the need for direct judicial control of the co-regulation via European standardisation.[1096] Lastly, a lack of democratic control of the standardisation process—since it is exercised by non-elected individuals, and there is a weak participation by societal groups—makes the retrospective mechanism of accountability, i.e. judicial review, indispensable.

After one accepts the need for judicial control of the European standardisation system, the next step is to address how the Courts reviewing the standardisation process can ensure legal accountability thereof.

[1093] Directive 85/374/EEC, OJ 1985 L210/29 as amended by Directive 1999/34/EC of 10 May 1999 on approximation of the laws, regulations and administrative provisions of the Member States concerning liability of defective products, OJ 1999 L141/20.

[1094] Ibid, Article 1.

[1095] Ibid, Article 7. The latter Article reads: 'The Producer shall not be liable as a result of this Directive if he proves…that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered'.

[1096] In Case C-300/95 *Commission v United Kingdom*, ECLI:EU:C:1997:255, the Court found that the producer would not be liable if technical and scientific information was not accessible to him/her at the time when a product was put into circulation. This reasoning opens the possibility for standardisation to become a defence against product liability claims and release a producer from liability. Because standardisation is an avenue, sometimes the only one, through which producers obtain scientific and technical knowledge and information about the expectations for a product. Following this logic, a producer could argue that as he/she followed the latest standards, he/she has complied with the technical and scientific information available at that time. Although, as mentioned above in the text, compliance with standards as such does not release a producer from the product liability.

As stated above, 'judicial review is fundamentally about "bounded government" and subjecting officialdom to the rule of law.'[1097] Viewing the Court as an instrument to constrain State/governmental intrusion into individual liberty has been described as a 'red-light' model by Harlow and Rawlings.[1098] They contrast this red-light model of judicial review—concerned primarily to control the excesses of the State—with what they call the 'green-light' model, which demands judicial deference towards administrative action.[1099]

Notably, both the red- and green-light models depict judicial review as operating on a substantive base. In the former model, the Court guards individual liberties from State intervention, whilst following the green-light model, the Court is deferential to the choices of governmental organs to further the public good.[1100]

Based on these above-mentioned models of judicial review, I argue that the Court's role in reviewing the standardisation process should be deferential to substance, i.e. similar to the 'green-light model' but active procedurally.[1101] However, the 'procedural activism' in reviewing the standardisation system should not necessarily be geared towards protecting individual freedoms as per the 'red-light model', but instead should aim to render standards-making inclusive, transparent, and accountable, so as to ensure that better standards are adopted, as well as to enhance overall legitimacy of standardisation. However, I admit that distinguishing between substantive and procedural review is easier to achieve on paper than in practice. That said, this should not lead us to abandon such distinction if it 'usefully informs judicial practice'.[1102]

Usually active Courts are commonly criticised for infringing the separation of powers, on account of them entering into the domain of law and policymakers. I concur with Corkin that the procedurally active Court does not face the same

[1097] Corkin, 'Refining Relative Authority' (n 148); M. Shapiro, 'Administrative Law Unbounded: Reflections on Government and Governance' (2001) 8 *Indiana Journal of Global Legal Studies* 369.

[1098] See: C. Harlow and R. Rawlings, *Law and Administration* (2nd edn, Butterworths 1997), 67.

[1099] Corkin, 'Refining Relative Authority' (n 148), 172.

[1100] Ibid.

[1101] The similar argument about the Court's role in reviewing 'remote lawmaking' is offered by Corkin, 'Refining Relative Authority' (n 148).

[1102] Ibid, 172.

dilemma, since the Court seeks to perfect or 'legitimise' the process of rule-making. In Corkin's words, the Court

> …directs its concern…towards legitimating the processes through which *others* exercise *their* law-making authority. It demands they are properly accountable, both legally and politically; transparent in their dealings; open to full and fair participation; responsive; informed; inclusive; appropriately deliberative; and so on.[1103]

The proposed role of the EU Courts, i.e. procedurally active and deferential to substance, in reviewing the standardisation process is analysed in detail in section 4 of this chapter.

7.3. The EU System of Judicial Supervision and European Standardisation

The EU's judicial architecture comprises the Court of Justice, General Court and Member States' courts.[1104] Although it is beyond the scope of this chapter to discuss the judicial review of European standardisation in the national courts, the important role of these 'ordinary courts of community [union] law'[1105] is worth noting. The preliminary ruling procedure provided by Article 267 TFEU links national courts to the Court at the EU level, in whose ambit the validity and interpretation of EU acts are requested. Whereas, Article 263 TFEU envisages the direct challenge of EU acts before the General Court. Consequently, judicial review of European standardisation at the CJEU includes a direct action before the General Court, and an indirect action through the mechanism of preliminary ruling, via national courts, to the ECJ.

The subsequent discussion on the judicial review of European standardisation is fleshed out in the context of these actions and addresses two main aspects: 1) amenability, that is, whether the HESs or the publication of the references by the Commission thereto generate 'decisions' susceptible to judicial review; 2) the scope of the judicial review.

[1103] Ibid, 175.

[1104] Article 19 TEU.

[1105] S. Bogojevic, 'Judicial Protection of Individual Applicants Revisited Access to Justice through the Prism of Judicial Subsidiarity' (2015) 34 (1) *Yearbook of European Law* 5.

7.3.1. The Co-regulation via European Standardisation and Article 263 TFEU: General Overview

In this section, I analyse whether the co-regulation via European standardisation can be the subject of direct actions provided by Article 263 TFEU before the CJEU. The discussion thereon encompasses several layers, as to what could be challenged, by whom and on what grounds. Consequently, I investigate whether the HESs or the Commission's decisions conferring legal effects to them are susceptible to direct judicial review. Next, I consider the standing of the relevant group of applicants possibly interested in challenging judicially the HESs or their legal effects. As to the legal grounds[1106] of judicial review of European standardisation, this section does not provide possible scenarios, as these might vary, but it is perhaps more plausible that an HES would be challenged alleging its non-compliance with the legislative requirements of a Directive or a Commission's mandate. Also, the HESs can come to the judicial realm in the context of reviewing the alleged infringement of the competition and internal market provisions in the European standardisation process. Although the request for a judicial review of an HES can concern the substance of the latter, I argue that the Court probably would constrain itself to the review of the process of standardisation. Meaning that a substantive challenge to an HES would be turned by the Court into the procedural review.

Article 263 TFEU provides direct access to the CJEU and allows legality review of legislative acts and acts of the institutions, bodies, offices, and agencies of the Union that are intended to produce legal effects vis-à-vis third parties.[1107] The EU acts can always be challenged by the EU institutions and by the Member States—so-called privileged applicants.[1108] The European Central Bank, Committee of the Regions and the Court of Auditors can bring actions only so as to protect their prerogatives.[1109] And private parties have standing against the EU acts addressed to them, or they need to prove direct and individual concern in the case of acts of general application, and only direct

[1106] Article 263 TFEU, para 2 lists the grounds of legality review as follows: '…lack of competence, infringement of an essential procedural requirement, infringement of the Treaties or of any rule of law relating to their application, or misuse of powers'.

[1107] Article 263 TFEU.

[1108] Ibid, para 2.

[1109] Ibid, para 3.

concern if challenging a regulatory act that does not entail implementing measures.[1110]

Looking at the operational framework of Article 263 TFEU, one can easily notice that the standards and standardisation are not a good fit for direct actions before the EU Courts. The European standards, including harmonised ones, are not *per se* acts of the EU. Moreover, the standards are voluntary and do not produce legal effects until the Commission publishes the reference to them in the official journal. In addition, the restricted interpretation of the *locus standi* rules concerning the private parties makes contestability of the HESs by business operators, manufacturers, and environmental or consumer associations extremely difficult.

Below, the direct judicial review of the HESs and the Commission's decisions thereto is examined. By doing so, this section demonstrates that uncertainty over the legal status of HESs, i.e. whether or not to regard them as acts of the EU, leaves the contestability of these standards obscure.[1111] In contrast, the direct review of the Commission's decisions conferring legal effect to HESs is possible. In turn, challenging the Commission's decisions before the Court can also induce an indirect review of standards and the standardisation process.

7.3.1.1. Ratione Materiae (1): What to Challenge—Direct Action Against European (Harmonised) Standards

For the Court to decide a case, it must have jurisdiction to render a judgment in that field. In other words, the case should fall under *ratione materiae* of the Court. The analysis of the judicial review of the European standardisation system, therefore, starts by answering the question of whether the HESs fall under the subject matter of annulment action. Article 263 TFEU states that the CJEU have jurisdiction to review the legality of acts of EU institutions, bodies, offices or agencies, other than recommendations and opinions that produce the legal effects.[1112]

[1110] Ibid, para 4.

[1111] In the recent *James Elliott* case (n 60), the Court established that a harmonised standard was a provision of EU law, permitting to deliver a preliminary ruling procedure interpreting a scope of this standard. Though the Court did not explicitly suggest that harmonised standards are the acts of the EU, but rather stressed the fact that they are adopted by the private bodies, which are not the institutions, agencies or bodies of the EU.

[1112] Article 263 TFEU.

The verbatim reading of Article 263 TFEU constrains the CJEU's jurisdiction to rule on the legality of the HESs due to two factors—namely the authorship and legal effects of these rules, or, in other words, the legal status of the ESOs and the legal nature of the HESs.

The ESOs are not founded on the basis of any primary or secondary EU act and hence are not institutions, bodies, offices or agencies of the EU. Rather these ESOs are private law bodies, with distinct legal personality, governed by Belgian law. In the light of these, the HESs do not qualify as acts of institutions, bodies, offices or agencies of the Union.

Besides, the HESs are voluntary technical rules laying down the technical means to comply with the legislative requirements.[1113] Although the HESs are formally voluntary rules, could they still be seen as '…producing legal effects vis-à-vis third parties'?[1114] The publication of a reference to an HES in the official journal creates legal effects to certain parties.[1115] Manufacturers using the HESs can benefit from the presumption of conformity with legislative requirements. In addition, the publication of the references to the HESs restricts the Member States from introducing technical regulations covering the same aspects as the HESs or contradicting them.[1116] The legal effects of the HESs stretch to the national standards bodies too. The latter are under the obligation to transpose an HES and do not introduce a new, contradictory standard.[1117]

The Court has given the meaning of a reviewable act to 'all EU measures…whatever their nature or form, which are intended to have legal effects.'[1118] It is already established case law that even if a measure/act is non-binding or has a form that is not recognised by the Treaty, this would not stop the Court from reviewing such a measure. Notably, various soft law

[1113] The Council, Resolution on a New Approach to Technical Harmonisation and Standardisation (n 14), Annex II; Commission, 'Blue Guide' (n 401), 40–2.

[1114] Article 263 TFEU. See also: according to the Court's judgment in Case 60/81 *IBM v Commission* ECLI:EU:C:1981:264, Preparatory acts cannot be challenged.

[1115] Decision No 768/2008/EC of 9 July 2008 (n 54), Article R8.

[1116] See for instance the following cases: Case C-112/97, *Commission v Italy* (n 22); Case C-100/00, *Commission v Italy*, ECLI:EU:C:2001:211; Case C-103/01, *Commission v Germany*, ECLI:EU:C:2003:301; and Case C-6/05, *Medipac-Kazantzidis* (n 356).

[1117] Regulation 1025/2012 (n 14), Article 3(6). All parties to whom the HESs create legal effects are potential applicants in the annulment action.

[1118] Case 22/70, *Commission v Council, (ERTA*), ECLI:EU:C:1971:32, para 42.

instruments—such as the Commission's Communications,[1119] Code of Conduct,[1120] or Internal Instructions adopted by the Commission—were the subject matters of admissible annulment actions before the CJEU.[1121] While the Court has opened the door to soft law instruments in annulment actions, these documents were still the products of the EU institution—the Commission—which is not true for the HESs. Although the Commission endorses the HESs, they remain the sole products of the ESOs' authorship.[1122]

The narrow reading of Article 263 TFEU would leave the HESs beyond the Court's jurisdiction in an annulment action. However, if we accept that judicial review of new forms of governance is necessary then whether the actions of the ESOs are susceptible to judicial review falls on two factors: the institutional character of the ESOs and the nature of the functions performed. This requires a broad approach to the *ratione materiae* of Article 263 TFEU, meaning that the Courts establishing jurisdiction over the HESs need to answer the question as to whether acts of the ESOs, i.e. the HESs, '…engage the normative criteria underpinning judicial review',[1123] such as abuse of power, protection of individual rights, and securing the public interest. As was argued above, the HESs undoubtedly concern public interests since they are used for legislative purposes to address safety, health, and environmental requirements, as well as produce legal effects for the Member States, national standards bodies, and business operators.

AG Sanchez-Bordona, in his opinion to the recent *James Elliott Construction* case,[1124] proposed a broad understanding of the notion of EU act and qualified the HES as the provision of EU law. It is worth remarking that a question was raised in the context of the preliminary ruling procedure, which could have influenced such approach. AG argued that the HESs are acts of the EU because of the Commission's control over these standards. Specifically, the Commission issues a mandate and publishes a reference in the official journal from which point the HESs acquire legal effects. In addition, the Commission

[1119] See for instance: Case, C-325/91 *France v Commission* (Transparency of Financial Regulations), ECLI:EU:C:1993:245; See on this matter: J. Scott, 'In Legal Limbo: Post-Legislative Guidance as a Challenge for European Administrative Law' (2011) 48 (2) *Common Market Law Review* 329.

[1120] Case C-303/90, *France v Commission* (Code of Conduct), ECLI:EU:C:1991:424.

[1121] Case C-366/88, *France v Commission* (Internal Instructions), ECLI:EU:C:1990:348.

[1122] Eliantonio, 'Judicial Control of the EU Harmonized Standards' (n 385).

[1123] Elliott, 'Judicial Review's Scope, Foundations and Purposes: Joining the Dots' (n 944), 94.

[1124] AG in Case C-613/14, *James Elliott* (n 219).

exercises *ex-ante* control on whether or not to publish the reference to an HES. Similarly, the Court too in *James Elliott* paid attention to the context in which a harmonised standard is developed. It argued that the Commission influences, delineates, and controls the ESO's task of developing an HES in pursuant to the mandate.[1125]

A broad approach to the subject matter of the annulment action, which enables establishment of the CJEU's jurisdiction over the HESs, at first blush, seems to contradict the literal reading of Article 263 TFEU. This broad approach takes into account the nature and function of an HES as opposed to its formal legal status. Such reasoning is not foreign to the CJEU. The Court usually pays attention to the content of a contested act/measure and to the circumstances surrounding its adoption before considering whether a measure constitutes an act of the EU.[1126] While the possibility of a direct challenge to the HESs remains unclear, contesting the Commission's decisions conferring legal effects to the HESs could be an indirect route for challenging these standards.

7.3.1.2. Ratione Materiae (2): What to Challenge—Direct Action Against the Commission's Decisions[1127] Concerning European Standardisation

The HESs become entangled with directives and carry the presumption of conformity due to the Commission's 'decisions' publishing references to these standards. This means that legal significance of the HESs stems from the Commission's administrative acts. Hence, the latter might be the subject of annulment action, which could also indirectly induce the review of the HESs or the process of standardisation.

During the first years of the existence of the New Approach strategy, the Commission did not 'adopt' or recognise the HESs. The only requirement, according to the Low Voltage Directive of 1973, was that '*for the purposes of information*[1128] the list of harmonised standards and their references

[1125] Case C-613/14 *James Elliott* (n 60), paras 43–5.

[1126] Joined Cases C-181/91 and C-248/91, *European Parliament v Council*, ECLI:EU:C:1993:271, para 15. Although here the question was whether the measure was attributable to the EU or the Member State.

[1127] The Commission's decisions refer collectively to decisions to publish references to the HESs in the official journal, as well as the Commission decisions on whether to withdraw or maintain a reference to HES following the Parliament's or a Member State's *ex-ante or ex-post* objections.

[1128] Emphasises added.

[were]…published in the official journal.'[1129] It is perhaps because of this wording that the Commission's published references to the HESs were called 'communications.'[1130] However, as already mentioned, the Commission has published a reference to the harmonised standard through an implementing decision in L series of the official journal.[1131] This fact has important implications for the justiciability of the Commission's reference concerning the harmonised standards.[1132]

Until recently, the Commission did not assess the compatibility of an HES with essential requirements, prior to publication. The control over the substance of the standards took place post publication of a reference and was set in the context of administrative procedure. This *ex-post* control is commonly known as safeguard procedure. Each new approach directive had a safeguard clause that allowed the Commission and the Member States, if they were concerned about a harmonised standard's compliance with the essential requirements, to bring the issue before the standing committee envisaged by the same directive and request the withdrawal of the reference to a standard.[1133] On the basis of the committee decision, the Commission either kept or withdrew the reference to an HES.

The similar procedure before the publication of the reference took place in practice, despite the fact that new approach directives did not envisage it.[1134] With the modification of the legal framework on European standardisation, Regulation 1025/2012 systematised the rules for *ex-ante* and *ex-post* control of the references to HESs. It also modified the parties who can start a procedure. Now, the European Parliament or a Member State can object to the publication

[1129] Directive 73/23/EEC (Low-voltage Directive) (n 317), Article 5 (emphasis added). The clause has survived the recast; see Article 5 of Directive 2006/95/EC of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits [2006] OJ L 374/10.

