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# *European Judiciary and Harmonised Standards: Which Intersection?*

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## **ABSTRACT**

In a seminal article, Harm Schepel has highlighted that the conditions exist for a multiplication of the points of contact between the ‘New Approach’ to technical harmonisation and the European judiciary through Art. 263 TFEU. Recent normative and judicial developments have confirmed his finding, and a more incisive role of the Court of Justice in technical standardisation is therefore suggested. Despite that, this paper argues that there are very confined possibilities for a meaningful judicial oversight over harmonised standards – i.e. private and not-binding technical standards endorsed by the Commission – for several and concurrent reasons. The argument builds around five hypotheses, each of them considering a different group of applicants potentially empowered to take an action for annulment against the decision of the Commission to publish a harmonised standard. Moreover, some general issues will be highlighted, which question the aptitude of the Court to deal with technical standardisation matters. Normative, judicial and empirical elements will be analysed, which point in one direction: it is unlikely that successful actions for annulment will be taken against the decisions of the Commission granting legal effects to harmonised standards.

**KEYWORDS:** Technical Harmonisation, Standardisation, Harmonised Standards, New Approach, Court of Justice.

# *European Judiciary and Harmonised Standards: Which Intersection?*

Pierluigi Cuccuru\*

## **1. Introduction**

The debate about the ‘New Approach to technical harmonisation and standards’<sup>1</sup> has been enriched by recent normative and judicial developments. The novelties have directly affected the relationships between the European Standardisation System and the EU legal order, simultaneously re-shaping the interplay between technical standards and the European judiciary. This paper considers the concrete possibilities for judicial engagement in standard-setting dynamics through the remedy envisaged by Art. 263 TFEU. As a premise, the paper outlines the essential features of European standardisation, focusing on harmonised standards (HSs) (section 2). It then touches upon the point of contact between Art. 263 TFEU and the New Approach to standardisation (section 3). The paper agrees with Harm Schepel that Regulation (EU) 1025/2012<sup>2</sup> urges the Commission to take upon itself the responsibility of the HSs it approves, and that accordingly discontent market players might take an action for annulment against the publication of HSs.<sup>3</sup> Although this *juridification* of the New Approach apparently multiplies litigation in standardisation-related matters, the paper argues that judicial scrutiny over publication of HSs will be marginal in practice, for many and heterogeneous reasons. These reasons will be presented considering five groups of prospective applicants who can possibly file an action for annulment against the publication of HSs. In addition, some general elements will be briefly taken into account, that question the substantive power as well as the technical ability of the Court to engage in a meaningful assessment of HSs contents (section 4). Some concluding remarks will follow (section 5).

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1 See for a thorough discussion H. Schepel, *The Constitution of Private Governance: Product Standards in the Regulation of Integrating Markets* (Hart, 2005). See also J. Falke, ‘Achievements and Unresolved Problems of European Standardisation: The Ingenuity of Practice and the Queries of Lawyers’, in C. Joerges, K. Ladeur, E. Vos (eds), *Integrating Scientific Expertise into Regulatory Decision-Making: National Traditions and European Innovations*, (Nomos, 1997), 187.

2 Regulation (EU) 1025/2012 on European standardisation [2012] OJ L316/12.

<sup>3</sup> H. Schepel, ‘The New Approach to the New Approach: The Juridification of Harmonized Standards in EU Law’ (2013) 20 (4) *Maastricht Journal of European and Comparative Law* 521, 528ff.

## 2. The Paths of European Technical Harmonisation. Essentials of the *New Approach*.

Still in the aftermath of *Cassis de Dijon*<sup>4</sup> the completion of the Internal Market was hindered by a substantial lack of harmonisation of products technical specifications across Member States (MSs). On the one hand, national authorities could maintain diverging technical regulations - invoking, for instance, the derogatory regime of the free movement of goods.<sup>5</sup> On the other hand, the National Standardisation Bodies (NSBs) of each Member State issued voluntary technical standards for application in the domestic market, which escaped free movement law. In this context, the mutual recognition principle<sup>6</sup> could not stand alone, but ought to be complemented by proactive harmonisation policies purposely tackling public and private technical barriers to intra-Community trade.

Up until the eighties, the EU legislature took the entire burden of harmonisation upon itself.<sup>7</sup> This *modus operandi* – the so-called ‘Old Approach’ - turned to be extremely time-consuming, inefficient and incapable to cope with technological developments.<sup>8</sup> At the same time, it lacked a strategy for tackling national private standards, which thus remained a major obstacle for the completion of the Internal Market.

Building on the notification system introduced by the 1983 Information Directive,<sup>9</sup> the Council Resolution on the ‘New Approach to Technical Harmonisation and Standards’ marked a

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4 Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* (*Cassis de Dijon*), ECLI:EU:C:1979:42.

5 Express derogations to free movement of goods are established by Art. 36 TFEU. Implicit derogations are justified by overriding reasons of general interests, according to the ‘mandatory requirements’ doctrine developed by the Court since *Cassis de Dijon*, *ibid.*, para. 8.

6 As introduced by the Court in *Cassis de Dijon* (n 4 *supra*), and further developed in the case law. See, recently, Case C-525/14 *Commission v Czech Republic*, ECLI:EU:C:2016:714, para. 35, and Case C-481/12 *UAB "Juvelta" v VĮ "Lietuvos prabavimo rūmai"*, ECLI:EU:C:2014:11, para. 17.

7 Very detailed directives were issued by the Council on proposal of the Commission, within the framework provided by Art. 100 EEC. These directives addressed single hazards or regulated specific products.

8 See J. Pelkmans, ‘The New Approach to Technical Harmonization and Standardization’, (1987) 25(3) *Journal of Common Market Studies* 249.

9 Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations [1983] OJ L109/8. Art. 8 therein requires technical regulations and private standards to be notified to the Commission, which in turn evaluates their impact on the Internal Market. Any objection triggers a standstill timeframe for national authorities to amend the contested act. This mechanism has been strengthened by the Court, that stated that failure to comply with the notification duty makes national technical regulations inapplicable to individuals. See Case C-194/94 *CIA Security International SA v Signalson SA and Securitel SPRL*, ECLI:EU:C:1996:172, para.48. See also Case C-443/98 *Unilever Italia SpA v Central Food SpA*,

radical regulatory shift in European standardisation policies.<sup>10</sup> The New Approach envisages an innovative public-private partnership between the EU and the EFTA countries on the one side, and recognised private standardisation bodies on the other side – the European Standardisation Organisations (ESOs). The ESOs are non-profit associations gathering the NSBs and relevant stakeholders around a European standardisation agenda. They are currently three, each of them operating in a different scientific domain<sup>11</sup>: the *Comité européen de normalisation* (CEN), the *Comité européen de normalisation électrotechnique* (CENELEC), and the *European Telecommunications Standards Institute* (ETSI).<sup>12</sup> Although amended over the years,<sup>13</sup> the New Approach has maintained its basic characteristics and has been finally systematised by Regulation (EU) 1025/2012.<sup>14</sup>

With the New Approach, the legislature limits itself to establishing the essential mandatory requirements – usually addressing safety, health, environmental and consumer’s protection issues - for the marketing of homogeneous categories of products.<sup>15</sup> The mandatory requirements are complemented by non-mandatory technical standards drafted by the ESOs upon request of the Commission, which are eventually referenced in the Official Journal of the EU as ‘harmonised standards’ (HSs) (see figure 1).

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ECLI:EU:C:2000:496, para. 49, and Case C-159/00 *Sapod Audic v Eco-Emballages SA*, ECLI:EU:C:2002:343, paras. 50-51. After many amendments, the 1983 Information Directive was repealed by Directive 98/34/EC [1998] OJ L204/1, and later by Regulation (EU) 1025/2012 (n 2 *supra*) and Directive (EU) 2015/1535 [2015] OJ L241/1.

<sup>10</sup> Council Resolution of 7 May 1985 on a New Approach to Technical Harmonisation and Standards [1985] OJ C136/1, which attached a ‘Model Directive’ (Annex II). The essential features of the New Approach were also sketched by the Commission’s ‘White Paper on the Completion of the Internal Market’ of 14 June 1985, COM (85) 310 final.

<sup>11</sup> For an overview of ESOs’ functioning, see M. P. Egan, *Constructing a European Market. Standards, Regulation and Governance* (OUP, 2001), 133 ff.

<sup>12</sup> Because of its peculiarities, the case of ETSI will not be considered in the present analysis. Any reference to the ESOs should be hereinafter intended as considering only CEN and CENELEC.