[1130] See for instance Commission Communication in the framework of the implementation of Directive 2009/48 on the safety of toys [2013] OJ C 149/2.

[1131] See section 4.3.2 of this thesis.

[1132] The discussion on this follows below. See also: A. Volpato and M. Eliantonio, 'The Butterflying Effect of Publishing References to Harmonised Standards in the L Series' (2019) *European Law blog* <http://europeanlawblog.eu/2019/03/07/the-butterfly-effect-of-publishing-references-to-harmonised-standards-in-the-l-series/> accessed 7 March 2019.

[1133] See for instance: Directive 87/404/EEC of 25 June 1987, on the harmonization of the laws of the Member States relating to simple pressure vessels [1987] OJ L 220/48, Article 6.

[1134] See for instance Commission Decision relating to the publication of the references for standards EN 13428, EN 13429, EN 13430, EN 13431, and EN 13432 [2001] OJ L 190/21.

of a reference to an HES or request the withdrawal thereof, and the Commission is no longer an eligible actor to trigger a safeguard clause.

With the updated version of the safeguard procedure, the Commission's action to publish a standard acquired a legal status. Firstly, Regulation makes it clear that before the publication of a reference, the Commission is required to check whether 'a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding union harmonisation legislation'.[1135] This means that the Commission's publication of a reference is more than just a rubber-stamping of the ESOs' standards (although in practice it still can be otherwise).

Although the Commission's publications of the references to the HESs were called 'recommendations', they could even then be reviewed under Article 263 TFEU.[1136] The Court previously stated that the annulment actions are allowed on the measures adopted by institutions regardless of 'their nature or form', as long as these measures 'intend to have legal effects.'[1137] The AG Sanchez-Bordona also argued that the Commission's decisions concerning the publication of references to the HESs are legal acts susceptible to a judicial review.

> Like those relating to the publication of harmonised technical standards, decisions adopted by the Commission concerning formal objections to harmonised technical standards raised by the Member States or the European Parliament are legal acts against which an action for annulment may be brought.[1138]

The judicial review of the Commission's references to the HESs under Article 263 TFEU becomes undeniable considering the fact that recently the Commission published a reference to the HESs as an implementing decision.[1139] The General Court's (GC) has already supported the view that the Commission's decision publishing a refence to the HES is a reviewable act under 263 TFEU. In the GC's words, '…the decisions relating to the

[1135] Regulation 1025/2012 (n 14), Article 10(6).

[1136] Schepel also supports the view that the Commission's 'decision' to publish a reference in the official journal is a reviewable legal act. See in this regard: Schepel, 'The New Approach to the New Approach' (n 371).

[1137] See Case C-135/93, *Kingdom of Spain v Commission*, ECLI:EU:C:1995:201, para 20; Case 22-70, *Commission v Council*, ECLI:EU:C:1971:32, para 42.

[1138] AG Opinion in Case C-613/14, *James Elliott* (n 219), para 54.

[1139] Commission Communication (2018/C 326/04) (n 488).

publication of harmonised standards are legal acts against which an action for annulment may be brought.'[1140] The Commission's 'decision' to publish or withdraw a reference to an HES is also subject to *ex-ante* and *ex-post* administrative control from the Member States and the European Parliament. The results of this administrative control might further be challenged judicially under an annulment procedure.[1141] A similar context was at hand in the *Schmoldt* case.[1142]

The latter case concerned the Commission's refusal to withdraw the standard that was allegedly in contradiction with the essential requirements of the relevant new approach directive. The Commission, after consultation with the CEN and relevant standing committee, concluded that there was no evidence of the alleged risk associated with a standard. Mr Schmoldt, who was a chair of the relevant working group of CEN, responsible for the adoption of the standard, disagreed with the Commission's finding and challenged the legality of the Commission's decision. The Court denied the standing to Mr Schmoldt, on the basis of finding that he was acting in a personal capacity rather than on behalf of CEN.[1143] Although the case was declared inadmissible due to the applicants' lack of individual concern, it is clear that the Commission's decision adopted in the context of a safeguard procedure concerning the publication of a reference to a standard is a reviewable act. At the same time, such judicial review can affect the legality of granting the presumption of conformity to the disputed HES.

Another way of challenging the legality of HESs is through contesting the process of standard-setting. The parties involved in standardisation are free to bring a claim before the Commission and point out the procedural deficiencies of standard-setting that amount to an infringement of, for instance, the EU competition rules. Consequently, the Commission's decision on this matter can be challenged before the Court. The *EMC* case concerned a similar scenario.[1144]

[1140] Ibid, para 60; T-264/03, *Jürgen Schmoldt* (n 1064), paras 91–4.

[1141] The case requesting the annulment of the Commission's decision to maintain the reference to a harmonised standard is currently pending before the General Court. The case is brought by Federal Republic of Germany. See: T-229/17, *Germany v Commission.*

[1142] T-264/03, *Jürgen Schmoldt* (n 1064).

[1143] The case will be elaborated below in more detail while discussing the standing requirements.

[1144] Case C-367/10 P *EMC* (n 415).

EMC—a company producing energetically modified cement—complained to the Commission about infringement of EU competition rules. Specifically, it argued that in the process of standard-setting, CEN and the European Cement Association had created a cartel. Consequently, a standard adopted by CEN as a result of this cartel excluded it from the market, since EMC's ecological cement did not fit the adopted standard. In order to prove the infringement of competition law provisions, EMC highlighted procedural deficiencies, namely that the standard-setting was discriminatory and designed to favour major cement producers on the market. EMC alleged that the procedure was controlled and influenced by the Cement Association and the chairman of the technical committee working on a particular standard, since the chairman held a senior executive position in a well-established cement company.

Without dwelling on the merits of this judgment,[1145] it suffices to say that both the Commission and the Courts relied on the by-laws of the ESOs to demonstrate that these internal rules ensure the observance of the EU competition law. If EMC were to win the case, establishing the infringement of competition rules during the standardisation process would undermine the legality of a standard and entail withdrawal of a reference to it.[1146]

To conclude, the Commission's decisions on the publication of the references to the HESs or concerning *ex-ante* or *ex-post* control of the publication of references are acts reviewable under annulment action. Challenging the Commission's decisions opens the possibility to indirectly question the legality of the standardisation process or to contest the products of this process, i.e. the HESs. However, it should be made clear that by annulling the Commission's decisions to publish the references to HESs, the Court could only cancel the legal effects granted over the HESs but would not invalidate the standards themselves. Meaning that an HES would continue to exist as a European standard, but it would be deprived of the status of the harmonised standard.

7.3.1.3. Ratione Personae: Who Can Challenge European Standardisation?

Rules on standing have the power to affect the participation in the regulatory process.[1147] Meaning that they delineate the group of applicants who can

[1145] This case was analysed in Chapter 6 of this thesis.

[1146] The latter scenario was discussed in more detail in Chapter 6, in the context of the interplay between competition law and European standardisation.

[1147] Bogojevic, 'Judicial Protection of Individual Applicants Revisited' (n 1105).

challenge the regulatory decisions. The standing requirements at the EU level are the result of EU judicial architecture and manifest the distribution of regulatory competences between the Member States and the EU, influencing the allocation of jurisdiction between Courts at the national and EU level.[1148] Private parties in most cases would enjoy indirect access to the CJEU through the national courts since the direct actions before the Courts at EU level are barred with strict standing requirements.

This section identifies possible applicants in the annulment action against European standardisation and discusses the standing of these parties. By doing so, it demonstrates that standing rules in the context of European standardisation do not manifest any unique characteristics and private parties face similar constraints as in any annulment action against the EU acts of general application.

If the HESs met the test of the reviewable act, then the Member States with other privileged applicants would have an automatic standing to bring the annulment action without demonstrating a specific link to a standard. But the non-privileged applicants—such as business operators—cannot easily fulfil the standard requirement for standing discussed below. The prospect of claiming standing in an annulment action concerning the European standardisation is not promising[1149] for four European stakeholder organisations either, which are recognised by Regulation 1025/2012,[1150] represent Small and Medium-sized Enterprises or Consumer, Environmental and Societal interests and receive Union financing.[1151]

According to the Court's case law, associations can assume standing in the following three scenarios: 1) a legal provision grants a procedural right to these associations;[1152] 2) every single member of the association is directly and

[1148] Ibid. See also: E. Stein and J. Vining, 'Citizen Access to Judicial Review of Administrative Action in a Transnational and Federal Context' (1976) 70 *American Journal of International Law* 219, at 233.

[1149] Colombo and Eliantonio, 'Harmonized Technical Standards as Part of EU Law' (n 512), 323–40.

[1150] Regulation (EU)1025/2012 (n 14), Annex III.

[1151] Ibid, Article 5.

[1152] T-12/93, *Comite Central d'Enterprise de la Societe Anonyme Vittel and Comite d'Etablissement de Pirval and Federation Generale Agroalimentaire v Commission of the Euroepean Communitites*, ECLI:EU:T:1995:78.

individually concerned;[1153] and 3) a measure/act affects the association's interest and especially its position as a negotiator.[1154]

It follows that the Annex III organisations representing consumer and environmental interests in the European standardisation and wishing to bring an annulment action against either a Commission's mandate or the decision to publish, maintain or withdraw the reference to an HESs are left to try their luck and claim standing in the light of the first scenario—appealing on their procedural rights under Regulation 1025/2012. Notably, Regulation on European standardisation requires the involvement of consumer and environmental associations during the standardisation process. It urges the ESOs to 'encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders.'[1155] Most importantly, Regulation 1025/2012 grants specific procedural rights to the stakeholder organisations that are financed by the EU and recognised by the same Regulation. Namely, these stakeholder organisations are requested to be consulted during the process of adoption of the annual Union work programme for European standardisation,[1156] in the process of adopting a standardisation request/mandate from the Commission,[1157] and before taking the decision on formal objections to harmonised standards.[1158]

However, the success of such motion is overshadowed by a recent judgment in Case T-600/15, where the GC denied standing to the number of environmental organisations challenging the Commission's implementing Regulation. In GC words

> …no provision of the contested act is directly applicable to the applicants, in the sense that it would confer rights or impose obligations on them.

[1153] Joined Cases T-447/93, T-448/93 and T-449/93, *Associazione Italiana Tenico Economica del Cemento and British Cement Association and Blue Circle Industries plc and Castle Cement Ltd and The Rugby Group plc and Titan Cement Company SA v Commission of the European Communities,* ECLI:EU:T:1995:130.

[1154] Case T-84/01, *Association contre L'horaire d'ete (ACHE) v Council of the European Union and European Parliament,* ECLI:EU:T:2002:5.

[1155] Regulation (EU) 1025/2012 (n 14), Article 5.

[1156] Ibid, Article 8(4).

[1157] Ibid, Article 10(2)

[1158] Ibid, Article 11 in conjunction with Articles 12, 22, 23.

> Consequently, the contested act does not affect their legal position, and therefore the condition of direct concern […] is not met.[1159]

When it comes to the standing of private parties—such as business operators, manufacturers or standardisation bodies wishing to bring annulment action against European standardisation—the requirement is to demonstrate direct and individual concern.[1160] This is so because the HESs and the Commission's decisions are acts of general application and not acts addressed to these private parties.

To prove a direct concern, an applicant needs to show a direct link between the challenged measure and the loss or damage that an applicant has suffered.[1161] The direct link means that the contested EU measure affects the applicant's legal situation directly, and leaves no discretion to the addressees of the measure who are required to implement it.[1162] Meeting a test of direct concern would not be a problem for private parties—such as business operators—since the publication of a reference to an HES indeed affects the legal position of manufacturers of goods covered by that standard. The similar is not true, however, with respect to the test of individual concern. A private party is considered to be individually concerned if:

> By reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and by virtue of these factors [the act] distinguishes them individually just in the case of the person addressed.[1163]

Moreover, the *Plaumann* test of individual concern requires private parties to prove that they belong to a 'closed group' of persons affected differently by the EU measure/act than all other persons.[1164] In the case of *Piraiki-*

[1159] Case T-600/15, *Pesticide Action Network Europe (PAN Europe) and other v Commission,* ECLI:EU:T:2016:601.

[1160] Article 263, para 4.

[1161] Case C-207/86, *Asociacion Profesional de Empresarios de Pesca Comunitarios (Apesco) v Commission of the European Communities*, ECLI:EU:C:1988:200; Case C-417/04P*, Regione Siciliana v Commission of the European Communities*, ECLI:EU:C:2006:282.

[1162] See among others, Case C-69/69, *SA Alcan Aluminium Raeren and others v Commission of the European Communities*, ECLI:EU:C:1970:53.

[1163] Case C-25/62, *Plaumann,* ECLI:EU:C:1963:17, 107.

[1164] Ibid.

Patraiki,[1165] the Court did not apply the 'fixed and ascertained group of persons'[1166] test and somewhat relaxed the *Plaumann* reasoning. The fact that traders concluded the contracts prior to the adoption of the contested decision was a sufficient factor to regard these traders as identifiable and hence individually concerned.[1167] That said, it is important to note that subsequent case law on the concept of individual concern does not follow the liberal approach of the *Piraiki-Patraiki* and *Codorniu*[1168] cases. Instead, in *Buralux*[1169] the Court upheld the *Plaumann* test of individual concern.

Considering the notoriously restrictive interpretation of individual concern, the prospects of standing for business operators in the annulment action against the HESs or the publication of references thereto are not promising. However, for a national standards body, the situation is arguably different. The Commission's publication of reference to the HESs that grants the presumption of conformity '…is, in effect, a judgment on the status of their national standards implementing the harmonised standard.'[1170] Then, the Commission's decision not to publish would have adverse legal effects on these standards bodies, because their standards transposing the European ones would have less use for economic operators, contrary to if the references to the HESs were published.[1171]

The Lisbon Treaty removed the requirement of individual concern though only with respect to regulatory acts not entailing implementing measures, as a response to criticism about the strict test of individual concern[1172] expressed in

[1165] Case 11/82, *Piraiki-Patraiki*, ECLI:EU:C:1985:18.

[1166] M. Bergström, 'Judicial Protection for Private Parties', in C.F. Bergström and D. Ritleng, (eds), *Rulemaking by the European Commission* (Oxford University Press 2016), 224.

[1167] Case 11/82, *Piraiki-Patraiki* (n 1160).

[1168] Case C-309/89, *Codorniu SA v Council,* ECLI:EU:C:1994:197, has modified the abstract terminology test and ruled that although a regulation it can still be reviewable under 263 TFEU para 4, as long as individual concern is demonstrated by private parties.

[1169] Case C-209/94 P, *Buralux SA and others v Council,* ECLI:EU:C:1996:54.

[1170] Schepel, *The Constitution of Private Governance* (n 111), 254.

[1171] Ibid.

[1172] One of the main arguments against strict standing requirements is that it deprives individuals of a right to effective judicial protection.

academia[1173] and within the Court.[1174] The definition of a regulatory act is not given in the Treaty.[1175] The Court attempted to clarify the notion of a regulatory act in *Inuit*.[1176] It noted that a legislator uses the word Act throughout Article 263 TFEU, although the first two limbs of this Article refer to an Act in general terms, while para 4 uses specifically the term of a regulatory act.[1177] Hence, according to the Court, there should be a distinction between these two, because act is a general term and includes legislative, non-legislative, and individual acts. In contrast, the concept of a regulatory act should be defined restrictively.[1178] Furthermore, the Court looked at the drafting history of para 4 of Article 263 TFEU and concluded that the intention of the drafters was not to relax the admissibility criteria concerning a legislative act, but to maintain the restrictive approach.[1179] On the basis of this finding, the Court argued that the regulatory act is an act of general application, but other than a legislative act.[1180]

[1173] The overly restrictive and cumbersome test of individual concern has been heavily criticised in academic circles. See for instance: A. Cygan, 'Protecting the Interests of Civil Society in Community Decision-Making: The Limits of Article 230 EC' (2003) 52 (4) *International and Comparative Law Quarterly* 995; A. Albors-Llorens, 'Sealing the Fate of Private Parties in Annulment Proceedings? The General Court and New Standing Test in Article 263 (4) TFEU' (2012) 71 (1) *Cambridge Law Journal* 52; X. Lewis, 'Standing of Private Claimants to Annul Generally Applicable European Community Measures: If the System is Broken, Where Should it be Fixed?' (2006) 30 *Fordham International Law Journal* 1496.

[1174] The AG Jacobs and the General Court have urged the ECJ to overturn the *Plaumann* test so as to abide with the principle of effective judicial protection. See: Case C-50/00 P, *Union de Pequenos Agricultres ('UPA') v Council*, ECLI:EU:C:2002:462. See also: Opinion of AG Jacobs, ECLI:EU:C:2002:197. The ECJ agreed that the notion of individual concern should be read in light of the principle of effective judicial protection, but refused to overturn the test of individual concern. According to the Court, that would amount to a modification of the treaty which goes beyond the Court's jurisdiction. See: Case C-50/00 P, *Union de Pequenos Agricultres ('UPA') v Council*, ECLI:EU:C:2002:462, para 40. See also: P.-A. Van Malleghem, 'Before the Law Stands a Gatekeeper: Or, what is a "Regulatory Act" in Article 263 (4) TFEU? Inuit Tapiriit Kanatami' (2014) 51 (4) *Common Market Law Review* 1187.

[1175] Treaty loosely divides all mandatory EU acts into two categories: legislative and non-legislative acts. According to Article 298 TFEU, legislative acts are the ones adopted under the ordinary or special legislative procedure, while the rest are non-legislative acts.

[1176] C-583/11 P *Inuit,* ECLI:EU:C:2013:625.

[1177] Ibid, paras 55–7.

[1178] Ibid, para 58.

[1179] Ibid, para 59.

[1180] Ibid, para 60.

Following the Court's reasoning in the *Inuit* case, the HESs could be regarded as regulatory acts, since they are not legislative acts. Furthermore, it would not matter whether the HESs are regarded as delegated or implementing acts envisaged respectively by Articles 290 and 291 TFEU.[1181] This is because neither delegated nor implementing acts are legislative acts. But to remove the requirement of individual concern, the regulatory act should not require any implementing measure. All HESs are transposed by the national standard bodies and published as national standards.[1182] Does this mean that national standards are actually the implementing measures for the purposes of Article 263 TFEU?

According to the Court's case law, an implementing measure encompasses any measure taken by the Member States or the EU institutions that are linked to the act that measure aims to implement.[1183] And 'in order to determine whether the measure being challenged entails implementing measures should be assessed by reference to the position of the person pleading the right to bring the proceedings.'[1184]

Would national standards be regarded as implementing measures although they are verbatim transpositions of harmonised standards? The ECJ found that even ancillary or mechanical implementation amounts to an implementing measure.[1185] Also, it is irrelevant 'whether or not the contested decision leaves a degree of discretion to the authorities responsible for the implementing measures.'[1186] This would entail that even a mechanical transposition of the HESs, without any discretionary powers of national standard bodies, amounts to implementation of the HESs and falls outside the scope of Article 364(4) TFEU.

Consequently, the private applicants would still need to satisfy the test of individual concern in order to bring an annulment action against the HESs, as well as against the Commission's decision concerning the HESs. The already

[1181] See discussion of whether the HESs can be regarded as delegated or implementing acts in Chapter 5.

[1182] Commission, 'Blue Guide' (n 401), 39.

[1183] Case C-274/12 P, *Telefónica SA v European Commission*, ECLI:EU:C:2013:852, paras 27–37.

[1184] Ibid, para 31.

[1185] Case C-456/13 P, *T & L Sugars Ltd*, ECLI:EU:C:2015:284, para 41.

[1186] The order of the Court in Case T-381/11, *Eurofer*, ECLI:EU:T:2012:273, para 59.

mentioned *Schmoldt* case[1187] demonstrates the difficulties for private applicants to meet the standing requirements, particularly the requirement of individual concern in an annulment action against the Commission's decision to maintain a publication of the reference to the HES. In *Schmoldt*, all three applicants were private parties: Mr Schmoldt, a chair of the part of CEN responsible for the development of a standard at stake; the German operator, manufacturing products falling under the scope of the standard; and the national association representing a relevant industry.

The Court refused standing to all three applicants. Specifically, the Court held that Schmoldt lacked standing because the relevant Community legislation did not lay down specific procedural guarantees for a person like him, although he participated in the development of a standard. Moreover, the relevant directive provided the procedural guarantees for CEN and Standing Committee,[1188] but not for Schmoldt who acted in a personal capacity and not as a representative of CEN.[1189]

Nor was a private operator, according to the Court, individually concerned by the contested decision. The contested decision related to the concerned business operator in a similar manner to any other manufacturer of the products falling under the scope of that standard. Hence, the Court found that the status alone was not enough to demonstrate that the company was individually concerned.[1190]

Finally, the private association representing the relevant industry was found not to be individually concerned, because, firstly, its members—e.g. Schmoldt and the business operator—were not individually concerned,[1191] and secondly, the association also failed to show any interest distinct from its members.[1192]

In terms of the restrictive interpretation of standing rules especially for non-privileged parties, the *Schmoldt* case is no different from the rest of the case law. But it remains a missed opportunity for the Court to have acted as a catalyst and promoted the wide participation in the standardisation process. The Court's catalyst function includes asking the governance bodies, i.e. the ESOs, to explicitly elaborate on and justify who has the right to participate and

[1187] T-264/03, *Jürgen Schmoldt* (n 1064).

[1188] Ibid, para 101.

[1189] Ibid, para 102.

[1190] Ibid, para 110.

[1191] Ibid, paras 127–30.

[1192] Ibid, paras 131–9.

in what form.[1193] This is different from the task of determining the standing rules on the basis of whether a party has a right-based claim to be allowed to influence the decision through judicial actions.

Some argue that the current trend indicates the Court's eagerness to give way to the participation exemption while considering the standing rules.[1194] Meaning that a person could be granted standing before the Court in cases where they enjoy 'specific procedural guarantees conferring upon them a right to participate in the political process.'[1195] The manifestation of this practice, as well as an illustration of the Court's catalyst role in promoting participation, is the *UEAPME* case.[1196]

UEAPME is a European organisation representing the interests of small and medium-sized businesses and it is included in the Commission's list of organisations to be consulted at the initial stage of 'social dialogue'. UEAPME brought a claim before the Court challenging the EU Directive on parental leave, which was adopted on the basis of a framework agreement agreed upon by some 'social partners' in the context of European social dialogue.

Even though UEAPME was consulted at the initial stage, it was not given a place at the negotiating table. Nor was there the explicit procedural right to participation. However, in the Court's words, the Commission and the Council are obliged

> [t]o ascertain whether, having regard to the content of the agreement in question, the signatories, taken together are sufficiently representative. Where that degree of representation is lacking, the Commission and the Council must refuse to implement the agreement at the Community level.[1197]

Interestingly, the matter of assessing the standing of UEAPME was turned into an issue of representation. The Court found that since the legislative procedure at hand did not provide for the participation of the Parliament, 'the participation of the people' must have been ensured by other means, such as through the parties, which are sufficiently representative of management and

[1193] Scott and Sturm, 'Court as Catalysts: Re-thinking the Judicial Role in New Governance' (n 1069), 577.

[1194] Ibid, 579.

[1195] Ibid.

[1196] Case T-135/96, *UEAPME*, ECLI:EU:T:1998:128.

[1197] Ibid, para 90.

labour.[1198] The Court views this as a requirement of 'the principle of democracy on which the Union is founded.'[1199]

In *UEAPME,* the Court granted the standing to the party that had been 'silenced' and denied participation. By doing so, the Court set the incentive to enhance participation in subsequent cases. As argued by Harlow, expanded rules on standing facilitate greater means for participation and representation.[1200] What is striking in *UEAPME* is that the Court did not review the legality of the outcome of the process, but sent it back for the new deliberation, that would meet the requirements of sufficient representation. In this manner, the Court set an incentive to include a wider spectrum of actors in the decision-making process, by imposing upon the Commission and the Council the duty to ensure the sufficient representation of social organisations consulted during the social dialogue.[1201] Realisation of this duty in its turn could avoid or mitigate the possibilities of challenging the measures later on judicially.[1202]

As opposed to *UEAPME,* the Court failed to perform a catalyst role and facilitate participation in *Schmoldt*.[1203] If the Court were to assume the catalyst role in the *Schmoldt* case, then a party not enjoying the explicit procedural right to participation but involved in the process of adoption of the contested decision would have benefited from the participation exemption.[1204]

[1198] Ibid, para 89.

[1199] Ibid.

[1200] C. Harlow, 'Public Law and Popular Justice', as cited in King, 'The Instrumental Value of Legal Accountability' (n 99).

[1201] P. Popelier, 'Preliminary Comments on the Role of Courts as Regulatory Watchdogs', (2012) 6 *Legisprudence* 257, at 263.

[1202] See detailed analysis of this case in Scott and Sturm, 'Court as Catalysts: Re-thinking the Judicial Role in New Governance' (n 1069).

[1203] T-264/03, *Jürgen Schmoldt* (n 1064).

[1204] Scott and Sturm, 'Court as Catalysts: Re-thinking the Judicial Role in New Governance' (n 1069). Mendes is also of the opinion that in general standing should be recognised for the parties enjoying the participation rights and 'whose substantive rights and legally protected interests have been affected by a legal act adopted in violation of their procedural right to participate. Standing should also be recognized for natural or legal persons who were denied access to decision-making procedures in violation of legal rules on participation…or whose views were ignored in violation of these rules'. See: J. Mendes, 'Participation and the Role of Law After Lisbon: A Legal View on Article 11 TEU' (2011) 48 (6) *Common Market Law Review* 1849.

It is difficult to disagree with Scott et al that the *Schmoldt* case is a missed opportunity to have promoted transparency in decision-making. It seems that the Court has suspected the private interests of Mr Schmoldt[1205] in bringing the proceeding, but never elaborated explicitly on that matter. It was obvious, though, that Schmoldt disagreed with the institutional viewpoint of CEN, but his standpoint was not recorded. The importance of monitoring and noting the different positions, including minority ones, in the cases of scientific complexity is extremely important and hence officially acknowledged.[1206] Taking this into account, the Court should have been even more inclined to use the opportunity and facilitate the transparency of the decision-making process in the co-regulation via European standardisation, by granting the standing to Schmoldt.

7.3.1.4. Interim Conclusion

This section has discussed the prospects of challenging European standardisation in annulment action before the CJEU and demonstrated the difficulties thereof. It is true that most of the hurdles are not idiosyncratic to the case of standardisation and are relevant to any annulment action. In addition, the annulment action against European standardisation is even more obscure due to uncertainty as to whether an HES is a reviewable act under Article 263 TFEU.

The ECJ has never admitted that restricted standing requirements are impediments to the effective judicial protection in the EU.[1207] On the contrary, the picture of the EU portrayed by the ECJ is that of the Union of complete remedies and effective judicial protection. The Court suggests that private parties have other means to contest the EU acts, namely an indirect action under Article 267 TFEU.[1208] The preliminary ruling procedure, with its outcomes, is different from annulment action because the former is addressed only to the national court that requests the ruling. However, the ECJ has gradually brought the effects of the annulment action and preliminary

[1205] T-264/03, *Jürgen Schmoldt* (n 1064).

[1206] See for instance Regulation (EC) 178/2002 (n 649), Article 28(7).

[1207] AG Kokott reminded us that there is 'no reason to fear a gap in the legal remedies available to individuals'. See: AG Kokott's opinion in the case C-583/11 P, *Inuit*, ECLI:EU:C:2013:21, para 115.

[1208] Order of the Court in Case C-503/07P*, Saint-Gobain Glass Deustchland v Commission,* ECLI:EU:C:2008:207, para 78; also Case C-50/00, *Union de Pequenos Agricultores*, ECLI:EU:C:2002:462, paras 12, 30, 37–42.

procedure closer together. In particular, the Court's finding concerning the validity of an EU act in preliminary ruling procedure has *erga omnes* effect and is sufficient reason for other national courts to regard that act as void.[1209] The 'convergence' of the effects of these procedures supports the Court's argument to view direct and indirect remedies as complementary. However, to supplement the limited direct access by the preliminary ruling procedure is problematic, because of the procedural difficulties faced by individuals intending to use Article 267 TFEU.[1210]

At the same time, it is difficult not to agree with the ECJ that there should be limited possibility for individuals to contest the legislative measures. Allowing the challenge of legislative acts by private parties could amount to the replacement of democratic legitimacy with judicial legitimacy. It is easy to accept this argument concerning the legislative acts, but a limited notion of a regulatory act and a wide category of implementing measures leaves the considerable number of non-legislative acts of general application immune from direct actions by private parties.

But one has to accept that the right to effective judicial protection does not mean only the direct access to the Court in Luxembourg. The national judges are judges 'de l'Union' too.[1211] Most probably, the doors to the judicial system for the cases concerning European standardisation will open at the national level.[1212] Consequently, through the national courts, the cases regarding European standardisation can reach the ECJ. This possibility is manifested by the *James Elliott Construction* case. The prospects of indirect action concerning European standardisation are considered below.

[1209] Case 66/80, *International Chemical Corporation*, ECLI:EU:C:1981:102.

[1210] See AG Jacobs in Case C-50/00, *UPA*, ECLI:EU:C:2002:197.

[1211] A. Kornezov, 'Shaping the New Architecture of the EU System of Judicial Remedies: Comment on Inuit' (2014) 39 (2) *European Law Review* 251–63.

[1212] See: X. Groussot, 'The EC System of Legal Remedies and Effective Judicial Protection: Does the System Really Need Reform?' (2003) 30 (3) *Legal Issues of Economic Integration* 221. The author here highlights the crucial role of the national courts in the system of judicial protection and by doing so puts an argument against the necessity of reforming the EU judicial system of remedies.

7.3.2. Preliminary Ruling Procedure and European Standardisation

The importance of preliminary ruling runs parallel with the story of European integration.[1213] It was through the preliminary ruling procedure that the Court has laid down the first stones in *sui generis* legal order by developing the doctrines of supremacy[1214] and direct effect.[1215]

Beyond being the tool for cooperation between national courts and the CJEU,[1216] the preliminary ruling procedure is an indirect way for the applicants to test the validity of EU actions. Indirect action has a great significance when considered in the light of the restricted standing rules for private applicants under Article 263 TFEU.[1217] Contesting the validity or requesting the interpretation of the HESs through the preliminary ruling procedure might be the only possible avenue left for the private applicants to access the CJEU. Especially so since the Court has been generous in accepting the cases for a preliminary ruling where the standing for an applicant under 263 TFEU was not certain.[1218]

This section provides a brief summary of a preliminary ruling procedure and discusses whether the HESs can be regarded as EU law provisions, subject to the preliminary ruling.

[1213] See on this matter: T. De La Mare and C. Donnelly, 'Preliminary Rulings and EU Legal Integration: Evolution and Stasis', in P. Craig and G. de Burca (eds), *The Evolution of EU Law* (2nd edn, Oxford University Press 2011), Chapter 13.

[1214] Case 6/64, *Flaminio Costa v E.N.E.L*, ECLI:EU:C:1964:66.

[1215] Case 26/62, *Van Gend & Loos v Netherlands Inland Revenue Administration*, ECLI:EU:C:1963:1.

[1216] M. Bobek, 'The Court of Justice, the National Courts and the Spirit of Cooperation: Between Dichtung and Warheit', in A. Lazowski and S. Blockmans (eds), *Research Handbook on EU Institutional Law* (Edward Elgar 2014), Chapter 14; see also: X. Groussot, 'Spirit, Are You There? Reinforced Judicial Dialogue and the Preliminary Ruling Procedure', *Eric Stein Working Paper No 4/2008*, available at <www.ssrn.com>.

[1217] H. Rasmussen, 'Why is Article 173 Interpreted against Private Parties?' (1980) 112 *European Law Review* 122–7.

[1218] Case C-408/95, *Eurotunnel SA v Sea France*, ECLI:EU:C:1997:532; Case C-241/95, *The Queen v Intervention Board for Agricultural Produce*, ECLI:EU:C:1996:496.

7.3.2.1. Preliminary Ruling Procedure Concerning European Standardisation: General Overview

In a nutshell, the preliminary ruling procedure is triggered by a court or a tribunal[1219] of a Member State[1220] requesting either the interpretation of the Treaties or validity and interpretation of the acts of the institutions, bodies, offices or agencies of the EU.[1221] In other words, when parties are affected by EU law through its application at the national level, the preliminary ruling procedure provides the opportunity to challenge the basis of this effect of EU law.

A preliminary ruling question concerning the HES might request either validity or interpretation of the harmonised standards. We could easily imagine the following two scenarios where the preliminary ruling on the HESs would be necessary to resolve a dispute before a national court.

A manufacturer of the toys established in Sweden wants to sell the product throughout the internal market, hence it needs to acquire CE marking. To this end, the manufacturer has to demonstrate compliance with the essential requirements of the Toys Directive.[1222] There are a couple of harmonised standards developed by the CEN according to the Commission's mandates. The references to these HESs are published in the official journal and provide presumption of conformity with the Directive. SIS (Swedish Standards Institute) has transposed these HESs as the Swedish standards. The manufacturer purchasing the national transposition of an HES finds out that the standard excludes the use of certain chemicals in the paint used for toys. The business operator firmly believes that such a formulation of a harmonised standard does not have a reasonable ground and aims to discriminate against traders like him/her who use these chemicals. He/she decides to challenge the HESs but lacks standing because of the impossibility of demonstrating the individual concern. The remaining option for them is to argue that the Swedish standard transposing the HES creates unjustified barriers to trade and bring the

[1219] Article 267 TFEU; Case C-355/89*, Department of Health and Social Security v Christopher Stewart Barr and Montrose Holdings Ltd*, ECLI:EU:C:1991:287.

[1220] On the detailed account of the preliminary ruling procedure see: M. Broberg and N. Fenger, *Preliminary Reference to the European Court of Justice* (2nd edn, Oxford University Press 2016).

[1221] Article 267 TFEU.

[1222] Directive 2009/48/EC on the Safety of Toys (n 418).

case before a national court. Consequently, they raise the question of the validity of the HES and request the preliminary ruling procedure.

In another scenario, the same manufacturer fails EC type of assessment procedure conducted by a notified body, because according to the latter the business operator unsuccessfully proved compliance with the essential requirements of the Directive. The manufacturer brings the case before a national court and argues that it has complied with the essential requirements by the alternative measures equivalent to the HESs. Since the dispute is about establishing whether the alternative measure is equivalent to the HES, the manufacturer might ask a national court to request a preliminary ruling concerning the interpretation of the HESs.