<sup>13</sup> Especially by the package of measures which goes under the name of ‘New Legislative Framework’ for product marketing of 9 July 2008, consisting of Regulation (EC) 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products [2008] OJ L218/30, Decision 768/2008/EC on a common framework for the marketing of products [2008] OJ L218/82, and Regulation (EC) 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State [2008] OJ L218/21. See in this regard Commission’s ‘Blue Guide on the Implementation of EU Products Rules’ [2016] OJ C272/1, para. 1.2.

<sup>14</sup> Moreover, the terms of the partnership are established by a cooperation agreement signed by the EU/EFTA and the ESOs. See Commission’s ‘General Guidelines for the Cooperation between CEN, CENELEC and ETSI and the EC and EFTA’ (2003/C 91/04), [2003] OJ C91/7, para. 3. The first version of these guidelines dates to 1984.

<sup>15</sup> As New Approach legislation is drafted under Art. 114 TFEU, the essential requirements set a maximum threshold, which MSs cannot overcome by imposing more restrictive criteria to products. See Case C-112/97 *Commission v Italy*, ECLI:EU:C:1999:168, para. 32. See also Case C-103/01 *Commission v Germany*, ECLI:EU:C:2003:301, para. 43. On the concept of ‘essential requirement’ see more in detail the Commission’s ‘Blue Guide on the Implementation of EU Products Rules’ (n 13 *supra*), para. 4.

Should a standardisation request be made, ‘national standardisation bodies shall not take any action which could prejudice the harmonisation intended’.<sup>16</sup> Once the request is accepted by the pertinent ESO, experts appointed by the NSBs and the interested stakeholders meet in a myriad of technical committees and working groups, and start the standardisation process. With the entry into force of Regulation (EU) 1025/2012, the pursuing of societal and small businesses’ interests in European standard-setting has been ‘institutionalised’ and entrusted to pan-European stakeholder associations selected on the basis of Annex III of the Regulation. The Annex III stakeholders enjoy participatory rights in ESOs’ activities and receive direct funding from the Commission.<sup>17</sup>

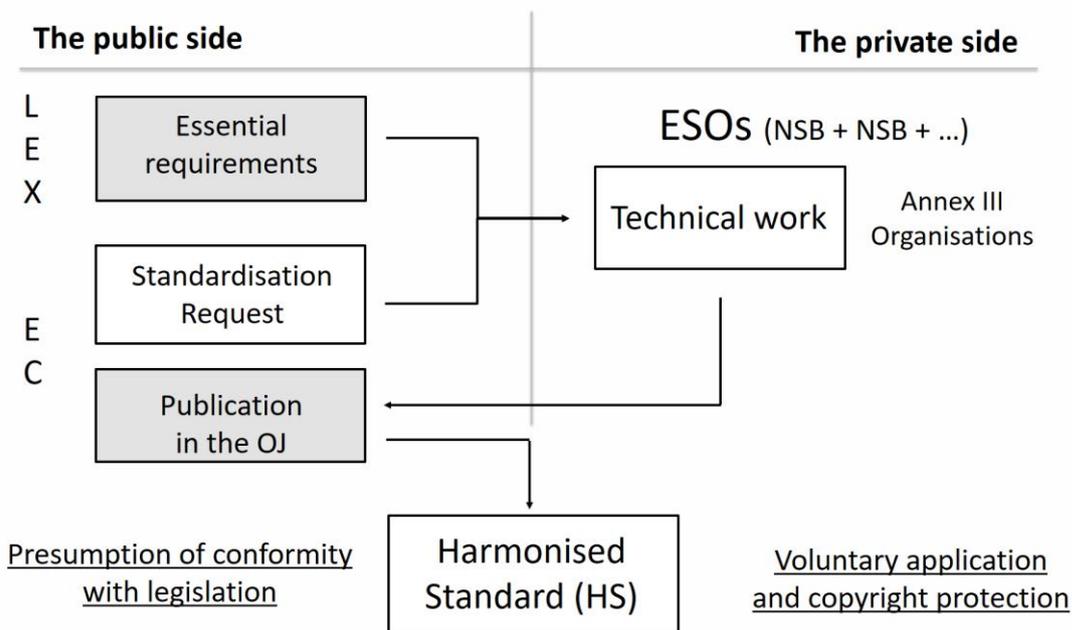


Figure 1. Development of a harmonised standard under the New Approach.

At the end of a consensus-based process, which balances the positions of the different NSBs and ideally ensures a fair trade-off among the interests of industry and society,<sup>18</sup>a preliminary draft

16 Art. 3(6), Reg. (EU) 1025/2012.

17 The so-called ‘Annex III organisations’ are currently four: the ANEC – The European Consumer Voice in Standardisation, the ECOS – European Environmental Citizens Organisation for Standardisation, the ETUC – European Trade Union Confederation, and the SBS – Small Business Standards.

18 The development of standards follows the so-called ‘Code of Good Practice’ established by the Annex III to the 1995 WTO Agreement on Technical Barriers to Trade (TBT Agreement). The Code has been further implemented by the 2000 TBT Committee’s ‘Decision on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the TBT Agreement’. It should be noted that consensus does not necessarily mean unanimity. Actually, CEN and CENELEC decision-making process combines qualified majority and weighted vote. In the case of CEN, the voting system mirrors the mechanism adopted by the

of the standard is released for public inquiry. Comments are taken into account before a final version of the standard is submitted to the technical committee for formal voting. If approved, the NSBs are obliged to translate the new European standard, of which they hold the copyright, and to sell it at the domestic level.<sup>19</sup> Although the ESOs also autonomously develop European standards considering industry's needs, only standards drafted upon Commission's request are referenced in the C series of the Official Journal of the EU as 'harmonised standards'.

Despite the reference in the OJ, HSs remain private measures of voluntary application. However, their publication carries along substantive legal effects. Goods manufactured in accordance to HSs are indeed presumed to fulfil the essential legislative requirements, and as such enjoy free movement within the Internal market. This presumption precludes MSs from imposing additional constraints on the trade of goods complying with HSs,<sup>20</sup> if not with a special administrative procedure. As they offer an easy way to unlock the Internal market, HSs have a persuasive effect on manufacturers, and accordingly exert a significant (regulatory) influence on both private<sup>21</sup> and public<sup>22</sup> markets.

### **3. The Role of the Court of Justice within the New Approach: Actions for Annulment against the Publication of Harmonised Standards.**

The ESOs are private non-profit associations that dialogue with the EU institutions through a mix of normative<sup>23</sup> and contractual<sup>24</sup> tools. The standards they issue – harmonised or not – do not have in any case the force of law, nor directly belong to the institutional architecture of the

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Council of the EU. See in this regard clause 6.1 and 6.2, CEN-CENELEC Internal Regulation, Part 2 – Common Rules for Standardization Work, 2017.

<sup>19</sup> See clause 10.3, CEN-CENELEC Internal Regulation, Part 2.

<sup>20</sup> See Art. 3(6), Reg (EU) 1025/2012. See also Case C-100/13 *Commission v Germany*, ECLI:EU:C:2014:2293, paras. 55 – 56.

<sup>21</sup> This is particularly evident with regard to product safety legislation, especially considered in its interplay with product liability rules. The General Product Safety Directive – but also the sector-specific safety legislation - presumes goods manufactured in accordance to HSs to be safe – see Art. 3(2), second limb, Directive 2001/95/CE on general product safety. Although compliance with HSs does not exclude *per se* liability for defective products - Art. 6(1), Directive 85/374/EEC -, non-compliance would likely imply it. In this respect see H. Schepel, *The Constitution of Private Governance* (n 1 *supra*), 348ff.

<sup>22</sup> HSs indeed 'constitute a common and transparent reference for public procurement' - see Commission's 'General Guidelines' (n 14 *supra*) para. 3 - and are a preferential means for buyers to establish the characteristics of products, and for bidders to prove the technical fitness of their bid. See Art. 42 (3), Dir. 2014/24/EU on public procurement [2014] OJ L94/65.

<sup>23</sup> Reg. (EU) 1025/2012.

<sup>24</sup> See the Cooperation Agreement between EU/EFTA and the ESOs (n 14 *supra*). Moreover, the request and acceptance of a standardisation work item amounts, essentially, to contractual relationship.

Union. As such, for a long time no direct involvement of European institutions in the development of HSs was deemed to exist. Consistently, the publication of the HSs in the Official Journal was considered to serve merely informative purposes.<sup>25</sup> ‘public authorities have committed themselves to not insisting on approving the technical content of such standards; no positive decision is required by which authorities approve the standards, even if previously such technical aspects were subject of regulation.’<sup>26</sup> Lacking any legally meaningful point of connection between European standardisation and the EU legal order, the role of the judiciary within the New Approach framework has been rather marginal,<sup>27</sup> raising some concerns about the accountability of the ESOs.