However, the jurisdiction to give the preliminary ruling is constrained within the EU acts, so it needs to be discussed whether the HESs can be regarded as the provisions of EU law, which is elaborated below.

7.3.2.2. Preliminary Ruling on a Harmonised Standard: The James Elliott Construction Case[1223]

According to Article 267 TFEU, the preliminary ruling can be requested about the binding EU Acts. However, the ECJ has gradually accepted the non-binding EU acts—such as recommendations or guidance documents—within the framework of the preliminary ruling procedure.[1224] As such, the voluntary nature of the HESs did not stop the Court from delivering the preliminary ruling in *James Elliott.* In the Court's words, 'the fact that a measure of EU law has no binding effect does not preclude the Court from ruling on its interpretation in proceeding for a preliminary ruling under Article 267

[1223] Some parts of this section are the same as a blog post published by the author; M. Medzmariashvili, 'A Harmonised (Technical) Standards: Provision of EU Law! (Judgment in C-613/14 James Elliott Construction)', <https://europeanlawblog.eu/2017/01/24/a-harmonised-european-technical-standard-provision-of-eu-law-judgment-in-c-61314-james-elliott-construction/>.

[1224] See for instance: Case C-322/88, *Grimaldi*, ECLI:EU:C:1989:646. Here the Court said that a non-binding document such as the Commission's recommendation should be taken into account by judicial authorities when ruling on the cases. See also: Case C-188/91, *Deutsche Shell*, EU:C:1993:24, para 1. More noticeable is the Court's use of these non-binding documents as an interpretative tool in the competition cases. See on this matter: O.A. Ştefan, 'European Competition Soft Law in European Courts: A Matter of Hard Principles?' (2008) 14 (6) *European Law Journal* 753–72.

TFEU.'[1225] But these non-binding standards can be the subject of a preliminary ruling if they are part of EU law.

In short, this case concerned the interpretation of certain Articles of the Directive 89/106 concerning the construction products and harmonised standard EN 1324:2002 adopted by CEN pursuant to the Commission's mandate M/125. This standard is a technical translation of the essential requirements laid down in the construction products Directive and covers aggregates for unbound and hydraulically bound materials for use in civil engineering work and construction. The Commission has referenced the later standard in the C series of the official journal and thus aggregates complying with this standard can freely be moved in the Union and are covered by the presumption of conformity.

In 2004, James Elliott Construction built a youth facility in Dublin using aggregates supplied by Irish Asphalt. Soon after completion of the building, cracks appeared in the floors and ceilings. James Elliott undertook remedial work at a total cost of EUR 1.5 million and consequently sued Irish Asphalt, arguing that the damage was caused by the presence of pyrite in aggregates. The case reached the Irish Supreme Court, which deemed it necessary to refer preliminary questions and inquired whether an HES adopted on the basis of the Commission's mandate can be interpreted by the Court; and if so, asked the ECJ to interpret the scope and limits of the HES's presumption of conformity.

Although the AG's and the Court's reasoning differ to some extent, they both come to the same conclusion that an HES is a provision of EU law. The verbatim reading of Article 267 TEFU suggests that the ECJ has jurisdiction to deliver a preliminary ruling concerning the Acts of the 'institutions, bodies, offices and agencies of the Union.' European Standards Organisations, unlike the EU bodies and agencies, were not set up to perform specific EU tasks. Rather, the ESOs had been established as private and non-profit associations under Belgian law. It follows that the ESOs do not qualify as institutions, bodies, offices or agencies of the EU. Thus, a literal reading of Article 267 TFEU would restrict the Court's jurisdiction with respect to HESs.

> The Court too admitted that '…indeed [these] bodies … cannot be described as "institutions, bodies, offices or agencies of the Union"', nevertheless, according

[1225] Case C-613/14, *James Elliott* (n 60), para 35.

> to the ECJ it has '…jurisdiction to interpret acts which … are by their nature measures implementing or applying an act of EU law.'[1226]

In other words, the nature of a measure and its relationship with an EU act are the determining factors to enable the Court to deliver a preliminary ruling on that measure. According to the ECJ, the rationale for this reasoning is to ensure the uniform application of the HESs throughout the union.[1227]

The Court also paid heed to the legal effects that the compliance with an HES entails. Namely, products conforming to technical requirements of an HES enjoy the right to free circulation and market access within the territory of all Member States of the EU.[1228] As a final point, according to the ECJ, the development of an HES is 'strictly governed by the essential requirements defined by the Directive'.[1229] In addition, the Commission plays an important role in this process, as it issues a mandate, approves the ESOs work programme, decides on the compliance of the draft HES with the mandate, and finally confers the legal effects on an HES by publishing the reference to it in the official journal.

There is a striking difference between the AG's opinion and the judgment when it comes to the qualification of the relationship between the Commission and ESOs. For the AG, the system of requesting the development of HESs is a result of 'controlled legislative delegation in favour of a private standardisation body.'[1230] This is because the HESs are adopted in pursuant to the Commission's mandate. And the Commission connects a standard to a relevant directive by publishing the reference to an HES in the official journal.

The Court, unlike the AG, was rather cautious and did not use the wording 'controlled delegation.' But, similarly, it stressed the Commission's role in the development of standards that encompasses issuing a mandate, approving the ESOs work programme adopted for the development of the HES, deciding on

[1226] Ibid, para 34.

[1227] Ibid.

[1228] Ibid, para 39.

[1229] Council Directive of 21 December 1998 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products (1998) OJ L 40/12.

[1230] AG Sanchez-Bordona in Case C-613/14, *James Elliott* (n 219), para 55.

the compliance of the draft HES with the mandate, and at last conferring the legal effects on an HES.[1231]

As a final point, the AG argued that activities of a standardisation body, despite their private nature, fall within the scope of EU law as demonstrated by the *Fra.bo* case.[1232] In the latter case, the Court did not hesitate to rule on the compatibility of the activities of the national standardisation body with the free movement rules.

Although the Court was not as daring as the AG in calling the system of co-regulation via EU standardisation 'controlled delegation' in favour of the ESOs, it still came to the conclusion that the HES is a provision of EU Law. The *James Elliott* case is indeed the first to officially recognise that an HES, notwithstanding its private and voluntary nature, forms part of EU law. It is an effect of *James Elliott* that the CJEU was recently asked to interpret the harmonised standard EN 1090-1:2009+A1:2011, attached to the Regulation 305/2011 laying down harmonised conditions for the marketing of construction products. The national Finnish court in this case was not curious about whether the CJEU has jurisdiction to interpret a harmonised standard, but considered this as an already established point and directly requested the interpretation of the harmonised standard.[1233] The CJEU, without hesitation and based on the *James Elliott* case, proceeded with the interpretation of the requested harmonised standard and delivered the ruling.

Although interpretation of an HES under the preliminary ruling procedure before the CJEU is not disputed, ruling on the validity of a harmonised standard in the context of the preliminary ruling is another issue. It is one thing to interpret a harmonised standard in the light of a directive, but it is quite another to rule on its validity. The HESs are parts of EU law and entail legal effects, but they are not products of EU institutions, agencies or offices. As such, it follows that it is highly unlikely that the Court will rule on the validity of the text that is not product of the EU.

However, if asked about the validity of the HESs under the preliminary ruling procedure, the Court would most probably be inclined to modify the question posed and turn it into a question of the validity of the Commission's 'decision'

[1231] Case C-613/14, *James Elliott* (n 60), paras 43–5.

[1232] Case C-171/11, *Fra.bo* (n 60).

[1233] Case C-630/16 *Anstar Oy*, ECLI:EU:C:2017:971.

publishing a reference to the HESs.[1234] Hence, the question about the validity of an HES would be turned into a question of the validity of the Commission's decision attaching this standard to a relevant Directive and granting the status of harmonised standard. The judgment on this matter might entail the invalidation of the status of a harmonised standard, but this would not yield the invalidity of a European standard itself. The result would be that the same European standard cannot be relied on to provide the presumption of compliance with the essential requirements.

7.3.2.3. Some Remarks on the James Elliott Construction Case

The *James Elliott* case certainly marks a significant step towards the clarification of legal aspects of European standardisation; however, at the same time, it leaves us pondering broader constitutional issues. First and foremost, we might ask: Is the regulatory mechanism leading to the development of an HES—'necessary implementing measure'[1235]—forming part of EU law, based on delegation? The Lisbon Treaty provides the procedure for adopting delegated and implementing acts envisaged in Articles 290 and 291 TFEU, respectively. However, these Articles do not present a closed system[1236] of delegated rule-making.

Is an HES the result of lawful delegation of rule-making power in favour of ESOs? Noticeably, the Court, as opposed to the AG, did not use the phrase 'controlled delegation' to describe the relationship between the EU institutions and ESOs. While it is unfair to criticise the Court for not addressing the delegation debate, this case still represents a missed opportunity for reflecting on the lawfulness of delegation in the context of the New Approach, at least *obiter dictum.*

The ECJ has so far not questioned the legality of delegation in the context of European standardisation. One explanation for this could be that the Court has never been asked directly about it. The fact that the ECJ in the *Cremonini*

[1234] The same position is shared by A.V. Waynege and D.R. Amariles, 'A New(ish) Approach to Judicial Review of Standardisation' (2017) 42 (6) *European Law Review* 882–93.

[1235] Case C-613/14, *James Elliott* (n 60), para 43.

[1236] L. Ankersmit, 'The Legal Limits to "Agencification" in the EU: Case C-270/12 *UK v Parliament and Council*', *EU law blog*, <http://europeanlawblog.eu/2014/01/27/the-legal-limits-to-agencification-in-the-eu-case-c-27012-uk-v-parliament-and-council/> accessed 30 November 2018.

case[1237] accepted the use of technical standards for legislative purposes without expressing *obiter dictum* any doubt about its legality is indicative of the Court's indirect support for this regulatory strategy. The *Cremonini* case concerned the Low Voltage Directive, which introduced the reference to the technical standards in the legislative material. In this case, the ECJ urged Italy to comply with the Low Voltage Directive and did not question the legality of referring to technical standards, even *obiter dictum*. Will the judgment in *James Elliott Construction* become a new *Cremonini*? And will it imply the ECJ's support of the new approach strategy which uses the technical standards for the harmonisation of technical requirements for products?

It is also important to repeat, as mentioned in Chapter 5, that the AG used the word 'delegation' only in connection with the word 'controlled'. This is a deliberate choice to make it seem as if the new approach strategy is compatible with the Court's case law. In the rather recent *ESMA* case,[1238] the Court allowed the delegation of discretionary power as long as it was followed by judicial control. This means that the mechanism of legal accountability—the judicial review—can justify the delegation of discretionary powers. Hence, in light of the *ESMA* reasoning, the delegation of rule-making power to the ESOs can be considered lawful only if it is a case of *controlled* delegation.

As to the last point, the ruling in *James Elliott* opens the judicial doors for the HESs at the EU level. Industrial and standardisation circles had been wary of this approach and regarded it as having the effect of opening Pandora's Box.[1239] Judicial involvement in standardisation is seen to undermine the effectiveness of the New Approach directives since it opens the way for each and every manufacturer to challenge each and every standard.[1240] However, opening the ECJ's door to an HES in a preliminary ruling procedure does not automatically establish the ECJ's jurisdiction over HESs in an annulment action too. The less contentious path is to bring an annulment action against the legal instruments connecting standards to the relevant EU Directives. This is the case in particular because the Commission's publication of the reference to an HES in the official journal, according to the Court, carries legal significance.

[1237] Case 815/79 *Criminal Proceedings against Gaetano Cremonini and Maria Luisa Vrankovich,* ECLI:EU:C:1980:273.

[1238] Case C-270/12, *ESMA* (n 635).

[1239] See: Gherardini, 'Harmonised European Standards and the EU Court of Justice' (n 836).

[1240] Schepel, 'The New Approach to New Approach' (n 371).

To conclude, the Court's ruling in the discussed case, in tandem with the *Fra.bo* judgment and in addition to Regulation 1025/2012, breaks down the private and voluntary frame of European standardisation. Opening the ECJ's door to the HESs is a positive development, despite the stated pitfalls of undermining the effectiveness of the new approach directives. Subjecting the HESs to judicial control is a good opportunity to ensure the legal accountability of the process of European standardisation.

7.3.3. Section Conclusion

The effective judicial protection in the EU legal system operates on two levels—namely directly before the CJEU and indirectly through national courts.[1241] The preliminary ruling procedure provides the link between the Courts at both EU and national levels. For their part, the national courts play an important role in the enforcement and application of EU law. In the words of Edward, national courts are 'powerhouses' that provide the CJEU with the crucial cases for the development of the essential principles of EU law.[1242]

Moreover, EU law is an integral part of the national legal system enforceable before the national courts. Similarly, there are no HESs; only the national transpositions of them exist. It is more plausible then that the cases concerning European standardisation would start at the national level and through national courts reach the ECJ under the preliminary ruling procedure. Hence, the national courts 'serve as a gateway of legal accountability.'[1243] Consequently, great importance would be ascribed to the preliminary ruling procedure to ensure the judicial control and legal accountability of European standardisation at the EU level, in the wake of restricted direct access to the CJEU.

Another issue to be addressed is how far judicial review of European standardisation should go. This question is not unique to the judicial review of standardisation, but rather characterises the broader discussion about the Court's role in dealing with scientific and complex technical matters. Below, some seminal cases of the EU risk regulation are discussed so as to envisage the scope of the judicial review and the Court's role in the co-regulation via European standardisation.

[1241] Bogojevic, 'Judicial Protection of Individual Applicants Revisited' (n 1105), 16.

[1242] D. Edwards, 'National Courts: The Powerhouse of Community Law' (2003) 5 *Cambridge Yearbook of European Legal Studies* 1, at 2.

[1243] Harlow and Rawlings, 'Promoting Accountability in Multilevel Governance' (n 52), 561.

7.4. The Scope of Judicial Review of the European Standardisation System—Drawing Lessons from the Case Law on Risk Regulation

In this section, I continue to discuss the role of the EU Courts in ensuring the legal accountability and perfecting the process of standards-making. This inevitably requires considering the ability of courts to review complex technical matters. To do so, I rely on widely known EU cases concerning risk regulation as an illustrative example in mapping the scope of judicial review in the EU context.[1244]

'Co-regulation' via European standardisation can be viewed as a case of utilising technical expertise in highly specialised fields. Quite often risks are regulated by means of standards.[1245] The latter are developed in the expert compiled committees of standards organisations and are products of advisory responsibility of experienced experts in risk management and control.[1246] Public authorities then use these standards to regulate risk or solve technically complex matters.

The scope and limits of the judicial review of the decisions based on scientific evidence or involving technical complexities have been the subject of academic discussions.[1247] Clearly, the judicial resolution of science-based measures entails assessment of not only the legal aspects, but also the underpinning scientific and technical decisions. The EU Courts, like other general courts,[1248] have trouble in dealing with technical complexities in such

[1244] This section gives a non-exclusive list of the cases concerning risk regulation and focuses only on the most discussed cases, the importance of which is widely recognised.

[1245] D. Demortain, *Scientists and the Regulation of Risk: Standardisation Control* (Edward Elgar 2011).

[1246] Ibid.

[1247] See for instance: Fisher, *Risk Regulation and Administrative Constitutionalism* (n 126); A. Alemanno, *Trade in Food: Regulatory and Judicial Approaches in the EU and WTO* (Cameron May 2007); A. Alemanno, 'The Shaping of Risk Regulation by Community Courts' (2008) 18 *Jean Monnet Working Paper*; M.B.A Van Asselt and E. Vos, 'EU Risk Regulation: The Role of Science in Political and Judicial Decision-Making', in H.W. Micklitz, T. Tridimas, and N.A. Patterson (eds), *Risk and EU Law* (Edward Elgar 2015).

[1248] This does not apply to specialised Courts. The latter are not as limited to deal with technical or scientific complexities as general courts. This is because specialised Courts are usually created to deal with a specific and complex area, e.g. environmental courts.

disputes.[1249] And to tackle this conundrum, the Court usually states that '…complex assessments imply a limited power of review on the parts of the Courts of European Union…'.[1250]

This provides reasons to argue against the Court's involvement in the cases of highly technical matters. Schepel, writing a comment on the ECJ's refusal to interpret a European standard in the *Latchways* case,[1251] said:

> Would it (Court of Justice) really corner itself in a position where it has to answer questions concerning 'the validity and interpretation' of harmonized standards? Would it have to come to a judgment whether a requirement to resist 10kN bears a reasonable relation to an 'essential requirement'? Does it even know what a kilo Newton is?[1252]

The above paragraph expresses scepticism about the judicial review of cases of a highly technical nature. True, the EU Courts lack expert knowledge, but this does not remove the need for judicial review of the European standardisation system. Moreover, scientific or technical convolution is not an uncommon part of the CJEU's case law, and the HESs in this regard do not pose any different technical intricacy to deny the Court's intervention.[1253] And if necessary the Court can summon experts on the basis of Article 70 of the rules of procedure of the Court of Justice.[1254] The judicial review of the European standardisation system becomes 'unavoidable' after *James Elliott* and even the ESOs recognise the inevitability of judicial intervention concerning the HESs and they advise the Commission

> …to set-up a structured process of 'technical interpretation on ENs (European Standards)' that will be made available to the Commission, whereby the ESOs provide technical interpretation of hENs (Harmonised European Standards)—

[1249] See C. Foster, *Science and the Precautionary Principle in International Courts and Tribunals: Expert Evidence, Burden of Proof and Finality* (Cambridge University Press 2011); Van Asselt and Vos, 'EU Risk Regulation' (n 1247), 126.