Nevertheless, the situation has rapidly evolved in the wake of recent normative and judicially-driven developments, which narrow the gap between HSs and European judiciary.

Art. 11(1), Reg. (EU) 1025/2012 establishes an administrative mechanism – the so-called ‘formal objection procedure’ - through which MSs and the European Parliament may challenge the conformity of HSs with the legislative framework they implement.<sup>28</sup> It states that the Commission shall *decide* whether the contested HS fulfils the essential requirements it must comply with.<sup>29</sup> At the same time, Art. 10 of the Regulation urges the Commission to proceed to publication only ‘[w]here a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation’.

As Harm Schepel has brilliantly pointed out, the aforementioned provisions acknowledge that the Commission shall exert a control on the merit of the standards it publishes, thus taking upon itself the responsibility of HSs. Coupled with the more permissive *locus standi* criteria envisaged by the Treaty of Lisbon for challenging the validity of regulatory acts,<sup>30</sup> Schepel has

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25 See explicitly Art. 5, third limb, Directive 73/23/EEC: ‘[f]or purposes of information the list of harmonized standards and their references shall be published in the Official Journal of the European Communities’.

26 Report from the Commission to the Council and the European Parliament ‘Efficiency and Accountability in European Standardisation under the New Approach’, COM (1998) 291 final, para. 6.

27 At national level too technical standards are rather difficult to be brought before a tribunal. For a comparative assessment on the legal status of technical standards in EU and EFTA countries, as well as their relevance before national judges, see H. Schepel and Josef Falke, *Legal Aspects of Standardization in the Member States of the EC and EFTA – Volume 1: Comparative Report* (2000), 68ff, 131ff and 181ff. The interplay between standards and domestic courts is also touched upon in R. van Gestel and H-W. Micklitz, ‘European Integration Through Standardization: How Judicial Review is Breaking Down the Club House of Private Standardization Bodies’ (2013)50 (1) *Common Market Law Review* 145.

28 The formal objection procedure has the same purpose of the so-called safeguard clause embedded in the New Approach directives, which replaces. See Art. 26(1), Reg. (UE) 1025/2012.

29 Similar wording had Art. R9(1), Annex I, Decision 768/2008/EC (n 13 *supra*)

30 See Art. 263(4) TFEU.

foreseen the substantial possibility to bring standardisation activities before the Court through an action for annulment against the publication of the HSs.<sup>31</sup>

He was right. Recent developments in the standardisation arena confirms that the ‘specifications delivered by the ESOs in support of Union legislation can never be automatically regarded as complying with the initial request, as this is a *political responsibility*.’<sup>32</sup> The remaining uncertainties in this regard – if any – have been cleared by the Court in two recent rulings. In the seminal *James Elliott* decision, which opens the doors to interpretative preliminary rulings on HSs, the Court has acknowledged the pivotal role played by the Commission in technical standardisation by stating that the publication of HSs is necessarily subjected to ‘confirmation by that institution of the compliance of the final drafts of the harmonised standards’.<sup>33</sup> In addition, the *Global Garden* case has unequivocally confirmed that the decisions to publish a HSs constitute ‘legal acts against which an action for annulment may be brought’.<sup>34</sup> In this context, it is evident that an intersection exists between the New Approach and the remedy provided by Art. 263 TFEU, in the form of an action for annulment against the publication of HSs. This judicial channel is autonomous of - and complementary to – the widening of the Court’s jurisdiction envisaged by *James Elliott*. There, the Court has claimed its jurisdiction over HSs when it comes to their interpretation in proceedings under Art. 267 TFEU, on the basis that HSs are substantially part of EU law.<sup>35</sup> However, at the same time the Court has observed that the ESOs ‘cannot be described as institutions, bodies, offices or agencies of the Union’,<sup>36</sup> i.e. those institutional players whose acts could be brought before the Court for a validity assessment. It follows that questioning the publication of the HSs through Art. 263 TFEU remains the only means for asking the Court – indirectly, via the review of the Commission’s assessment - an appraisal of the ‘goodness’ of HSs.

Nonetheless, the conditions for exploiting this judicial channel are still underinvestigated.<sup>37</sup> Considering several – and concurrent – factors, it is suggested that the space for direct actions

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31 H. Schepel, ‘*The New Approach to the New Approach*’ (n 3 *supra*) 528ff.

32 Commission’s “Vademecum on European Standardisation in support of Union Legislation and policies, Part 1 - Role of the Commission's Standardisation requests to the European standardisation organisations” of 27 October 2015, SWD(2015) 205 final, 9. Emphasis added.

33 Case C-613/14 *James Elliott Construction Limited v Irish Asphalt Limited*, ECLI: EU:C:2016:821, para. 45. See the case-note by A. Volpato, ‘The Harmonized Standards before the ECJ: *James Elliott Construction*’ (2017) 54(2) *Common Market Law Review* 591.

34 Case T-474/15 *Global Garden Products Italy SpA v Commission*, ECLI:EU:T:2017:36, para. 60.

35 Case *James Elliott* (n 33 *supra*), para. 40

36 *ibid.*, para. 34.

37 However, see the analysis by 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 European and Comparative Law* 323.

for annulment against the publication of HSs might remain limited in the practice. Taking Schepel's findings as a starting point, the argument builds around five relevant hypotheses, each of them focusing on a different group of applicants who might have interest to take action against the publication of HSs: Member States; National Standardisation Bodies; Annex III stakeholders; European Standardisation Organisations; manufactures. For each category, it is argued that there are normative, judicial and/or empirical elements which limit the likelihood that the Court will intervene in standardisation dynamics through Art. 263 TFEU.

(i) Member States.

Most of the challenges against HSs stem from MSs that consider some technical specifications to be inconsistent with the essential requirements they should fulfil. In theory, this friction can lead to an action for annulment against the publication of the contested HS. However, a specific dispute-settlement tool exists, which deals with issues of conformity raised by a MS: The formal objection procedure, established under Art. 11 of Regulation (EU) 1025/2012,<sup>38</sup> allows MSs and the European Parliament to question the conformity of a published or to-be published HS with the legislative essential requirements it should comply with. Non-conformity claims are jointly processed by the Commission and a committee of experts.<sup>39</sup> At the end of this administrative procedure, the Commission can either (i) maintain, (ii) maintain with restrictions or (iii) withdraw an existing HS, as well as (iv) publish, (v) publish with restrictions or (vi) reject a proposed standard.

Arguably, this dispute resolution channel pre-empts – at least at first instance - recourse to judicial remedies. First, this is implicit in the special and *ad hoc* character of the mechanism. Second, this is suggested by the *Cremonini* judgment, which deals with the 'safeguard procedure', the ancestor of the formal objection procedure. *Cremonini* stresses that the safeguard procedure '[...] takes place between the Commission and the Member States and [...] precludes in this connexion any action by the judicial authority as such'.<sup>40</sup> It follows that '[...] since a judicial authority is not empowered, where there is a presumption of conformity, to adopt any measure restricting the free movement of the goods, such a step may be taken only in

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<sup>38</sup> See n 28 *supra*.

<sup>39</sup> The expert committee is established under Art. 22, Reg (EU) 182/2011 on 'comitology procedure'. The opinion of the committee assumes different significance depending on whether the formal objection has been promoted before or after the publication of the contested HS. In the former case, committee opinion is advisory; in the latter, binding. See Art. 11 (4) (5), Reg (EU) 1025/2012.

<sup>40</sup> Case C-815-79 *Criminal proceedings against Gaetano Cremonini and Maria Luisa Vrankovich*, ECLI:EU:C:1980:273, para. 11.

*the context of [the safeguard procedure] by a national administrative authority acting on behalf of the Member State*'.<sup>41</sup> The reasoning can be extended to the formal objection procedure: judges cannot take any measure restricting the free movement of goods that boast a presumption of conformity with legislation, as this is a matter for national authorities to deal with through the established procedure.<sup>42</sup> Actions for annulment against the publication of HSs are therefore precluded to MSs – which could at most resort to Art. 263 TFEU as an ‘appellate tool’ against the conclusive act of the formal objection procedure. This finding is directly corroborated by empirical evidences. Since the entry into force of Regulation (EU) 1025/2012, 6 formal objections have been decided,<sup>43</sup> whereas no judicial action for the annulment of the publication of HSs has been filed.

## (ii) National Standardisation Bodies.

As the Treaty of Lisbon has softened the standing requirements under Art. 263(4), natural and legal persons could challenge the validity of EU regulatory acts – i.e. ‘all acts of general application apart from legislative acts’<sup>44</sup> – provided that they are of direct concern to them<sup>45</sup> and do not entail implementing measures.<sup>46</sup> Upon these premises, Schepel has suggested that an action for annulment against the publication (and denial of publication?) of HSs<sup>47</sup> might be

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41 *ibid.*, para 13.

42 See H. Schepel, *The Constitution of Private Governance* (n 1 *supra*), 236.

43 See <[http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/formal-objections\\_en](http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/formal-objections_en)> (last accessed on 1 November 2017).

44 See Case T-18/10 *Inuit Tapiriit Kanatami and others v Parliament and Council* (Inuit I), ECLI:EU:T:2011:419, para. 56, reiterated in appeal by Case C-583/11P *Inuit I*, ECLI:EU:C:2013:625, paras. 60-61. See also Case T-262/10 *Microban International Ltd and Microban (Europe) Ltd v Commission*, ECLI:EU:T:2011:623, para. 21.

45 The direct concern test requires the challenged measure to directly affect the legal position of the applicant, as well as its effects to depend automatically from an act of the Union, with no discretion left to the implementing authorities. Any application of the measure – if any – should be purely mechanical and preserve the consequentiality between the contested act and the harmful circumstances. See, for instance, Joined Cases C-445/07 and C-455/07 *Commission v Ente per le Ville Vesuviane*, ECLI:EU:C:2009:529, para. 45; Case C-486/01 *Front National v Parliament*, ECLI:EU:C:2004:394, para. 34.

46 Should intermediate measures exist, claims should be directed against the implementing act, either under Art. 263 TFEU – where implementation is attributable to the Union’s institutions – or through domestic litigation - with or without the need for a preliminary reference under Art. 267 TFEU, where implementation takes place at national level. See Case C-274/12 P *Telefónica SA v European Commission*, ECLI:EU:C:2013:852, para.28; Case C-456/13 P T & L Sugars Ltd and Sidul Açúcares, Unipessoal Lda v Commission, ECLI:EU:C:2015:284, para. 31. On that point see C. Buchanan and L. Bolzonello, ‘Towards a Definition of ‘Implementing Measures’ under Article 263, Paragraph 4, TFEU’ (2015) 6(4) *European Journal of Risk Regulation* 671. See also M. Rhimes, ‘The EU Courts Stand Their Ground: Why are the Standing Rules for Direct Actions still so Restrictive?’ (2016) 9(1) *European Journal of Legal Studies* 103, 115 ff.

47 Standardisation requests and the publication of standards are issued in the exercise of the implementing powers of the Commission, and as such should be considered ‘regulatory act’. See Case *Microban* (n 44 *supra*), paras. 22

taken by a wide variety of non-privileged applicants under Art. 263 TFEU.<sup>48</sup> This would include outvoted NSB, the Annex III organisations, the ESOs, and eventually also the manufacturers. Although it is agreed that some theoretical support in this sense might exist in some circumstances, it is at the same time suggested that the chance for meaningful judicial actions under Art. 263 TFEU will be remote.

The NSBs are obliged to adopt the European standard – including HSs - at domestic level, as well as to refrain from issuing or maintaining any other competing national standard. This primarily follows from the associative link between each NSB and the ESOs,<sup>49</sup> and can as well be inferred from the wording of Regulation (EU) 1025/2012, when it comes to HSs.<sup>50</sup> Of course, it may happen that a NSB disagrees with a HS it has the duty to implement. However, this can hardly amount to situation ‘of direct concern’ which the outvoted NSB could bring before the Court through an action for annulment against the publication of a HS. Indeed, as just mentioned, the obligation to implement European standards at national level is primarily established by CEN-CENELEC internal rules, to which the publication of the Commission nothing adds. Against this context, NSBs would rather resort to the specific CEN/CENELEC appeal procedure that members – i.e. NSBs - and partner organisations may trigger for settling internal conflicts of technical or administrative nature.<sup>51</sup> An appeal may be lodged ‘[...] against any action, or inaction, on the part of a Technical Committee, other body, or officer of CEN/CENELEC if [a] member or partner organization considers that such action or inaction is not in accordance with the Statutes/Articles of Association or CEN/CENELEC Internal Regulations, or otherwise with the aims of CEN/CENELEC or not in the best interests of the European market or such public concerns as safety, health or the environment.’<sup>52</sup> Arguably, the broad formulation of the grounds of appeal is able to filter most of the complaints of the NSBs. Moreover, it would be in any case reasonable to suppose that where an outvoted NSB – no

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to 25. Moreover, Case T-264/03 *Schmoldt and Others v Commission*, ECLI:EU:T:2004:157, paras. 93-94 acknowledges that the decision refusing to withdraw a HS is ‘of general application by virtue of its nature and scope’. Indirectly, that should be reasonably true for the decision to publish a HS as well. At the same time, although HSs are implemented at national level by NSBs, their legal effects stem directly from the publication. No intermediate measure therefore exists.

48 H. Schepel, ‘The New Approach to the New Approach’ (n 33 *supra*), 531.

49 See para. 3.2, CEN-CENELEC Guide 12 ‘The Concept of Affiliation with CEN and CENELEC’, 4<sup>th</sup> ed., 2016. See also clause 10.3, CEN-CENELEC Internal Regulation, Part 2.

50 Art. 3(6), Reg (EU) 1025/2012.

51 See clause 7, CEN-CENELEC Internal Regulation, Part 2 – Common Rules for Standardization Work, 2017.

52 *ibid*, clause 7.1.

matter whether or not embedded in the institutional architecture of a MS<sup>53</sup> - harbors doubts about the goodness of a HS, it would in the first place signal its concerns to national authorities, that would possibly file a formal objection under Art. 11, Regulation (EU) 1025/2012. That leads back to hypothesis (i) above, with no exercise of judicial power involved.

(iii) Annex III organisations.

The so-called ‘Annex III organisations’ promote societal and SMEs’ interests within the European Standardisation System. As such, they can participate in the standard-setting process of the ESOs, without voting rights.

In abstract, a HS issued in breach of the participatory rights of Annex III organisations may be published in the OJ, without such a defect being detected by the Commission. The publication therefore becomes of direct concern for the stakeholders whose prerogatives have been disregarded, and could as such be potentially relevant under Art. 263 TFEU.

However, it is suggested that this hypothesis has little chance to materialize in the practice. On the one hand, a formal breach of the Annex III organisations’ rights can hardly emerge. On the other hand, if a conflict does arise, this latter is unlikely to be settled in a courtroom.

Underrepresentation and asymmetries between industry and societal stakeholders represent the most recurrent complaints of Annex III organisations.<sup>54</sup> Nevertheless, no formal breach of the Annex III organisations’ participatory rights has been denounced so far. This arguably depends on two elements. First, the current normative framework does not leave much space for a breach of participatory rights to occur, as it fails to clearly shape these rights in the first place. Regulation (EU) 1025/2012 gives an extremely vague definition of the prerogatives granted to Annex III organisations,<sup>55</sup> only establishing the right to be consulted at the very preliminary

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53 The NSBs may have different legal status. A mixed approach – private status with public mandate/oversight – is prevalent, but public (e.g. Belgium) or substantially private (e.g. United Kingdom) NSBs do exist. See H. Schepel and J. Falke (n 27 *supra*) 62ff.

54 See, for instance, the EXPRESS report ‘Standardization for a Competitive and Innovative Europe: A Vision for 2020’ (2010), paras. 3.4 and 3.6.3; European Parliament resolution on the future of European Standardisation, 2010, para. 9; Commission’s ‘Report on the implementation of Regulation (EU) 1025/2012 from 2013 to 2015’, COM(2016) 212 final, 4. Societal stakeholders’ participation is also addressed by actions 9, 10 and 15 of the ‘Joint Initiative on Standardisation under the Single market Strategy’ (2016) signed by the Commission, the ESOs, the NSBs, relevant industrial and societal stakeholders.