[1250] Case T-257/07, *France v Commission*, ECLI:EU:T:2011:444, para 85; Case C-236/01, *Monsanto*, ECLI:EU:C:2003:431, para 135.

[1251] Case C-185/08, *Latchways* (n 1075).

[1252] Schepel, 'The New Approach to New Approach' (n 371), 532.

[1253] A.V. Wayenberge and D.A. Restrepo, 'James Elliott Construction: A New(ish) Approach to Judicial Review of Standardisation' (2017) 6 *European Law Review* 882.

[1254] Consolidated Version of the Rules of Procedure of the Court of Justice of 25 September 2012 (OJ L 265, 29.9.2012), as amended on 18 June 2013 (OJ L 173, 26.6.2013, 65) and on 19 July 2016 (OJ L 217, 12.8.2016, 69). Ibid.

> through the expertise of their Technical Committees—in support to the European Commission where it is itself involved in a court case brought to the European Court of Justice involving hENs.[1255]

However, this does not resolve the complexity of judicial review in cases concerning technical aspects. The heart of the problem lies in finding an answer to the following question: What role and scope should the judicial review of the European standardisation system have? Advocate General Maduro presented the dilemma of dealing with scientific complexity in the *Dutch Vitamin* case, by asking:

> […] must the Community judicature's review be restricted to addressing the various stages of the decision-making process, or should it assess the quality of scientific analysis conducted or even review the latitude attributed to policy as opposed to science?[1256]

The resolution of this dilemma will depend on the circumstances of the case, as well as on the formulation of invalidity grounds by the parties of the case.[1257] Generally, judicial review concerns the challenge to law, fact, and discretion, and it varies according to whether it is a preliminary ruling procedure under 267 or an annulment action under 263 TFEU.

A paradigmatic question of law concerning the interpretation of legal provisions does not raise any specific problem in the cases related to European standardisation. In contrast, '[j]udicial review of facts, is…multifaceted',[1258] and assessment of facts involving scientific and technical complexity is complicated.

The extent of judicial review of the European standardisation system would depend on the grounds of contestation brought by parties and can equally relate

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[1255] CEN and CENELEC, 'Position on the Consequences of the Judgment of the Court of Justice on *James Elliott Construction Limited v Irish Asphalt Limited*' <https://www.cencenelec.eu/news/policy_opinions/PolicyOpinions/PositionPaper_Consequences_Judgment_Elliott%20case.pdf> accessed 15 September 2017.

[1256] Opinion of AG Maduro in the Case C-41/02, *Commission of the European Communities v Kingdom of the Netherlands*, ECLI:EU:C:2004:520, para 32.

[1257] See A. Alemanno, 'Comment to Case C-77/09, *Gowan Comercio Internacionale Servios Lda v Ministero della Salute*, Judgment of the Court of Justice (Second Chamber) of 22 December 2010' (2011) 48 (4) *Common Market Law Review* 1329.

[1258] X. Groussot, 'Case C-310/04, *Kingdom of Spain v Council of the European Union*, Judgment of the Court (Second Chamber) of 7 September 2006' (2007) 44 *Common Market Law Review* 761, at 777.

to the interpretation of law, review of facts or discretion. It is impossible to imagine all plausible scenarios. However, the most contestable is judicial review of European standardisation that entails the assessment of scientific and technical facts. This could equally be an issue in the cases of challenging the HESs or the Commission's decision to publish a reference to a certain standard.

The issue of judicial review of the European standardisation system forms part of a bigger picture, i.e. the role of EU courts in cases concerning scientific and technical complexities. The Court's case law on these matters, according to Vos,[1259] evolved from a 'relatively tolerant level of scrutiny'[1260] to a court with the role of 'informational catalyst.'[1261]

The early cases are based on a deferential approach in assessing the legality of EU measures.[1262] Even though the EU Courts have developed different standards of review depending on whether it concerned the EU or Member States measures, usually, under both circumstances, the Court was inclined not to get involved in the scientific and complex technical issues underlying the measures.[1263]

[1259] See: E. Vos, 'The European Court of Justice in the Face of Scientific Uncertainty and Complexity', in M. Dawson, B. de Witte, and E. Muir (eds), *Judicial Activism at the European Court of Justice* (Edward Elgar 2013), 142–66.

[1260] F.J. Jacobs, 'The Principle of Proportionality', in E. Ellis (ed.), *The Principles of Proportionality in the Laws of Europe* (Hart Publishing 1999), 4.

[1261] The term is coined by Scott and Sturm, 'Courts as Catalysts: Re-thinking the Judicial Role in New Governance' (n 1069), 565–94.

[1262] The scope of judicial review varies according to the field to which a contested EU measure relates. It is true that the Court's scope of judicial review is limited to the assessment of whether a disputed EU measure is based on manifest error or misuse of power. Such a limited review is pertinent to the fields where EU institutions have wide discretion, e.g. in the field of Common Agricultural Policy. See for instance Case C-189/01, *H. Jippes, Afdeling Groningen van de Nederlandse Vereniging tot Bescherming van Dieren and Afdeling Assen en omstreken van de Nederlandse Vereniging tot Bescherming van Dieren v Minister van Landbouw, Natuurbeheer en Visserij*, ECLI:EU:C:2001:420. According to Groussot, the EU legislature enjoys broad discretion '…in the fields of economic, political and social policies. Those are the areas where the adoption of new rules requires complex and technical assessment…'. See: Groussot, 'Case C-310/04, *Kingdom of Spain v Council of the European Union*, Judgment of the Court (Second Chamber) of 7 September 2006' (n 1258), 776. See also: P. Dąbrowska-Kłosińska, 'Risk, Precaution and Scientific Complexity before the Court of Justice of the European Union', in L. Gruszczynski and W. Werner, *Deference in International Courts and Tribunals: Standard of Review and Margin of Appreciation*, (Oxford Scholarship Online 2014), 194.

[1263] A. Alemanno, 'Science and EU Risk Regulation: The Role of Experts in Decision-Making and Judicial Review', (2007) *Young Researchers Workshop on Science and Law*, ISUFI, Lecce, Italy. Generally speaking, the legality of an action of the EU institution is affected if

> According to the Court's case law, where a Community authority is called upon, in the performance of its duties, to make complex assessments, it enjoys a wide measure of discretion, the exercise of which is subject to limited judicial review in the course of which the Community judicature may not substitute its assessment of the facts for the assessment made by the authority concerned and to verifying, in particular, that the action taken by that authority is not vitiated by a manifest error or a misuse of powers and that it did not clearly exceed the bounds of its discretion.[1264]

Incomplete judicial review of the substance of a measure is compensated by insistence on the procedure,[1265] for instance, the Commission is required to state reasons underpinning its decision, as well as to 'examine carefully and impartially all the relevant aspects of the individual case.'[1266] This means that the Commission cannot rubber stamp scientific advice without careful consideration, or else it would amount to an infringement of the duty 'to examine carefully and impartially all the relevant aspects of the case in point.'[1267]

The *Fedesa* case[1268] is a vivid illustration of the Court's limited judicial review of substantive issues. This case concerned the challenge of the validity of the

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it is found to be 'manifestly inappropriate having regard to the objective which competent institution is seeking to pursue'. See: Case C-331/88, *The Queen v Minister of Agriculture, Fisheries and Food and Secretary of State for Health*, (*Fedesa and other*), ECLI:EU:C:1990:391, para 14. Usually broad discretion of the EU Legislators or the Commission in certain fields leads the Court to use the less restrictive standard of review with respect to measures in those fields.

[1264] Case C-120/97, *Upjohn Ltd v The Licensing Authority established by the Medicines Act 1968 and Others*, ECLI:EU:C:1999:14, para 34; Case C-127/95, *Norbrook Laboratories Ltd v Ministry of Agriculture, Fisheries and Food*, ECLI:EU:C:1998:151, para 90. See also: Case T-177/13, *TestBioTech eV and Others v European Commission*, ECLI:EU:T:2016:736, paras 77–80. Similar passages are found in Case T-257/07, *France v Commission* (n 1250), para 85; and Case C 236/01, *Monsanto* (n 1250), para 135.

[1265] The CJEU reiterated the importance of procedural principles in the cases where the EU institutions enjoy wide discretion and the Court is constrained with limited scope of judicial review. See: Case C-269/90, *Technische Universität München,* ECLI:EU:C:1991:438, para 14; T-413/03*, Shandong Reipu Biochemicals Co. Ltd v Council of the European Union,* ECLI:EU:T:2006:211, para 63; T-177/13, *TestBioTech eV and Others v European Commission,* ECLI:EU:T:2016:736, para 80.

[1266] Case C-269/90*, Technische Universität München* (n 1265), para 14.

[1267] Schepel, *The Constitution of Private Governance* (n 111), 251–2.

[1268] Case C-331/88, *Fedesa* (n 1263).

Second Hormone Directive,[1269] which banned the use of some hormones in livestock farming. The Commission proposed to allow the use of particular hormones for fattening purposes,[1270] on the basis of scientific advice that pointed to no harmful effects to the health of consumers by altering the characteristics of meat via disputed hormones.[1271] Nonetheless, the Parliament and Council strongly opposed this proposal and adopted the Directive banning the use of relevant hormones. The consumers' expectations and anxieties were explicitly referred as the basis of the decision.[1272]

Fedesa—the European Federation for Animal Health, an organisation representing mostly the companies involved in animal health products—challenged the national implementation of the 1988 Hormones Directive and questioned the validity of the Directive itself. Consequently, the case reached the ECJ by means of the preliminary ruling procedure.

Here the Court repeated the usual mantra and limited the investigation to 'whether the measure in question [was] vitiated by a manifest error or misuse of power, or whether the authority in question has manifestly exceeded the limits of discretion.'[1273] In *Fedesa*, the Court did not find it necessary to examine whether the Directive was based on scientific evidence, but rather upheld that in view of divergent public appraisals, the Directive should not have been based purely on scientific data.[1274] The limited reasoning and unwillingness of the Court to engage in the assessment of the factual basis of the Directive is a clear manifestation of the Court's traditional 'light touch' approach, prevalent in the earlier cases.[1275]

It comes as no surprise that the Court's reasoning in *Fedesa* has been regarded as 'lending support to a reliance on broad EU public opinion in *place of*

[1269] Council Directive 88/146/EEC of 17 March 1988 prohibiting the use in livestock farming of certain substances having a hormonal action OJ [1988] L 70/16.

[1270] Commission's proposal to a Council Directive amending Directive 81/602/EEC concerning prohibition of certain substances having a thyrostatic action OJ 1984/C 170/04, Article 1.

[1271] Ibid, Recital 7.

[1272] Council Directive 85/649/EEC of 31 December 1985 prohibiting the use in livestock farming of certain substances having a hormonal action (1985) OJ L 382, Recital 2.

[1273] Case C-331/88, *Fedesa* (n 1263), para 8.

[1274] Ibid, para 10.

[1275] The Court widely used such a limited review in cases of EU legislative acts adopted within the framework of the common agricultural policy. See the analysis of this matter in J. Scott, *On Kith and Kine (and Crustaceans): Trade and Environment in the EU and WTO* (Harvard Law School 2000), 125–67.

science.'[1276] That said, it is quite possible that such an approach was not motivated by a desire to hear public and uphold social conceptions of risk, but rather with no desire to engage with the factual and scientific basis of the Directive.

In contrast to the *Fedesa* line of reasoning, as Craig has rightly noted, the Court in its 'modern'[1277] case law exercises reviewing powers with greater intensity.[1278] The Court now engages with the factual basis underpinning the scientific evidence[1279] and by doing so uses widely 'proceduralist' tests to tackle the increased uncertainty with the realisation that science cannot provide zero-risk situations.[1280]

The obvious manifestation of the Court's nuanced and intense review, touching the substance of scientific evidence, is the *Pfizer* case.[1281] The case concerned the legal action brought by the producer of an antibiotic called 'virginiamycin', against the Council's decision banning the use of that antibiotic in feeding stuff to boost the growth of poultry and pigs. The Council's decision was based on the precautionary principle to tackle a risk of transferring antibiotic resistance from animal to the human.

Usually, Member States adopt measures restricting the functioning of the internal market from the perspective of health, safety, and environmental protection applying the precautionary principle. According to the General Court, the precautionary principle is a general principle of EU law which requires public authorities

> [t]o take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests.[1282] [Also] where there is scientific uncertainty as to the existence or extent of risks to

[1276] C. Hilson, 'Beyond Rationality? Judicial Review and Public Concern in the EU and WTO' (2005) 56 (3) *Northern Ireland Legal Quarterly* 320–41.

[1277] Craig coined the phrase 'modern case law': P. Craig, *EU Administrative Law* (Oxford University Press 2006).

[1278] Ibid, 446–7.

[1279] Dąbrowska-Kłosińska, 'Risk, Precaution and Scientific Complexity before the Court of Justice of the European Union' (n 1262), 194.

[1280] Asselt and Vos, 'EU Risk Regulation' (n 1247), 127.

[1281] Case T-13/99, *Pfizer,* ECLI:EU:T:2002:209.

[1282] See joined cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00, *Artegodan and others v Commission*, ECLI:EU:T:2002:283, paras 183 and 184.

> human health, the precautionary principle allows the institutions to take protective measures without having to wait until the reality and seriousness of those risks become fully apparent…or until the adverse health effects materialise.[1283]

Every New Approach directive that uses standardisation as a tool for harmonisation of technical requirements envisages the 'safeguard clause', which is similar to the precautionary principle.[1284] The CJEU has held, on several occasions, that the safeguard clause is a specific expression of the precautionary principle.[1285] It suffices to say that the safeguard clause allows the Member States to withdraw a defective product from the market or apply restricted measures and notify them to the Commission. One of the bases of triggering this clause and regarding the product defective is a shortcoming in the standards themselves.[1286] In that case, the Commission shall notify the relevant ESO and standardisation committee in order to consider the withdrawal of a standard.[1287]

The similarity between the precautionary principle and safeguard clause makes the *Pfizer* case even more relevant for the purposes of projecting the Court's role in reviewing the European standardisation used for legislative purposes.

Going through the *Pfizer* case, spanning 519 paragraphs, quickly reveals the Court's in-depth analysis as opposed to the short judgment in the *Fedesa* case. The Court required the EU institutions to conduct a detailed risk assessment before applying the precautionary principle. In its turn, the risk assessment, according to the Court, should be carried out '…as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence, [since these are] important procedural

[1283] Case T-257/07, *France v Commission* (n 1250), paras 66–8.

[1284] Even more, for example, Directive 2009/48/EC on the Safety of Toys (n 418) states that 'where the available scientific evidence is insufficient to allow an accurate risk assessment, Member States, when taking measures under this Directive, should apply the precautionary principle, which is a principle of Community law'. (See Recital 38 of that Directive). In the same Directive, the safeguard clause is inscribed in Article 42 allowing Member States taking measures against toys presenting risk.

[1285] See for instance Case C-236/01, *Monsanto Agricoltura Italia* (n 1250), para 110.

[1286] See: Directive 2009/48/EC on the Safety of Toys (n 418), Article 42(5)(b).

[1287] Ibid, Article 43(3).

guarantees whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures.'[1288]

It follows that the scientific evidence, according to the Court, should be judged on the basis of independence, excellence, and transparency. These principles are internal parts of the governance process in the EU and not the inventions of the EU Courts. Therefore, while elaborating on these canons as the toolbox and standard for judicial review, the Court referred to the Commission's communications on the health, food safety, and the precautionary principle that incorporates these principles.[1289]

The Court did not regard scientific evidence as the *per se* legitimate ground for exercising public authority.[1290] This is indeed a right approach, since the scientific advice, although 'scientifically legitimate', has 'neither democratic legitimacy nor political responsibility.'[1291]

In the words of Corkin:

> …The Court ensures risk regulation is based on scientific facts, whilst protecting the institutions' regulatory discretion, vis-à-vis those facts, necessary to deal with the political dimensions. Its deference effectively allocates authority, in the first instance to the scientific community, which is left to bring scientific debates closer to resolution, but ultimately to the institutions that are left to draw regulatory conclusions from debates the scientists could not close down, supervised by the people of Europe to whom they must account.[1292]

Furthermore, the Court not only looked at the quality of the risk assessment, but also insisted that the Commission and the Council had understood 'the ramifications of the scientific question raised and had decided upon a policy in full knowledge of the facts.'[1293] By engaging in the analysis of scientific evidence advanced by the parties, the Court came to the conclusion that the EU institutions were right.

[1288] Case T-13/99, *Pfizer* (n 128a), para 172.

[1289] Ibid, para 159.

[1290] Ibid, para 201.

[1291] Ibid, para 201. See also: A. Alemanno, 'The Shaping of European Risk Regulation by Community Courts', *Jean Monnet Working Paper 18/08*, 59.

[1292] J. Corkin, 'Science, Legitimacy and the Law: Regulating Risk Regulation Judiciously in the European Community' (2008) 33 (3) *European Law Review* 372.

[1293] T-13/99, *Pfizer* (n 1281), para 162.