55 Art. 5(1), Reg. (EU) 1025/2012: ‘European standardisation organisations shall encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders, including SMEs, consumer organisations and environmental and social stakeholders in their standardisation activities. They shall in particular encourage and facilitate such representation and participation through the European stakeholder organisations receiving Union financing in accordance with this Regulation [...]’.

phase of standardisation<sup>56</sup> and to be notified of the most relevant acts of the process.<sup>57</sup> As such, the Regulation sets out a programmatic framework for encouraging the ‘appropriate representation and effective participation of societal stakeholders’,<sup>58</sup> rather than fully-fledged participatory rights. This elusiveness makes it difficult *ab origine* to draw the ‘infringement of a right to participate’: once stakeholders are duly informed of the most relevant steps of standard-setting process, no legally enforceable right exists.<sup>59</sup>

Furthermore – and partially as a consequence of what has just been highlighted - Annex III stakeholders’ efforts for building a better trade-off among industry and society’s interests proceed through political dialogue with the ESOs and the Commission, that loosely connects with a normative dimension. In negotiations-based relationships, judicial litigation is perceived as an irritant with counterproductive effects.<sup>60</sup> Of course, that is not to say that judges could not play a role in defining a benchmark of good practices that can clarify and enhance stakeholders’ involvement in European standardisation. The Court can serve as a catalyst<sup>61</sup> for the completion of the objectives of fair participation, inclusiveness and openness embedded in the Regulation (EU) 1025/2012. However, it is a matter of fact that political dialogue seems to be preferred so far,<sup>62</sup> with little space left for judicial activity.

Moreover, it should be highlighted that even where the Annex III organisations would denounce a breach of their rights, this claim would hardly be addressed against the publication of the HSs, or settled in a courtroom. First, an action for annulment under Art. 263(4) TFEU cannot but be grounded on the lack of effective supervision by the Commission of the fulfilment of stakeholders’ prerogatives. Arguably, this would hardly fulfil the ‘direct concern’ requirement established under Art. 263 TFEU, as the breach would not be causally connected to the activity of the Commission. Second, Annex III organisations strongly rely on the Commission for financing their activities and raising their voice in the standardisation arena:<sup>63</sup> Would they ever take a judicial action against their main partner and funding body?

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<sup>56</sup> See Arts 8(4) and 10(2), Reg. (EU) 1025/2012.

<sup>57</sup> Art. 12, Reg. (EU) 1025/2012.

<sup>58</sup> See Art. 5(1), Reg. (EU) 1025/2012.

<sup>59</sup> In this light, it has been argued that Annex III stakeholders lack *ab origine* standing under Art. 263 TFEU. See C. Colombo and M. Eliantonio, ‘Harmonized Technical Standards as Part of EU law’ (n 37 *supra*) 331.

<sup>60</sup> Interview with ETUC officer, Brussels, 13 March 2017.

<sup>61</sup> J. Scott and S. P. Sturm, ‘Courts as Catalysts: Re-thinking the Judicial Role in New Governance’ (2007)13(2) *Columbia Journal of European Law* 565.

<sup>62</sup> The most recent outcome of such a dialogue being the so-called ‘right of opinion’, which allows Annex III organisations to express a positive or negative opinion on a draft standard. See Clause 1.2.2 CEN-CENELEC Guide 25 ‘The Concept of Partnership with European Organizations and other Stakeholders’, 2<sup>nd</sup> ed., 2017.

<sup>63</sup> The conditions of this funding are set out by a Framework Partnership Agreement between the Commission and each stakeholder with the Commission, signed in 2014.

All that considered, Annex III organisations are more likely to address any complain to the ESOs themselves. In this case, the appeal procedure envisaged by CEN-CENELEC Internal Regulation would once again represent the most natural forum for dealing with the issue,<sup>64</sup> especially considering that also actions or inactions ‘not in the best interests of the European market or such public concerns as safety, health or the environment’ are caught by the appeal procedure.<sup>65</sup> However, the standing of Annex III stakeholders is not unconditional: ‘[t]he right of a partner organization to lodge an appeal is limited to matters associated with work carried out by CEN/CENELEC Technical Bodies to which the partner organization has contributed’.<sup>66</sup> This limitation, which has been intended to prevent unfounded appeals,<sup>67</sup> however excludes the most extreme case of participatory asymmetry, i.e. non participation - for instance because of lack of available resources.

(iv) European Standardisation Organisations.

The rejection by the Commission of a requested HS, as well as the withdrawal of a published one, directly and negatively affects the ESOs. While remaining in the ESOs’ portfolio as non-harmonised European standards, standards developed upon request of the Commission but eventually not published cannot boast the presumption of conformity with legislative requirements, therefore losing (part of) their appeal for market players. This represents a significant economic loss for the NSBs holding copyright on the standards in the respective MSs.

Yet, does the rejection or withdrawal of a HS disfavour the ESOs in a legally relevant manner? On the one hand, the Commission is under the obligation to publish a reference of any HS where it complies with the legislative requirements and the terms of the request it must fulfil. On the other hand, the Commission surely maintains substantial discretion when it comes to carrying out such an assessment, the ESOs having no right to get their standards published, nor a legitimate expectation of approval that they may possibly defend before the Court through an action for annulment.<sup>68</sup>

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<sup>64</sup> Annex III stakeholders enjoy the status of partner organisations within the ESOs, to which the appeal procedure has been extended in 2015. See Clause 7, CENELEC Internal Regulation, Part 2.

<sup>65</sup> *ibid.*

<sup>66</sup> *ibid.*

<sup>67</sup> Interview with CEN-CENELEC officer, Brussels, 14 April 2017.

<sup>68</sup> Under EU law, for a legitimate expectation to arise it is necessary ‘[f]irst, precise, unconditional and consistent assurances originating from authorised and reliable sources have been given to the person concerned by the European Union authorities. Second, those assurances must be such as to give rise to a legitimate expectation on the part of the person to whom they are addressed. Third, the assurances given must comply with the applicable rules’,

Obviously, this does not mean that the Commission enjoys purely arbitrary powers when checking the soundness of the requested standards. As any other EU institutions, the Commission has the duty to state the reasons for any legal act it issues.<sup>69</sup> Against manifestly unmotivated and/or scarcely circumstanced rejections/withdrawal of HSs, it is therefore possible to denounce the infringement of an essential procedural requirement through Art. 263 TFEU.

A different analysis should be made where whatsoever decision from the Commission lacks about a standard submitted for publication. Even though Regulation (EU) 1025/2012 only asks the Commission to publish ‘without delay’ a HS when it ‘satisfies the requirements it aims to cover’,<sup>70</sup> it could be surely argued that the conformity assessment of standards should be performed in a reasonable time.<sup>71</sup> In extreme situations, the inaction of the Commission could be challenged by the ESOs through an action for failure to act under Art. 265(3) TFEU.

As a final remark, it should just be noted that in the practice recourse to the Court is however *a priori* hindered by the ‘permanent, open and transparent dialogue’<sup>72</sup> between the ESOs and the Commission, as it is reasonable to believe that highly controversial standards will not be submitted for publication in the first place.

(v) Manufacturers.

Any technical standard implies some switching costs, as most of the time manufacturers willing to adopt it would have to adapt their product design or productive process to the new technical specifications. These costs weight differently on competing firms: some may easily take advantage of the new standard; some others are disfavoured as their productive model deviates significantly from the standard. In brief, standardisation has winners and losers. This asymmetry becomes extremely relevant whenever standards are deeply embedded in an industry’s customs or productive cycles, to the extent that they are perceived as *de facto*

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Case T-387/09 *Applied Microengineering v Commission*, ECLI:EU:T:2012:501, para.58. See also Case T-347/03 *Branco v Commission*, ECLI:EU:T:2005:265, para. 102.

<sup>69</sup> See both Art. 296 TFEU and Art. 41(2), third limb, of the Charter of Fundamental Rights of the Union.

<sup>70</sup> Art. 10(6), Reg. (EU) 1025/2012.

<sup>71</sup> Due to the high number of standards awaiting publication, the Commission has recently adopted the Action Plan ‘Structural Solution to Decrease the Stock of Non-Cited Harmonised Standards’, 9 October 2017, <<http://ec.europa.eu/docsroom/documents/25881>> (last accessed 1 November 2017).

<sup>72</sup> See Commission’s ‘General Guidelines for the Cooperation between CEN, CENELEC and ETSI and the EC and EFTA’ (n 14 *supra*), para. 4.

mandatory for staying into the business.<sup>73</sup> In this case, market players are persuaded – if not in practice obliged – to comply with the new technical standard and bear the unbalances generated by standardisation.

What if a manufacturer feels to have been unduly disadvantaged by a European standard – harmonised or not? This hypothesis will be considered through the lens of economic law,<sup>74</sup> taking into account the role that (i) competition law and (ii) free movement law may play in grounding a judicial action against the shortcomings of standardisation.

(i) Where the asymmetry that standards generate depends on collusion,<sup>75</sup> competition law applies. The European Standardisation System is naturally subjected to antitrust rules, especially as it offers a fertile ground for those ‘agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States’ caught by Art. 101 TFEU. Actually, this is exactly how standardisation is supposed to work: it is a quest for commonly agreed technical specifications intended to have a steering effect on the market.

Despite this ‘natural predisposition’, the case-law of the Court dealing with standard-setting activities is quite scarce,<sup>76</sup> if we exclude the strand of litigation stemming from the interplay between patented technologies and standardisation.<sup>77</sup>

Two reasons for this scarcity are suggested, which adds to the general decline of antitrust litigation before European judges.<sup>78</sup> First, the Commission’s guidelines on the application of competition law to standardisation agreements envisage a generous ‘safe harbour’ which substantially shields ESOs’ standards from antitrust challenges.<sup>79</sup> Indeed, ‘[w]here participation

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<sup>73</sup> The strength of *de facto* mandatory standards is apparent in Case C-171/11 *Fra.bo v Deutsche Vereinigung des Gas- und Wasserfaches eV*, ECLI:EU:C:2012:453, as well as in Case T-432/05 *EMC Development AB v European Commission*, ECLI:EU:T:2010:189.

<sup>74</sup> A specific analysis of the litigation concerning the use of standards in private contracts, as well as of the liability issues connected to the certification of products, falls beyond the scope of this paper. See in this regard, see. B. van Leeuwen, *European Standardisation of Services and its Impact on Private Law* (Hart, 2017)

<sup>75</sup> ‘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’, Commission’s ‘Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements’ (2011/C 11/01) [2011] OJ C11/1, para. 264; more details at paras. 265ff.

<sup>76</sup> One being Case *EMC Development* (n 73 *supra*).

<sup>77</sup> See B. Lundqvist, ‘The Interface between EU Competition Law and Standard Essential Patents – from *Orange-Book-Standard* to the *Huawei* Case’ (2015) 11(2-3) *European Competition Journal* 367; P. Larouche, G. van Overwalle, ‘Interoperability Standards, Patents and Competition Policy’, in P. Delimatsis (ed), *The Law, Economics and Politics of International Standardisation* (CUP, 2015), 367.

<sup>78</sup> See M. Prek and S. Lefèvre, ‘Competition Litigation before the General Court: Quality if not Quantity?’ (2016) 53(1) *Common Market Law Review* 65.

<sup>79</sup> The safe harbour has been applied, for instance, in Case *EMC Development* (n 73 *supra*), paras 61ff.

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 [...].<sup>80</sup> This presumption of compliance encompasses all standardisation activities carried out by the ESOs, as they surely are – at least on paper – carried out on a transparent, open and non-discriminatory basis. As a consequence, judicial action on competition law grounds against the effects of European standards - HSs included – is naturally discouraged.

Second, the decentralised architecture of EU antitrust enforcement downsizes *per se* the space for judicial intervention at European level: most of the anti-competitive behaviours are detected and dealt with by administrative authorities through the European Competition Network (ECN),<sup>81</sup> which assigns the proceedings either to the Commission or the national competition authorities.<sup>82</sup> In addition, whenever a case eventually reaches the Court, judicial scrutiny would be in any case limited to procedural issues because of the technical complexity of competition law litigation.<sup>83</sup>

(ii) Whenever standards are – or presumed to be – in line with competition law, their effects on the market would not be something standardisation bodies can be reasonably blamed for. Yet, the Court’s reasoning in the *Fra.bo* judgment<sup>84</sup> suggests this possibility, upon certain conditions. *Fra.bo* is an Italian manufacture of copper fittings, to whom a certification has been

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80 See Commission’s ‘Guidelines’ (n 75 *supra*), para. 280. See also CEN-CENELEC Guide 31 ‘Competition law for participants in CEN- CENELEC activities’ 1<sup>st</sup>ed., 2015), which provides a clear list of ‘Dos’ and ‘Don’ts’ for preventing the breach of antitrust legislation.

81 The essential functioning of the ECN established under the umbrella of Regulation (EC) 1/2003 is devised by a ‘Joint Statement of the Council and the Commission on the functioning of the network of Competition Authorities’ (No 15435/02 ADD 1), and further detailed in the ‘Commission Notice on cooperation within the Network of Competition Authorities’ (2004/C 101/03). For an overview see F. Cengiz, ‘Multi-level Governance in Competition: the European Competition Network Policy’ (2010) 35(5) *European Law Review* 660.

82 In 2016, the ECN dealt with 145 new cases; in 2015, with 179. <<http://ec.europa.eu/competition/ecn/statistics.html>>. In the same two years, the General Court received, respectively, 18 and 17 new competition law cases, whereas the Court of Justice 35 and 40, including appeals against the decisions of the general Court (23 out of 35 in 2016 - roughly 65% - and 32 out of 40 – 80% - in 2015). See Court of Justice of the EU ‘Annual Report 2016: Judicial Activity’, 89 and 208 <[https://curia.europa.eu/jcms/upload/docs/application/pdf/2017-03/ra\\_jur\\_2016\\_en\\_web.pdf](https://curia.europa.eu/jcms/upload/docs/application/pdf/2017-03/ra_jur_2016_en_web.pdf)> and ‘Annual Report 2015: Judicial Activity’, 77 and 196 <[https://curia.europa.eu/jcms/upload/docs/application/pdf/2016-08/rapport\\_annuel\\_2015\\_activite\\_judiciaire\\_en\\_web.pdf](https://curia.europa.eu/jcms/upload/docs/application/pdf/2016-08/rapport_annuel_2015_activite_judiciaire_en_web.pdf)>. All documents accessed 1 November 2017.

83 See, for instance, Case *EMC Development* (n 73 *supra*) paras. 57-60. The limits to judicial review have in the past fed the debate about the compatibility of EU competition law enforcement mechanism with Art. 6(1) ECHR on due process. See A. Sánchez Graells, ‘The EU’s Accession to the ECHR and Due Process Rights in EU Competition Law Matters: Nothing New Under the Sun?’, in V. Kosta, N. Skoutaris and V. Tzevelekos (eds), *The Accession of the EU to the ECHR* (Hart, 2014), 255.

84 Case *Fra.bo* (n 73 *supra*).

denied by a German private standardisation and certification body. At the time of the judgment, the market and regulatory framework in Germany were such that the lack of that specific private certification *de facto* precluded access to the market. Building upon these circumstances, the Court stated that Art. 34 TFEU prohibiting obstacles to the free movement of goods also applies to ‘standardisation and certification activities of a private-law body, where the national legislation considers the products certified by that body to be compliant with national law’.<sup>85</sup> This can be interpreted in two ways. First, private standards *per se* are caught by free movement law should they hinder market freedoms. Second, consistently with its rationale, Art. 34 TFEU rather applies to the public endorsement of private standards - i.e. the regulatory framework they operate within. This distinction carries along substantial consequences. In the first case, manufacturers could directly challenge private technical standards under free movement law, insofar intra-community trade is hindered. This inevitably calls into question the controversial doctrine of the horizontal application of fundamental freedoms to private relationships, which is deep-rooted in the domains of the free movement of workers and services.<sup>86</sup> However, this doctrine has not been convincingly extended to the free movements of goods,<sup>87</sup> nor *Fra.bo* offers sufficient elements for afterthoughts. In contrast with the opinion of the AG,<sup>88</sup> the Court has indeed carefully avoided any reference to its precedent case-law supporting the horizontal

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85 *ibid.*, para. 32.

86 For a discussion on the horizontal effect of EU fundamental freedoms see, P. Caro de Sousa, ‘Horizontal Expressions of Vertical Desires. Horizontal Effect and the Scope of EU Fundamental Freedoms’ (2013) 3(2) *Cambridge Journal of International and Comparative Law* 479; 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(2) *European Law Journal* 177; A. Hartkamp, ‘The Effect of the EC Treaty in Private Law: On Direct and Indirect Horizontal Effects of Primary Community Law’ (2010) 3 *European Review of Private Law* 527. On this point see also AG Maduro Opinion in Case *Viking* (C-438/05) delivered on 23 May 2007, ECLI:EU:C:2007:292, para. 29 ff. More specifically on the puzzling horizontal effect of free movement of goods P. Verbruggen, ‘The Impact of Primary EU Law on Private Law Relationships: Horizontal Direct Effect under the Free Movement of Goods and Services’ (2014) 2 *European Review of Private Law* 201; C. Krenn, ‘A Missing Piece in the Horizontal Effect ‘Jigsaw’: Horizontal Direct Effect and the Free Movement of Goods’ (2012) 49 *Common Market Law Review* 177.