> …[T]he Court finds that the Community institutions did not exceed the bounds of the discretion conferred on them by the Treaty when they took the view that the various experiments and observations referred to in recitals 19 and 20 to the contested regulation were not mere conjecture but amounted to sufficiently reliable and cogent scientific evidence for them to conclude that there was a proper scientific basis for a possible link between the use of virginiamycin as an additive in feedingstuffs and the development of streptogramin resistance in humans.[1294]

At the same time, the *Pfizer* case is a striking example of law and science speaking two different languages. The Court is unable to understand scientific evidence and this itself should set limits to the Court's role in assessing the merits of scientific data.[1295] Meaning that the Court is not required to substitute one scientific finding with another or decide about the merits of the scientific data.[1296] In other words, the Court should not act as a scientist; rather it should assess whether the process of delivering scientific evidence is organised on the basis of the principles of independence, excellence, and transparency. In addition, the EU institutions adopting a decision on the basis of scientific data should conduct a full and thorough analysis of risk and apply the best scientific information available.

Although the *Pfizer* judgment is a manifestation of the Court's rather nuanced approach in contrast with previous case law, as Vos et al note, regrettably it still fails to apply all the parameters for the revision of the actions of the EU institutions set out at the beginning of the judgment.[1297] Firstly, the Court failed to address whether the institutions based their action on as 'thorough [a] risk assessment as possible', or had taken account of the 'best scientific data available.' Secondly, the Court accepted the only case of potential transfer of antibiotic resistance and an experimental study by Danish authorities to be sufficient evidence to 'adequately back up' the risk.[1298] One would have

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[1294] Ibid, para 389.

[1295] The vivid example of the Court's inability to understand the scientific merits follows from the discussion between the Judge and a scientist during the hearing. See on this: M.B.A. Van Asselt and E. Vos, 'Precautionary Principle and the Uncertainty Paradox' (2006) 19 (4) *Journal of Risk Research* 313.

[1296] Asselt and Vos, 'EU Risk Regulation: The Role of Science in Political and Judicial Decision-Making' (n 1247), 128. The authors warn the Court not to overstep the limits of judicial function, 'by judging also on the science'.

[1297] Asselt and Vos, 'Precautionary Principle and the Uncertainty Paradox' (n 1295).

[1298] T-13/99, *Pfizer* (n 1281), para 144.

expected the Court to have further subjected the advice relayed by the EU institutions to the requirements of excellence, independence, and transparency, as these principles have been declared as having the 'utmost importance' for ensuring that a regulatory decision is underpinned by 'proper scientific' evidence.[1299]

According to Scott et al, the Court as the informational catalyst would strive to ensure that decision-makers have the appropriate type and quality of information to reach a decision which is consistent with legal norms and underpinning objectives.[1300] The seeds of this type of reasoning are clearly visible in *Pfizer*, where the Court laid down the yardstick for assessing the scientific evidence, specifically on the basis of excellence, independence, and transparency. The latter were drawn from the principles circumscribing the governance in health and food safety. Unfortunately, the scientific evidence was not reviewed in the light of these declared requirements, though such an action would be required for the Court to fulfil the catalyst function.[1301]

In short, the difficulties of reviewing administrative actions based on scientific expertise requires a combination of broad discretion accorded to the institutions and limited judicial review.[1302] The Court addresses this conundrum by focusing on the procedure and assessing the adherence to procedural guarantees. The plausibility of scientific evidence is also assessed through procedural guarantees—such as the principles of 'excellence, transparency and independence.'[1303] Proceduralisation of the judicial review does not necessarily mean a limited review. By elaborating procedural guarantees of decision-making that would become the yardstick of judicial review, and assessing the plausibility of scientific evidence, the CJEU indirectly reviews scientific evidence and political choices made by public authorities.[1304]

[1299] Ibid, para 268.

[1300] Scott and Sturm, 'Courts as Catalysts: Re-thinking the Judicial Role in New Governance' (n 1069), 582.

[1301] Ibid.

[1302] Dąbrowska-Kłosińska, 'Risk, Precaution and Scientific Complexity before the Court of Justice of the European Union' (n 1262), 200.

[1303] T-257/07, *France v Commission* (n 1250), paras 73 and 89.

[1304] Dąbrowska-Kłosińska, 'Risk, Precaution and Scientific Complexity before the Court of Justice of the European Union' (n 1262), 205.

In light of the discussed cases, it seems clear that the CJEU might not feel confident in discussing the technical complexities of the cases and would focus instead on the assessment of the procedure leading to the adoption of measures concerning technical and scientific aspects. Certainly, the ESOs are better equipped with the technical expertise to develop the HESs and such knowledge is missing at the judicial level. In the wake of this, the Court would and should be inclined to review the procedure and not the substance of the decisions undertaken by the Commission or the ESOs. This means that although the ground of a judicial review could concern the substance of the HESs and the Commission decisions, the Court most probably would show deference to the expert-dominated rule-making by turning the issue into one of procedural review.[1305] It follows that the Court would rather ask whether the procedure was inclusive and independent from bias, and whether the decisions were based on the best expertise available. The insistence on procedure is important, because the latter can influence the substance of a measure, since 'procedure rationalises…action.'[1306]

To be an effective form of legal accountability, judicial review of the European standardisation system should go beyond mere window-dressing, but not so far as to assess the merits of the standards. The 'process-oriented review' does not imply 'judicial surrender.'[1307] On the contrary, there is a risk that the process-oriented review could be turned into the substantive review.[1308] Indeed, there is an extremely thin line between process-oriented and substantive review.[1309] Then the troubling question is whether the Court would be able to restrain itself from the substantial review of an HES when reviewing the compliance of the latter with the essential requirements of a Directive or the Commission's mandate or when considering the Commission's decision to publish a reference to a pertinent standard.

Finding the golden mean is both necessary and difficult. With these caveats in mind, this section concurs with Scott et al and suggests that the role of

[1305] On semi-procedural judicial review see: I. Bar-Siman-Tov, 'Semi-procedural Judicial Review' (2012) 6 *Legisprudence* 271.

[1306] Mendes, 'The Making of Delegated and Implementing Acts' (n 719).

[1307] K. Lenaerts, 'The European Court of Justice and Process-oriented Review', College of Europe, Research Papers in Law, 1/2012, 16. It is worth remarking that the latter paper discussed the judicial review of the acts of EU institutions.

[1308] J. Öberg, 'The Rise of the Procedural Paradigm: Judicial Review of EU Legislation in Vertical Competence Disputes' (2017) 13 *European Constitutional Law Review* 248, at 256.

[1309] Ibid.

informational catalyst is suitable for the Court reviewing the co-regulation via European standardisation. That is to say, the scope of the judicial review should not go so far as to assess the technical soundness of the HESs. Rather the Court should review the *process* of standardisation or the Commission's decision-making, depending on whether a case concerns the challenge to an HES or the Commission's decision about publication of reference to a standard. In order to develop the yardstick of the judicial review, the Court would be inclined to look at the governance framework of the co-regulation via European standardisation similarly as in the *Pfizer* case. To this end, the principles provided by Regulation 1025/2012—such as openness/participation, non-discrimination/independence from special interest, and transparency—would be fundamental to the process of standardisation and to the judicial review of the European standardisation system.[1310] The procedural review is not necessarily a weak review and has its merits. In particular, it could be a catalyst inviting standardisers to refine the process in light of the principles of participation, transparency, openness, and non-discrimination.[1311] These procedural principles not only legitimise the private rule-making, but also serve the purpose of protecting the parties directly affected by such rule-making.[1312] The procedural standards guiding the process of standards-making could themselves be considered as essential elements for upholding the rule of law.[1313]

Consequently, judicial review of co-regulation via European standardisation is to be confined mainly to the process.[1314] The Court cannot replace one

[1310] Regulation (EU) 1025/201 (n 14), preamble 2, Annex II.

[1311] See on the Court's catalyst role: Scott and Sturm, 'Courts as Catalysts: Re-thinking the Judicial Role in New Governance' (n 1069); M. Dawson, *New Governance and the Transformation of European Law* (n 108), 256–66 (for the general discussion on this topic).

[1312] See: Mendes, 'EU Law and Global Regulatory Regimes' (n 504).

[1313] On the link between rule of law and procedural principle of participation see: Mendes, 'Rule of Law and Participation: A Normative Analysis of Internationalized Rulemaking as Composite Procedure' (n 791).

[1314] The procedure-oriented judicial review could be seen as part of the broader proceduralisation of EU law. Although it is important to note that this thesis has not intended to address the proceduralisation of EU law as manifested in different fields of EU law by inserting the procedural rules in EU secondary legislation, such as in consumer protection or data protection laws. The latter type of proceduralisation of EU law, i.e. introducing the procedural rules in secondary legislation, or harmonising the procedural law in EU, has been addressed widely, see among many others: O. Dubos, 'The Origins of the Proceduralisation of EU Law: A Grey Area of European Federalism' (2015) 8 *Review of European Administrative Law* 7; M. Eliantonio and E. Muir, 'Concluding Thoughts: Legitimacy,

technical standard with another, or judge whether the standard is the best technical solution available. Hence, the judicial review of the European standardisation system would be limited, or, in other words, deferential to the substance as in cases of risk regulation discussed above, and focused rather on the procedure. The Court would most likely conduct the review of the process of standardisation, checking whether this process was structured in a manner as to deliver legitimate and well-thought-out standards. In its turn, procedurally active but substantially deferential judicial review of the European standardisation system has the potential to perform the role of a catalyst for the betterment of the standardisation process.

7.5. Conclusion

In this chapter, I investigated the prospect of judicial review of the European standardisation system and analysed its potential to serve the purpose of making the standardisation process accountable. Firstly, the formal possibility of subjecting European standardisation to judiciary at the EU level was explored, and it was subsequently explained that the direct challenge of the HESs before the CJEU is merely impossible. By contrast, indirect action—preliminary ruling procedure—on the HESs is already established by the case law. I also argued that a more promising route to bring the European standardisation system under the judicial review is through challenging the Commission's 'decision' to publish or withdraw the references to European standards in the official journal.

Beyond the legal constraints of bringing the judicial action against the European standardisation process before the CJEU, the judicial review of the European standardisation system is controversial on a substantive level, mainly for the following two issues: 1) why should a private standardisation, though used for public purposes, be reviewed judicially?; and 2) how should this judicial review be exercised so as to serve the purpose of accountability and not undermine the flexibility of private regulation?

If we accept that the need for judicial review in general cannot be denied, '[t]he availability of judicial review is the necessary condition, psychologically if not logically, of a system of administrative power which purports to be legitimate,

Rationale and Extent of the Incidental Proceduralisation of EU Law' (2015) 8 *Review of European Administrative Law* 177.

or legally valid.'[1315] Then the disagreement is rather around the role of the Court in reviewing technical matters, such as standardisation, and not about the necessity of it. There are noticeable similarities among scholars interested in a judicial review of scientific agencies or the new forms of governance in general. For instance, Scott argues for a Court's role as a catalyst. Fisher proposes the Court's role as a necessary irritant. By reviewing the case law concerning the environmental agencies in the UK, she concludes that actually, '[t]he courts appear to serve as a necessary irritant, encouraging the agency to develop much stronger administrative governance and deliberative decisions on complex science-policy issues'.[1316]

These scholars do not dismiss the judicial review in complex technical and scientific matters. They consider it as a form of legal accountability and admit that the role of courts in cases concerning scientific and technical complexity is neither that of a traditional norm enforcer, nor that of 'amateur policy makers.'[1317] Rather the courts should have a symbiotic relationship with the forms of new governance, and encourage a transparent, open, and motivated decision-making process.

Similarly, I argued that for the judicial review to be an affective mechanism of accountability of the European standardisation system, it should be procedural and aimed at promoting a transparent, participatory, and motivated decision-making process. To do so, the Court should assume a catalyst function, that is to say, it should be an irritant for the ESOs to follow these procedural principles. In so doing, these principles could become the canons of the co-regulation via standardisation, as well as the yardstick of the judicial review. In turn, 'proceduralisation' (could) 'enhance(s) the rationality of decision-making.'[1318]

In framing the Court's role of judicial review of scientific agencies, Fisher suggests:

[1315] L.L. Jaffe, *Judicial Control of Administrative Action*, cited in E. Fisher, P. Pascual, and W. Wagner, 'Rethinking Judicial Review of Expert Agencies' (2014) 93 *Texas Law Review* 1681.

[1316] Fisher et al, 'Rethinking Judicial Review of Expert Agencies' (Ibid), 1681.

[1317] Vos, 'The European Court of Justice in the Face of Scientific Uncertainty and Complexity' (n 1259), 164.

[1318] D. Curtin, H. Hofmann, and J. Mendes, 'Constitutionalising EU Executive Rule-Making Procedures: A Research Agenda' (2013) 19 (1) *European Law Journal* 1, at 4.

> Generalist courts presiding over expert battles—at least when operating at their best—may actually improve the rigor of science-intensive decisions by insisting on agency-generated yardsticks while in turn benefitting from those improved yardsticks in reviewing agency action.[1319]

As Scott et al rightly suggest, the conceptualisation of the Court's role as 'catalyst' would prompt decision-making on expert-required fields, with the involvement of affected parties, to be based on adequate informational grounds and exercised in a deliberative, accountable, and transparent manner.[1320] On the one hand, the decision-makers would be forced to deliver high-quality decisions based on relevant information.[1321] On the other, the Court applying this yardstick can assess whether the decisions are convincing in light of the information provided.[1322]

It goes without saying that this does not mean that judges should become 'amateur scientists',[1323] but rather as Jasanoff suggests:

> Judges need to reject mythical versions of both 'pure science' and 'junk science'. […] Most of all, they need to retain the convictions that courts are not a forum for resolving scientific disputes definitively, but rather for doing justice on a case-by-case basis with the aid of all available scientific knowledge that meets the threshold test of relevance and reliability.[1324]

The danger with the Court's 'over'-involvement in scientific and technical matters stems from the fact that science is not an original domain of the Court. Consequently, other mechanisms of accountability—for example, political mechanisms—have been preferred on occasion.[1325] It was not the intention of

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[1319] Fisher et al, 'Rethinking Judicial Review of Expert Agencies' (n 1316), 1715.

[1320] Scott and Sturm, 'Courts as Catalysts: Rethinking the Judicial Role in New Governance' (n 1069).

[1321] Ibid, 582–3.

[1322] Craig, *EU Administrative Law* (n 110), 479.

[1323] Vos, 'The European Court of Justice in the Face of Scientific Uncertainty and Complexity' (n 1259), 164.

[1324] S. Jasanoff, 'Judging Science: Issues, Assumptions, and Models', in *Report of the 1997 Forum of State Court Judge, The Rooscoe Pound Foundation, Scientific Evidence in Courts: Concepts and Controversies* (1997) 19, cited in Vos, 'The European Court of Justice in the Face of Scientific Uncertainty and Complexity' (n 1259), 164.

[1325] Scott and Sturm opined that preference for political accountability instead of judicial review is sometimes motivated by the impediments to access courts, for instance, where there is no specific 'clearly defined norm with sufficient binding force to acquire the identity of a

this chapter to regard the judicial review as the only form of accountability. Rather I argued that judicial review of the European standardisation system can fulfil the catalyst function—that is, to be informed by the process of governance and facilitate more accountable rule-making.

In sum, the judicial review of the European standardisation system is a necessity, since the HESs regulate vital aspects of health, safety, and environment and are used in EU legislation in this regard, while the HESs purport to represent the general interest. Having agreed that the judicial review is necessary for the legitimacy of the European standardisation system, the next question concerned how the Courts can make the standardisation system more accountable and what role the Courts can play to this end. In response to this, I suggested that the substantially deferential but procedurally active Court could be a catalyst for the improvement and 'perfection' of the process of standards-making and reducing obstructions to the flexibility and effectiveness of the co-regulation via European standardisation.

challengeable legal act under article 230 (264 now) TFEU'. See: Scott and Sturm, 'Courts as Catalysts: Rethinking the Judicial Role in New Governance' (n 1067), 592.

8. Thesis Conclusions

In writing this thesis, I set myself the tasks of positioning the European standardisation system within the EU law framework, and of investigating the possibility of regulation and accountability thereof through EU law and by means of judicial review. This exercise is as ambitious as it is contentious, because it brings standardisation—a field commonly viewed as non-legal—under the legal realm. As explained in Chapter 3, the New Approach strategy enabled the use of the HESs for harmonisation purposes and achieved flexibility in regulation, arguably, by keeping standardisation beyond the reach of law. The upside of this is largely considered to be faster and more flexible harmonisation of technical requirements in the internal market. At the same time, the obvious concern with the European standardisation system is that the standards produced lack democratic legitimacy and are developed through a standard-setting procedure that does not follow the formal principles of lawmaking.[1326]

This is not to argue that standards should not be created in a flexible and quick fashion. This is especially the case with harmonising product requirements in the EU's internal market where the legislative process has been protracted and bogged down in details,[1327] and in instances where sensitive issues, such as health and safety, call for rapid responses. By relying on technical expertise, the process of standard-setting is considered better informed and quicker.[1328] Ultimately, after more than 30 years of the New Approach strategy, the use of standardisation is more relevant than ever in EU sectors of goods and services.

However, accountability of the European standardisation system is required, especially considering the wide application of standards in the European

[1326] See discussion on this in Chapter 1.

[1327] See discussion on this in Chapter 3.