87 The debate on this point dates back to the Court’s famous – as much as ambiguous – statement in Case C-58/80 *Dansk Supermarked v Imerco*, ECLI:EU:C:1981:17, para. 17: ‘[...] it is impossible in any circumstances for agreements between individuals to derogate from the mandatory provisions of the Treaty on the free movement of goods.’ Nevertheless, the subsequent decisions of the Court confirmed that ‘[...] a contractual provision cannot be regarded as a barrier to trade for the purposes of Article 30 of the Treaty [now Art. 34 TFEU] since it was not imposed by a Member State but agreed between individuals’, Case *Sapod Audic* (n 9 *supra*), para. 74. On the interplay between Case *Fra.bo* and the horizontal effect doctrine see H. van Harten and T. Nauta, ‘Towards Horizontal Direct Effect for the Free Movement of Goods? Comment on *Fra.bo*’ (2013) 38(5) *European Law Review*, 677.

88 See AG Trstenjak Opinion in Case *Fra.bo* (n 73 *supra*) delivered on 28 March 2012, ECLI:EU:C:2012:176, paras. 27ff.

effect of free movement law, therefore (consciously) failing to offer any concrete ground for arguing in favour of the application of the free movement of goods to private behaviours.

In the second case, discontent manufacturers would take action against the public measure endorsing technical standards, considered as the factor causing their dominance over the market. This interpretation should be preferred and, as Schepel noted, easily applies to the New Approach context.<sup>89</sup> Indeed, as HSs are the most attractive means to abide by product legislation *because* of the presumption of conformity with legislative requirements they boast – i.e. because of the endorsement by public authorities - any restrictive effect they entail might be causally linked to their publication by the Commission, and as free movement law also applies to EU institutions<sup>90</sup> and the Treaty of Lisbon envisages more permissive *locus standi* criteria under Art. 263(4) TFEU, discontent manufacturers might denounce a breach of their free movement rights by taking an action for annulment against the publication of an allegedly restrictive HS.

This is indirectly corroborated by the *James Elliott* ruling.<sup>91</sup> The case concerns a widely used HS in the construction sector, which was embedded in a supply contract between two Irish undertakings. The plaintiff denounced the breach of the agreement claiming that the material provided - a construction aggregate - did not meet the agreed quality, which was determined by reference to a national standard implementing a HS. As a preliminary point, the Court concluded that HSs are an integral part of EU law,<sup>92</sup> and accordingly fall within its jurisdiction under Art. 267 TFEU. Among the supporting arguments, the Court acknowledges the pervasive role played by the Commission throughout standardisation process, which amounts to a strict public control over HSs.<sup>93</sup> Although specifically building upon Art. 267 TFEU, the judgment is telling in a broader sense: it acknowledges that HSs have no immunity from judicial oversight at European level. It does so directly – affirming the jurisdiction of the Court for interpretative preliminary rulings on HSs – but also indirectly: *James Elliott* highlights the strong ties between HSs and the

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89 H. Schepel, 'The New Approach to the New Approach' (n 3 *supra*), 528.

<sup>90</sup> See Joined Cases C-154/04 and C-155/04, *Alliance for Natural Health and Nutri-Link Ltd v Secretary of State for Health*, ECLI:EU:C:2005:449, para. 49; Case C-114/96, ***Criminal proceedings against René Kieffer and Romain Thill***, ECLI:EU:C:1997:316, para. 27; Case 15/83 *Denkavit Nederland BV v Hoofdprodukschap voor Akkerbouwprodukten*, ECLI:EU:C:1984:183, para. 15; Joined Cases C-80/77 and C-81/77, *Société les Commissionnaires Réunis S.a.r.l. v Reveceur des Douanes*, ECLI:EU:C:1978:87.

<sup>91</sup> Case *James Elliott* (n 33 *supra*).

<sup>92</sup> Case *James Elliott* (n 33 *supra*), para.40. However, some elements could have been already inferred from Case *Latchways*. In this decision, the Court neglected its jurisdiction over a technical standard issued by the CEN, on the basis that it was not issued upon Commission's request, and as such had no link with EU law. *A contrario*, this suggests that a different solution could have been reached with regard to harmonised standards. See Case C-185/08 *Latchways plc and Eurosafe Solutions BV v Kedge Safety Systems BV and Consolidated Nederland BV*, ECLI:EU:C:2010:619, paras. 32ff.

<sup>93</sup> Case *James Elliott* (n 33 *supra*), paras. 43ff.

Commission, and as such – it could be argued - corroborates the possibility to link the effects of HSs to the public institutions of the EU. It is this second aspect which is of importance in the present analysis: jointly considered, *Fra.bo* and *James Elliott* suggest that public authorities do exert a substantial influence over standardisation activities. Therefore, a plausible theoretical ground exists for an action for annulment to be taken by a discontent manufacturer against the publication of a HS on free movement law grounds.

Nevertheless, this eventuality relies on slippery assumptions. First, it implies that the presumption of conformity is the exclusive – or at least the preponderant – source of the alleged restriction of intra-Community trade attributable to a HS – i.e. it presupposes that the fragmentation of the market is something the Commission could be directly blamed for. However, establishing this cause-effect link seems to be rather arbitrary: It would be incredibly difficult to ascertain whether, and to which extent, the spread of a HS – and therefore of the restrictive effects it carries along - depends on the presumption of conformity it boasts, or rather on the structure of the market that *per se* accepts the standard as a ‘good standard’.<sup>94</sup> The proof of causality between the public endorsement of HSs and their restrictive effects on market freedoms would require a complex assessment of the *reasons* why an industry relies on a specific standard: Is that because of the presumption of conformity? Is that because the standard is ‘good’?<sup>95</sup> Is it rather a combination of both? Moreover, what if the HS merely formalises the technical rules on which the market already relies?<sup>96</sup>

Second, even where such a causality is somehow ascertained, the Court would probably struggle to undertake the proportionality test implied in free movement law litigation. The restrictions to Art. 34 TFEU caused by a HS – or better, by the presumption of conformity they ground - would be lawful if pursuing a legitimate aim and justified by overriding reasons of general interest,<sup>97</sup> as well as if proportional – i.e. (i) suitable, (ii) necessary and (iii) proportional strictly speaking.<sup>98</sup> Surely enough, the existence of uniform European technical standards is justified by the general interest of the Union to have a common market without barriers. The problems would arise when it comes to assessing the proportionality of a HS with respect to the

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<sup>94</sup> However, this link seems to have been presumed in Case *Fra.bo* (n 73 *supra*).

<sup>95</sup> This issue is widely addressed in H. Schepel, ‘*Between Standards and Regulation: On the Concept of ‘de facto mandatory standards’ after Tuna II and Fra.bo*’ in P. Delimatsis (ed) (n 77 *supra*), 199.

<sup>96</sup> This issue glimpses in Case *EMC Development* (n 73 *supra*), para. 117: ‘[...] the applicant does not explain how it is possible to infer from the fact that products complying with the Standard represent a very large proportion of cement sold in Europe that the Standard dominates the market, which, in turn, relies on the Standard’.

<sup>97</sup> This is the core of the mandatory requirements doctrine developed since the *Cassis de Dijon* decision (n 4 *supra*), para. 8.

<sup>98</sup> See, *inter alia*, Case C-36/02, *Omega*, EU:C:2004:614, para. 36; Case C- 341/05, *Laval* EU:C:2007:809, para. 101; Case C- 438/05, *Viking Line*, EU:C:2007:772, para. 75.

market restrictions it causes. Assuming that any technical standards affect manufacturers in some way, the Court would in this case have to investigate whether different technical specifications could have been adopted by the ESOs, which minimise the prejudice to intra-community trade, that the Commission should have known about when assessing the conformity of HSs with the essential requirements, and in light of which publication should have been denied. Evidently, this is a very complex and demanding analysis, which would ask an appraisal of any suitable alternative to the allegedly restrictive HS – including no standardisation at all – available at the time of its publication and eventually discarded. Such an assessment would be materially impossible to perform by any non-specialised court, because of obvious cognitive limits. More fundamentally, this appraisal would erode the boundaries between judicial activity and the technical discretion of the Commission. This unveils the underpinning concern of any form of interplay between technical standardisation and judicial oversight: Should courts enter the merit of technical choices? If so, to which extent?