[1328] For instance, changes in Harmonised European Standards do not require changes in EU legislation. The Commission only needs to update the list of references to these standards. By doing so, the EU legislation is in accordance with the current state of the art, without the need to make changes in it through the legislative procedure.

context. The European standards are used in EU legislation and policy documents to regulate public life at large—including the size of the beds we sleep in, the chemical compound of the paint that covers the walls of our houses, the safety of the toys our children play with, and so on. Yet these standards are mostly developed by private parties and exist without external checks. Ultimately, this means that the HESs that are used in EU legislation and that 'translate' the essential requirements concerning health, safety, and environment carry out important regulatory functions and yet remain largely unaccountable. Therefore, the starting premise of this thesis is that since the HESs are used in EU legislation and policy and have great impact on public lives, the need for a legal framework that regulates and accounts for the European standardisation system is undeniable.

In light of the foregoing, I proposed conceiving of EU law as a framework for regulation of the European standardisation system and the judicial review at the EU level as a mechanism for rendering it more accountable and catalysing the perfection of the standardisation process.

To do so, I investigated the possibility of regulation and accountability of the European standardisation system through EU law and by means of judicial review, the results of which are summarised below in three-limbed conclusions.

In the first limb, the findings on mapping the understandings and regulation of the European standardisation system under EU law are discussed. In this section, I discern, present, and contrast the different perspectives on the co-regulation via European standardisation system that entail different legal frameworks for the regulation of the European standardisation system. In the second limb, I discuss conclusions in respect of whether and how the judicial review at the EU level can trigger and ensure the accountability of the European standardisation system and the limitations that the judiciary faces in this regard. Finally, in the third limb, I outline some thoughts about potential future research and a practical way forward with respect to more accountable standardisation.

8.1. Regulation of the European Standardisation System through EU Law

The HESs have been indispensable elements of EU product rules and nowadays they are extensively used in EU legislation and policy documents not only in the products sectors, but also in the services sectors. The adoption of EU Regulation 1025/2012[1329] is a clear signal of the juridification of the European standardisation system, as it is the EU legislative piece that concerns European standardisation and sets out the process for 'mandated' standardisation. However, the same Regulation has left unresolved at least three crucial issues concerning the European standardisation. More precisely, the following areas remain unclear: the legal positioning of the European standardisation system under EU administrative governance; the legal status of the HESs; and the parts of EU law that apply to, regulate, and control the European standardisation system.

The lack of clarity around these issues gives the impression that the European standardisation system falls beyond the scope of EU law. My aim with this thesis has been to clarify this ambivalence and offer an 'Ariadne's thread' to guide through the complex issues concerning understanding, regulation, and accountability of the European standardisation system under EU law.

As a reminder to the reader, in discussing the issue of regulation and accountability of the European standardisation system, I have reviewed relevant EU official documents and CJEU case law, and examined the co-regulation via European standardisation through the lens of EU constitutional and economic laws. In doing so, I uncovered and presented three different understandings of the co-regulation via European standardisation that entail different legal frameworks for the regulation and accountability thereof. I have 'labelled' these views as the 'Official View', EU constitutional and economic law perspectives. Consequently, my argument is that despite the fact that understandings of the co-regulation via European standardisation differ—entailing different legal frameworks—all these perspectives indicate that the European standardisation system falls under the scope of EU law. Moreover, since the HESs perform important functions that affect public life, legal accountability of this system is imperative. Hence, I suggest that the application of EU law to, and the judicial supervision of, the European standardisation system should be geared towards triggering and ensuring an

[1329] Regulation (EU) 1025/2012 (n 14).

accountable standardisation process and enhancing the overall legitimacy of the system.

8.1.1. Three Different Perspectives and One Desideratum —Accountable Standardisation

In this section, I summarise the findings on the understanding and regulation of the European standardisation system under EU law, conveyed as: the 'Official View'; EU constitutional law perspective; and EU economic law perspective. As mentioned, although the understandings and regulation of the European standardisation system differ following these distinct perspectives, the commonality among them is to recognise that the 'mandated' standardisation affects areas of public concern and, as such, implicitly admit the need for an accountable standardisation process.

At the outset of the thesis, it was noted that the cooperation between the Commission and the ESOs is not explicitly based on any EU Treaty provision.[1330] It is not clear whether the Commission's request for an HES is based on delegation of rule-making power and it is also unclear what, if not delegation, provides the EU's legal basis to 'entrust' the private ESOs with the task of developing EU implementing measures in the form of HESs. Moreover, the legal status of the ESOs and HESs is not addressed in EU law. Traditionally, EU institutions, and especially the Commission, used the formally voluntary status of the HESs to argue against the need for any regulation of the European standardisation system. However, the de facto mandatory status of the HESs and their important regulatory functions fed into another narrative of requiring stricter legal control of the HESs, as well as portraying them as rules of delegated rule-making.

I started the investigation of the understanding and regulation of the European standardisation system under EU law by unravelling the 'Official View' on the interplay between the HESs and the New Approach directives. To do so, I investigated the EU binding acts,[1331] the official documents, including those of

[1330] One could say that after Regulation 1025/2012 requesting the development of HESs from the ESOs is regulated by Article 10 of that Regulation. The latter Article sets out the procedure for 'mandating' an HES. The Regulation itself is based on Article 114 TFEU. Does this mean that the Commission's mandate is also based on the same Treaty Article? This is not clear.

[1331] The Council resolution of 7 May 1985, officially introducing the New Approach and providing the general framework for it (n 14). See also: The New Legislative Framework

the Commission, various documents on the implementation of product rules,[1332] as well as the New Approach and the New Legislative frameworks.[1333]

The findings in this regard showed that the New Approach was originally designed to operate on a clear distinction between law and standards. Hence, formally the HESs do not replace the law, but rather 'translate the essential requirements into detailed technical requirements.'[1334] The EU officials and the ESOs have long insisted on keeping the 'bright line',[1335] at least formally, between the Directives and the HESs, as well as between the tasks of legislators and private bodies. This request for separation sought to insulate standardisation from the reach of law. The delegation of rule-making powers to the ESOs or concentration of public-like tasks within the ESOs was formally—that is, on paper—avoided. However, it is one thing to separate the EU directives and the HESs on paper and another to make it work in practice.

Having examined the Directive on the Safety of Toys[1336] as an example of the New Approach strategy, I argued that the HESs are de facto mandatory, regulate important aspects of public life, and are closely linked to the essential requirements of the Toys directive.

More importantly, the current developments at the EU legislative and judicial level suggest that there is a clear shift away from the 'officially' supported separation between EU directives and the HESs. To be more precise, the EU 'Official View' tilts towards bringing the European standardisation system under the EU law framework. This is demonstrated by the adoption of Regulation 1025/2012 that strengthens procedural and functional links

consisting of the Regulation 764/2008 of 9 July 2008 (n 322), Regulation No 765/2008 (n 54) and Decision 768/2008 (n 54).

[1332] Various documents from the Commission on the implementation of product rules, e.g. Commission, 'Blue Guide' (n 401); The Commission, 'Vademecum on European Standardisation in Support of Union Legislation and Policies and others' of 27 October 2015 (staff working document, in three parts) 205 final. Although these documents do not have binding force, they help to understand the complex system of the New Legislative Framework, as well as present important legal value in the absence of the judicial decisions.

[1333] The New Legislative Framework builds on the New Approach and complements it with all necessary elements for conformity assessment, accreditation and market surveillance. The New Legislative Framework consists of Regulation (EC)765/2008 (n 54) and Decision 768/2008 (n 54).

[1334] Commission, 'Blue Guide' (n 401), 49.

[1335] The term used by Schepel in 'Private Regulators in Law' (n 56).

[1336] The (EC) Directive 2009/48/EC on the Safety of Toys (n 418).

between the HESs and EU law. In addition, now the cooperation between the Commission and the ESOs is governed by EU public law —the Regulation on European standardisation.[1337]

In the same vein, the recent *James Elliott* case is evidence of the changes taking place within the 'Official View'. In the latter case, the CJEU was not convinced by the 'official separation' of the EU directives and the HESs, nor was the formally voluntary status of the HESs enough to leave the HES at stake beyond the Court's jurisdiction. Rather the Court pointed out that the HES entails legal effects[1338] and hence forms part of EU law. In the Court's words, the HES is not merely a voluntary, private rule, but is rather

> …a necessary implementation measure…initiated, managed and monitored by the Commission and its legal effects are subject to prior publication by the Commission of its references in the 'C' series of the *Official Journal of the European Union.*[1339]

It follows that the HESs perform important regulatory functions and, as such, entail legal effects for business operators, national standards bodies, and Member States too.[1340] The Commission and the ESOs also admit that standardisation 'has an effect on a number of areas of public concern'.[1341] Indeed, the HESs fulfil public functions by encoding technical translations of legal requirements on matters such as health, safety, and environment. As such, not only do they provide technical translations, but they also replace legislative requirements and determine vital aspects of public concern. Since the legislative requirements cannot always be made in the requisite detail, the standards fill the vacuum left by the legislator and, thus, are necessary complements to the EU legislation. This pierces the private and voluntary nature of standardisation and moves it into the public realm.

The 'Official View', as discussed above, has progressed from denying any legal status of the HESs to recognising their legal impact and declaring them as forming part of EU law. In the wake of this development, I argued that the

[1337] Regulation (EU) 1025/2012 (n 14).

[1338] Case C-613/14, *James Elliott* (n 60), para 42.

[1339] Ibid, para 43.

[1340] See discussion of the legal effects of the HESs in Chapter 5 of this thesis.

[1341] General guidelines for the cooperation between CEN, CENELEC and ETSI and the Commission (n 458).

'Delegation Framework' for understanding and regulation of the European standardisation system has acquired greater strength.

In EU constitutional and administrative law scholarship, the development of the HESs in response to the Commission's mandates has been viewed as delegated rule-making for some time.[1342] This is not surprising. In a democratic legal order, only the government can adopt legal acts or delegate this function to non-governmental bodies, meaning that if the HESs are acts with legal effects that regulate important aspects of public life, then the authority adopting such acts belongs to governmental bodies and private bodies—such as the ESOs—can acquire this power through delegation of rule-making power from the EU institutions. The more recent support of the 'Delegation' view is the AG's Opinion in *James Elliott*, where the AG described the European standardisation system as 'legislative delegation in favour of private standardisation bod[ies]'.[1343]

After examining in detail the European standardisation system through the lens of EU constitutional law, I argued that HESs resemble EU implementing acts and are developed by virtue of delegation of rule-making power from the Commission to the ESOs. In its turn, the EU constitutional law prescribes the conditions for the lawfulness of delegation of rule-making powers to private bodies such as the ESOs, requiring administrative and judicial control of delegated powers.

In juxtaposing the 'Delegation Framework' and the 'Official View', it becomes clear that these two perspectives provide contrasting understandings of the European standardisation system, entailing different legal frameworks for the regulation thereof. Originally, the 'Official View' regarded the European standardisation system as purely private activity and kept it beyond the reach of EU public law. However, recently, within the 'Official View', there is recognition of important functions that the European standardisation performs, as well as an acceptance of the fact that HESs entail legal effects, all of which points to the need for an accountable standardisation system. Under the 'Delegation Framework', on the other hand, ESOs are explicitly seen as

[1342] In the legal scholarship, the use of European standardisation for legislative purposes is regarded commonly as a system of delegated rule-making. See for instance: Gestel and Micklitz, 'European Integration through standardization' (n 63), 151, 177; Hofmann et al, 'Rule-Making by Private Parties' (n 63). For a general conceptualisation of delegation to private parties see: Donnelly, *Delegation of Governmental Power to Private Parties* (n 63); for a contradicting view see: Joerges et al, 'The Law's Problems' (n 49).

[1343] AG in the Case C-613/14, *James Elliott* (n 219), para 55.

exercising public tasks when developing the HESs based on the Commission's mandate, for which EU constitutional law requires administrative and judicial control.

There can be no doubt that accepting the 'Delegation Framework' provided by EU constitutional law has certain implications for the European standardisation system. Firstly, it equates standardisation to lawmaking. This could lead to a fading of the differences drawn between functional and procedural aspects of standard-setting and lawmaking. It also overlooks the pertinent features of the 'new regulatory' strategy—that is, using non-binding rules for legislative purposes,[1344] where strict legal control over the ESOs could threaten the flexibility of the standardisation process. Perhaps as a result of this fear, there has been an official 'silence' in respect of regarding the cooperation between the EU institutions and the ESOs as delegated rule-making.

Although the above-discussed two perspectives—the 'Official View' and EU constitutional law perspective—provide different legal frameworks, that is, 'Separation' or 'Delegation' frameworks, respectively, for understanding and regulation of the European standardisation system, they both do so by operating through the public-private distinction. In other words, they place the European standardisation system *ex-ante* under the public or the private domain and view it, respectively, as either private or delegated (public) rule-making. Ultimately, these two views provide private or public law frameworks for regulation of the European standardisation system.

This dichotomy, however, is overly simplistic. The co-regulation via European standardisation involves both public and private actors. The standardisation itself is private regulation, consisting of experts and business operators, who agree on voluntary standards. However, the development of the HESs is conditioned, triggered, and financed by the Commission. Also, these standards are later used for regulating purposes—e.g. harmonising legislative requirements concerning health, safety, and the environment. Therefore, this co-regulatory strategy swings between the public and private spheres[1345] and has a hybrid public-private nature. In this light, subjecting the European

[1344] The similar argument about the judicial review against the forms of new governance generally and conceptualising it through traditional constitutionalism terms is found in Dawson, *New Governance and Transformation of European Law* (n 108), 76.

[1345] See: Glenn, 'Transnational Legal Thought' (n 68), 76. See also: Cafaggi, 'Private Regulation in European Private Law' (n 68). These sources treat standards as a continuum running from non-law to law.

standardisation system to either a completely private or an entirely public law framework is wrong. Instead a fluid (flexible) framework is required.

As opposed to the 'Official View' or the EU constitutional law perspective, seen through the EU economic law lens, European standardisation is neither purely private nor public activity and could be subject to both the internal market and the competition law provisions. Moreover, the EU economic law has potential to deal with a mixed regulatory strategy in the form of European standardisation without following a strict public-private distinction. In particular, the free movement and competition law provisions would focus on the effects of the HES rather than the abstract legal nature of these standards. However, EU economic law most probably would be deferential to the substance of standards and would focus mainly on standardisation process.

In view of the above, the EU economic law offers a more flexible framework for regulation of the European standardisation system. While some fear that the strict constitutional and administrative control of the European standardisation system would undermine the efficiency of this co-regulatory strategy, the EU economic law, by contrast, offers a 'gentle tool' with which to discipline the standardisation process, i.e. to make it 'public-regarding', without undermining its private nature. More specifically, the EU economic law can facilitate the adherence to the procedural principles of good governance such as openness, transparency, and non-discrimination in the standard-setting process, while pursuing the primary goal of market integration.[1346] In short, the EU economic law could be a back door through which the catalyst Court[1347] can introduce constitutional principles of good governance and facilitate the adoption of safe, non-discriminatory, and legitimate standards.

To conclude, my general argument based on the investigation summarised above is that the co-regulation via European standardisation is not beyond the reach of law as the 'Official View' on the New Approach had originally hoped. The current developments at the legislative and judicial level bring the European standardisation system in the ambit of EU law and stress the need to unfold the legal framework applicable thereto. Unpacking the legal framework of the European standardisation system is a complex exercise since there are different perspectives on European standardisation used in EU legislation and policy, entailing different legal ambits. However, all three perspectives

[1346] See discussion on this in Chapter 6 of this thesis.

[1347] For more discussion on this see Chapters 6 and 7 of this thesis.

analysed herein indicate that the European standardisation system could fall under the scope of regulation of EU law, pointing to the need for legal accountability thereof and ultimately opening the door for judicial review. In its turn, judicial review, as a mechanism of legal accountability, could be a catalyst for an inclusive, open, and transparent standards-setting process, the discussion of which follows below.

8.2. Judicial Review as a Catalyst for an Accountable Standardisation Process

In this section, I summarise the findings on judicial review of the European standardisation system at the EU level. This includes discussions of whether the European standardisation system can be subject to judicial review under EU law and what role the CJEU should have so as to ensure an accountable standardisation process.

The Courts form the cornerstone of legal accountability as their role is one of a watchdog of administrative and governmental actions, protecting individual freedoms from encroachment by the State[1348] by disciplining excessive State powers, sustaining the rule of law, and safeguarding public interests.[1349] At the EU level, the Court, in addition to all these, is a guardian of the institutional balance and ensures that each institution acts within the powers conferred on it. By doing so, the Courts at the EU level are not only guardians of the allocation of competences between States and the EU; they can also protect the rights of private parties from excessive actions of the EU institutions and guard the institutional balance.

Consequently, judicial review is an indispensable mechanism of legal accountability in all democratic legal orders, including the EU. Hence, I have regarded the judicial review as a mechanism of accountability that encompasses arrangements of holding a subject, i.e. standardisation, accountable before a set forum—in our case, the CJEU.[1350] In other words, I

[1348] See: C. Harlow and R. Rawlings, 'Red and Green Light Theories', in *Law and Administration* (3rd edn, Cambridge University Press 2009).

[1349] Elliott, 'Judicial Review's Scope, Foundations and Purposes: Joining the Dots' (n 944), 80.

[1350] See discussion on this in Chapter 1.

conceptualised judicial review at the EU level as a mechanism for holding the standardisation system accountable by means of law.

The topic of judicial review of the European standardisation system is controversial for several reasons. First and foremost, it is disputable whether the HESs could be the subject of judicial review in the context of preliminary ruling and annulment procedures. This uncertainty is owed to the fact that the legal status of the ESOs and the HESs under EU law is not clearly set.

In addition, the case law to guide us on this matter is extremely limited and until recently has been non-existent. But, as mentioned many times throughout this thesis, the Court in *James Elliott* established that the HES is an EU implementing measure falling under the jurisdiction of the ECJ in the context of preliminary ruling procedure. After *James Elliott*, one can safely assume that the ECJ has jurisdiction to interpret the HESs, especially since the Court has confirmed this finding in the recent *Anstar Oy* case[1351] which marks the second occasion where the ECJ has delivered the preliminary ruling interpreting the HES.

Although it took some time before the HESs knocked on the ECJ's door for a preliminary ruling, it is now clear that the ECJ will not shut the door on the interpretation of the HESs. But a similar claim cannot be made concerning the ECJ's jurisdiction to rule on the validity of the HESs in the context of preliminary ruling procedure. It is one thing to interpret a harmonised standard in the light of a directive and another to rule on its validity. The HESs are part of EU law and entail legal effects, but they are not developed by the EU institutions, agencies or offices. As such, it follows that it is highly unlikely that the Court will rule on the validity of a text that is not product of the EU.

Also, the prospect of the HESs forming the basis of an annulment action is not promising, since the ECJ did not state in *James Elliott* that the HESs are acts of the EU institutions, bodies or agencies. Although the prospect of challenging the legality of the HESs directly before the CJEU is unlikely, I have argued that the European standardisation system can still be indirectly reviewed in annulment actions. This could be done by challenging the legality of the Commission's 'decisions' concerning the publication or maintenance of references to the HESs. The Commission's 'decisions' on the publication of the references to the HESs or concerning *ex-ante* or *ex-post* control of the publication of references are the acts reviewable under annulment action.[1352]

[1351] C-630/16, *Anstar Oy*, ECLI:EU:C:2017:971.

[1352] See discussion on this matter in Chapter 7 of this thesis.

Challenging the Commission's 'decisions' opens the possibility to indirectly question the legality of the standardisation process or to contest the products of this process, i.e. the HESs. However, it should be made clear that by annulling the Commission's 'decisions' to publish the references to HESs, the Court could cancel only the legal effects granted over the HESs, but would not invalidate the standards themselves. Meaning that an HES would continue to exist as a European standard, but it would be deprived of the status of the harmonised standard.

After sketching out the possible ways of 'subjecting' the European standardisation system to the judicial control in the context of preliminary and annulment actions, I have addressed the second contentious issue, namely why the judicial review should extend to and encompass the European standardisation system.

Nobody would dispute the judicial supervision of governmental powers, but it is quite different to put forward a proposal of overseeing private, expert bodies—such as the ESOs—through the EU judiciary. The latter incorporates layers of controversy concerning whether the Courts could be used to limit private regulation in the form of standardisation and what consequences this could have on private regulation.

In this thesis, I have put forward three reasons in support of the judicial control of the European standardisation process. First and foremost, the regulatory power of the HESs is extremely important. These privately developed technical rules are important pillars in achieving the safety goals of the New Approach directives and regulating vital aspects of public life—such as safety, health, and environment. The influential power of European standardisation, not only over the market players, but also on our daily lives, requires judicial oversight of the process of standardisation. The danger that these privately developed standards could be designed to meet the wishes of business circles to the detriment of public interest increases the need for an accountable standardisation process.

Second, the lack of democratic control—i.e. entrusting the non-elected private standards bodies with the task of developing rules for legislative purposes—heightens the need for the third-party control in the form of judicial review. Finally, the weak participation of societal groups in the standard-setting process makes a retrospective mechanism of accountability—i.e. judicial review—necessary.

Consequently, my argument has been that the absolute denial of the judicial review of the standardisation system is not viable; rather the controversy is

owed to what role the Courts could have so as not to over-formalise the standardisation process and also efficiently deal with technical complexities.

It is true that the shift to the New Approach was rationalised on the grounds that it offers a speedier harmonisation of technical requirements through non-binding technical standards. According to the Commission, the preference for softer rules for the implementation of EU law is based on the rationale that legal rules 'would create excessive rigidity and risk slowing the adoption of particular policies.'[1353] It is then obvious that judicialisation is not in favour with the original presuppositions of using technical standards.[1354] The judicial review could entail more far-reaching legal effects for these standards than originally desired; it could also undermine the flexibility of this private rule-making by formalising it, and make it more burdensome and protracted. Hence, the non-binding technical standards and judicial review 'make an uncomfortable pair.'[1355]

More broadly, the juxtaposition of judicial review and efficiency of European standardisation has at its heart an unresolved dilemma of accountability threatening the independence of private regulators, such as the ESOs. However, one has to keep in mind that independence without accountability is like freedom without responsibility. Nevertheless, the relationship between accountability and efficiency of standardisation is usually presented as a catch-22. This unresolved dilemma is due to the assumption that the relationship between accountability and efficiency of private rule-making is a zero-sum game. It is hard to concur with the latter assumption, because an accountable and judicially reviewed standardisation process has greater legitimacy, leading to wider acceptance of the technical standards. Eventually, accountability could even contribute to the effectiveness of standardisation.

Accountability of the European standardisation system should not be sacrificed on the 'altar' of flexibility. It is far less obvious how the requirements of openness, transparency, and inclusiveness of the standardisation process, or judicial oversight in some instances, could remove the benefits of using private

[1353] Commission, 'European Governance: A White Paper' (n 37).

[1354] E. Mak, 'The Judicial Review of Regulatory Instruments: The Least Imperfect Alternative' (2012) 6 *Legisprudence* 301, at 316.

[1355] Popelier, 'Preliminary Comments on the Role of Courts as Regulatory Watchdogs' (n 1201), 259. This piece discusses judicial review of soft law instruments but does not discuss standardisation specifically. However, since the HESs share some similarities with soft law, such as being non-binding, that are used for regulatory purposes, the reasoning developed in this article is applicable to the case of standardisation too.

standards for legislative purposes and not achieve quite the contrary—namely ensuring the 'public-regarding' and legitimate standardisation.

The next major concern about the judicial review of the European standardisation system is that the Courts lack the ability to assess the rules that require expert knowledge and are technically complex. It is common to view lawyers as inappropriate arbiters to engage with an interpretation of technical rules.

The above-described objections, as I have argued, should not be understood as requiring an absolute denial of judicial review of standardisation process. Rather they demand to address the issue of what role and scope the judicial review can have in the context of standardisation. Consequently, I have put forward the argument for a procedure-oriented judicial review.[1356] In view of the flexibility offered by the hybrid public-private European standardisation system, judicial review as a mechanism of legal accountability should be limited to holding the public leg, i.e. the Commission, fully legally accountable for the legal effects of the HESs. In reviewing the private leg, i.e. the European standardisation process within the ESOs, the judicial review has to focus on the process of standard-setting and its adherence to the procedural principles of good governance.

By focusing on the process of standardisation, the Court, on the one hand, would be able to show deference to the expert-made rules, and on the other, could scrutinise the process that is a guarantor of the quality of the substance of a measure. The adherence to the procedural principles—such as participation, openness, and transparency—during standard-setting ensures good outcomes, i.e. the HESs that respect public interests.

These procedural principles should be seen not only as the yardstick of judicial review of the standardisation process, but also as the canons of the co-regulation via standardisation. In other words, openness, inclusiveness, and transparency are a proxy for well-reasoned, free from bias standardisation. To achieve this, the role of the Court in reviewing the European standardisation system is to be like that of a catalyst, promoting participation, enhancing the technical expertise, and urging for a transparent and accountable standardisation process. In this manner, the judicial review could be a guardian of an inclusive, transparent, and eventually accountable standardisation process. One should stress that the more successfully the EU Courts improve the standardisation process through the procedural activism, the more

[1356] See discussion on this in Chapter 7.

deferential they should become to the substance of the products of standardisation, i.e. the HESs.[1357]

The benefit of the procedure-oriented judicial review is that it avoids judgments on the substance of a technical rule while, at the same time, it can induce development of better standards by instigating a more accountable standardisation process. However, as outlined, the instances in which standardisation would become the subject of judicial review at the EU level are limited, hence the consideration on the other ways of ensuring accountability of the standardisation system beyond the traditional legal mechanism of judicial review should follow.

8.3. A Way Forward

> Accountability can be too little, too great, but rarely just right.[1358]

As a final thought here, I put forward considerations for possible areas of future research and set out practical ways of enhancing *ex-ante* accountability of the European standardisation system.

One cannot expect that regulation through EU law and retrospective mechanism of accountability in the form of judicial review can entirely resolve the concerns of legitimacy and accountability faced by the co-regulation via European standardisation. Neither EU law nor the judicial review is a magic bullet in this regard. This requires recognition of the limits of my thesis and reflecting on the paths forward.

Generally, judicial review is able only to deal with a small amount of cases. The private rule-making in the form of standardisation does not easily become a subject of the legal challenge unlike State measures that are usually monitored by means of administrative law. This in itself is not necessarily a bad thing, considering that the extreme juridification of standardisation might be destructive—for example, reducing the benefits of using private rule-making instead of legislative instruments. At the same time, this specificity of private rule-making in the form of European standardisation should not be an argument to entirely exclude the role of law. With the increased reliance on

[1357] Something similar is suggested by Corkin about the procedural activism of the Court in 'disciplining' remote lawmaking. See: Corkin, 'Refining Relative Authority' (n 148).

[1358] Black, 'Calling Regulators to Account' (n 1081).

privately developed standards for regulatory purposes, I have argued that there would be increased instances of intersection between law and standards occurring in the Court's room.

Another limitation concerning the judicial review at the EU level as a mechanism of legal accountability stems from the peculiarity of a preliminary ruling procedure. The latter procedure is largely dependent on the discretion of a national judge, in other words it is a national judge which initiates the preliminary ruling procedure and is not obliged to do so, unless it is a court against whose decision there is no legal remedy.

It is important to note that the traditional mechanism of legal accountability, such as judicial review, when used in the case of European standardisation, has to reflect on the specificities of this private rule-making, and display caution so as not to undermine its efficiency. This requires a case-by-case approach and the Courts taking into consideration, in each case, the risks and benefits of using the HESs. In addition, the Courts have to cope with limited technical knowledge and refrain from assessing the substance of technical standards. Therefore, my first suggestion is that much research is needed to substantially rethink the role of Courts in reviewing the new form of governance inter alia the co-regulation via European standardisation. The main challenge here is to find a role for the Court that ensures legal control over the private standardisation process and, at the same time, preserve its advantages.[1359]

The second consideration concerns the *ex-ante* mechanisms of accountability. Although the role I have ascribed to the EU Courts was one of triggering *ex-ante* accountability, the judicial review can be triggered only post factum and is a retrospective mechanism of accountability. No matter how successful the *ex-post* mechanism of accountability in the form of judicial review is, it cannot replace *ex-ante* accountability. And the other way around is also true—*ex-ante* means of accountability cannot substitute or replace the judicial review.[1360]

[1359] Dawson, *New Governance and Transformation of European Law* (n 108), 92. He makes the same statement with regard to new governance in the form of the Open Method of Coordination.

[1360] Harlow and Rawlings, 'Promoting Accountability in Multilevel Governance' (n 52), 544. However, the European Parliament's resolution urging for more *ex-ante* control of the standardisation process and ignoring the Court's judgment in Case 613/14, *James Elliott* (n 60), seems to suggest that an *ex-ante* mechanism is sufficient. This view is not shared by this thesis, nor by 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' (2017) *EU Law blog* <http://europeanlawblog.eu/2017/09/25/the-eps-

One of the strongest objections against the privately developed standards is that they lack democratic legitimacy and uphold technocracy. In its recent resolution on European standards, the European Parliament highlights the accountability gaps in the standardisation process. It stresses the lack of democratic oversight and, to this end, recommends the Commission to ensure the Parliament's involvement in policymaking initiatives regarding standardisation, in addition to requiring the strengthening of *ex-ante* mechanisms of control.[1361] The issue then to be addressed in future research concerning the European standardisation system is that of finding a mechanism of accountability that enhances its democratic legitimacy. To this end, this thesis suggests focusing on *ex-ante* remedies in the form of procedural principles of openness, transparency, and inclusiveness so as to ensure a 'public-regarding' standardisation process.

Finally, besides the need for future research, I put forward several practical ways of enhancing the *ex-ante* accountability within the European standardisation system. It is true that there is still much to be improved in terms of the transparency, inclusiveness, and openness of the standardisation process. While EU Regulation 1025/2012 brought some positive changes regarding the inclusiveness and transparency of the standardisation process, as noted earlier, a closer look at them reveals that these are just marginal developments. In particular, the representation of societal stakeholders in the standardisation process is fairly weak. These stakeholders do not enjoy formal legal status in the standardisation process, i.e. cannot vote for the draft version of a standard and only have 'the opportunity' to submit comments.[1362]

Improving this is not the sole task of the EU legislator. It is also the responsibility of the Commission and standardisers. To do so, all actors involved in the European standardisation process should assume responsibility and become accountable to each other. For instance, the Commission should draft a mandate clearly and within the limits of its competences. In its turn, the EU Parliament should oversee the limits of the Commission's competence in a similar manner as in cases of delegated acts.[1363] When it comes to the

european-standards-resolution-in-the-wake-of-james-elliott-construction-carving-ever-more-holes-in-pandoras-box/> Accessed 30 September 2017.

[1361] EU Parliament, 'Resolutions of 4 July 2017 on European Standards for the 21st Century (2016/2274 (INI))', recommendations 45, 46, 69, 71–3.

[1362] 'European Integration through standardization' (n 63), 179.

[1363] See Article 291 TFEU that envisages the procedure to oversee the Commission's delegated acts by the EU Parliament.

precision and clarity of the mandate, this should be assessed by the ESOs and societal stakeholders.

The process of standards-drafting should also be improved, i.e. made more transparent and inclusive, allowing active participation with the clear legal status to interested public authorities, the Commission representatives, and societal groups. Such multi-layered yet non-hierarchical *ex-ante* control could achieve the equilibrium, as Hettne suggests, where 'no one controls the standardisation body, yet the body is "under control".'[1364] It should not be forgotten that the effectiveness of such an *ex-ante* mechanism should be subject to retrospective control in the form of judicial supervision.

Finally, reflecting on the form of promoting such *ex-ante* accountability, I suggest doing so through self-imposed commitments by signing, for instance, memoranda between the EU institutions, ESOs, and societal stakeholders engaged with standardisation.

In sum, a way forward should be geared towards improving the *ex-ante* accountability, so as to strengthen the 'voice' of society, through participation of societal stakeholders, as well as public authorities in the process of standardisation, rendering the latter 'public-regarding'. This requires combined efforts at the policy level, in the standard-setting community, as well as in research circles.

[1364] Hettne, 'Standards, Technical Barriers and EU Internal Market Rules' (n 273).

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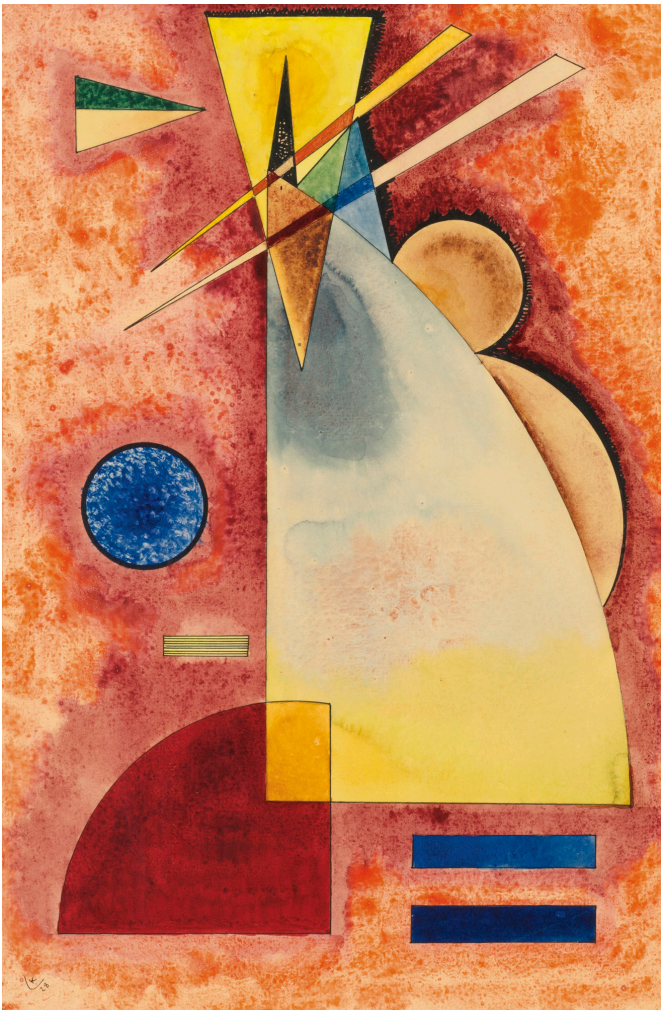

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