#### **4. Powers and limits of the Court in dealing with technical standards. An overview.**

The suitability of non-specialised courts to deal with highly technical matters is an old but yet incredibly topical issue, which reflects the growing complexity of regulation, litigation, and adjudication in technology-driven societies. Should courts enter the merit of scientific choices? Are they cognitively capable to make informed decision in this sense? Where does the judicial role end? The issues these questions evoke are undeniably relevant for any and every hypothesis of judicial intervention on European standardisation so far sketched: The Court's engagement in standardisation – whichever form it takes – is likely to require some sort of appraisal on the technical contents of standards, and/or the evaluation of their scientific rationale, and/or a comparative analysis of the reasons why alternative designs are to be preferred. Two main interrogatives arise: Does the Court have the substantive to check the technical soundness of the Commission's appraisal on HSs – e.g. to evaluate the conformity of HSs with the essential requirements they should fulfil? Does it have the necessary expertise to enter the merit of HSs?

An appraisal of the technical fitness of HSs, intended to offer a benchmark against which the Commission's decision to publish a standard could be tested, poorly fits with the confined power of review the Court of Justice enjoys under Art. 263 TFEU. Direct actions for annulment can be filed 'on grounds of 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.’<sup>99</sup> Arguably, the incorrect evaluation of the compliance of HSs with primary legislation would constitute an ‘infringement of the Treaties or of any rule of law relating to their application’ imputable to the Commission. However, it is questionable whether this ground for action may encompass the technical assessment of the contents of HSs: Does Art. 263 TFEU provide the Court with the substantive power to evaluate the soundness of the reasons underpinning the decision to publish or reject a HS? A positive answer would be inconsistent with the traditional deference of the Court towards discretionary decisions of the Commission.<sup>100</sup> As especially evident from competition law litigation, the Court usually adopts a cautious approach and refrains from a substantive evaluation of technical issues, limiting itself ‘to verifying whether the relevant rules on procedure and on the statement of reasons have been complied with, whether the facts have been accurately stated and whether there has been any manifest error of assessment or a misuse of powers’.<sup>101</sup> In sum, the Court remains at the edge of technical matters, and at most analyses the formal/procedural correctness of the measure at stake, as well as the adequacy of the information underpinning the decision.<sup>102</sup> It is hard to think a reason why such an approach should be abandoned when it comes to reviewing the decision to publish a HS.

Moreover, the powers of review of the Court should be framed also taking into account the interconnection between the European Standardisation System and the international layer of technical standardisation. The ESOs entertain stable relationships with their international counterparts – namely ISO,<sup>103</sup> IEC,<sup>104</sup> ITU<sup>105</sup> - which are formalised by periodical agreements.<sup>106</sup> Therein, the primacy of international standards over European standards is

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<sup>99</sup> Art. 263(2) TFEU.

<sup>100</sup> See, for instance, Case C-301/97, *Netherlands v. Council*, ECLI:EU:C:2001:621, para. 105; C- 354/89 *Schiocchet v. Commission*, ECLI:EU:C:1991:149, para. 14.

<sup>101</sup> Case *EMC Development* (n 73 *supra*) para. 60. See also *ibid.*, Case *Schiocchet v. Commission*.

<sup>102</sup> See, for instance, Case T-13/99, *Pfizer Animal Health SA v Council*, EU:T:2002:209; Case C-269/90, *Technische Universität München v Hauptzollamt München-Mitte*, EU:C:1991:438; Case C-331/88 *The Queen v Minister of Agriculture, Fisheries and Food and Secretary of State for Health (Fedesa)* EU:C:1990:391. See in this regard 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*, (Elgar, 2013) 142. See also, with a focus on free movement case law, C. Joerges, ‘Scientific Expertise in Social Regulation and the European Court of Justice: Legal Frameworks for Denationalized Governance Structures’, in C. Joerges, and others (n 1 *supra*) 295.

<sup>103</sup> The *International Organization for Standardization*, established in 1947.

<sup>104</sup> The *International Electrotechnical Commission*, established in 1906.

<sup>105</sup> The *International Telecommunication Union*, founded in 1865.

<sup>106</sup> These are the ‘Vienna Agreement’ between the ISO and the CEN, lastly amended in 2001; the ‘Frankfurt Agreement’ between the IEC and the CENELEC (previously ‘Dresden Agreement’), 2016; the ‘Memorandum of Understanding’ between the ETSI and the ITU, lastly reviewed in 2012.

acknowledged. This implies that standard-development should be primarily entrusted to the International Standardisation Bodies (ISBs), to which a synchronised approval by ESOs and ISBs of the same standard follows. The ISBs take the lead also when standardisation is triggered upon request of the Commission, unless there is evidence that they cannot meet the terms of the request.<sup>107</sup> Because of this mechanism, 24% of the HSs drafted by CEN are identical to ISO publications, whereas 57% of CENELEC's HSs are developed by IEC.<sup>108</sup> It is therefore evident that any judicial interpretation or scrutiny on the conformity of the contents of HSs with European legislation would have some kind of spill-over effect on the international layers of standardisation, and would therefore affect the market at a global level.

On a different note, assumed that the Court has the substantive power – and the willingness – to engage in scientific discourses, it is still to be assessed whether it has the expertise to do so: Would the Court be ‘cognitively’ able to establish whether a technical specification satisfies the criteria established by harmonisation legislation, or whether it disproportionately disfavour some market players? HSs exist on heterogeneous technological and scientific domains, which include chemicals, medical devices, explosives, cosmetics, pressure vessels, packaging, toys and much more. Approaching these documents – even reading them – requires a specialized knowledge, which the Court cannot boast. The issue is further exacerbated in light of the traditional reluctance of the Court to appoint *ex officio* external experts for dealing with complex technical issues.<sup>109</sup> The ESOs are well aware of that. Probably fearing a multiplication of interpretative rulings on HSs in the aftermath of *James Elliott*, the CEN and CENELEC have indeed ‘[...] propose[d] to 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 standards] – through the expertise of their Technical Committees – in support to the EC where it is itself involved in a court case brought to the European Court of Justice involving hENs. This in view to ensure that the European Court is provided with the *correct interpretation* on the hENs, while allowing CEN and CENELEC to have visibility on the European Court cases involving their standards.’<sup>110</sup> Surely enough, this

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107 See the details of that procedure in the ISO-CEN ‘Guidelines for the implementation of the Agreement on Technical Cooperation between ISO and CEN’, 7<sup>th</sup> ed., 2016, clause 5 and Annex A.

108 See ‘CEN-CENELEC Quarterly Statistical Pack’, 3<sup>rd</sup> quarter, 2017, 14.

109 See E. Barbier de la Serre and A. Sibony, ‘Expert evidence before the EC Courts’ (2008) 45(4) *Common Market Law Review* 941.

110 ‘CEN and CENELEC position on the consequences of the judgment of the European Court of Justice on *James Elliott Construction Limited v Irish Asphalt Limited*’, 17 May 2017, <[https://www.cencenelec.eu/News/Policy\\_Opinions/PolicyOpinions/PositionPaper\\_Consequences\\_Judgment\\_Elliott%20case.pdf](https://www.cencenelec.eu/News/Policy_Opinions/PolicyOpinions/PositionPaper_Consequences_Judgment_Elliott%20case.pdf)> (last accessed on 1 November 2017). Emphasis added.

proposal has the merit of providing a means for integrating technical expertise into judicial proceedings dealing with HSs. At the same time, if not counterbalanced by other mechanisms of experts' appointment, it raises some doubts about the opportunity to confer *de facto* to the ESOs the monopoly on the 'correct interpretation' of the HSs before the Court.

As a last remark, it should just be noted that the aforementioned concerns do not emerge in the same fashion when it comes to standards for services, a domain which is acquiring growing importance. Indeed, European standardisation of services also and primarily means 'standardisation of the social interaction between service provider and customer [...] which is much more dominated by cultural and personal preferences, and which is also significantly less scientific than product standardisation.' As such, 'the discussion on the standards is inevitably less technical and more politicised.' Against this context, the cognitive gap of the Court narrows, and the deferential approach of the Court has far less reason to exist: should HSs enter the service sector, the European judiciary could (and should) be able to enter the merit of the contents of standardisation through an appraisal of the conformity assessment conducted by the Commission at the time of publishing a HS.

## **5. Concluding remarks.**

Recent normative and judicial developments have re-shaped the significance of the Commission's involvement in the development of harmonised standards. As such, the publication of such standards in the OJ – far from being a merely informative task - amounts to a political responsibility, and therefore constitutes a legal act against which an action for annulment might be brought. On this premise, and considering the softening of the standing requirements for challenging the validity of regulatory acts, Schepel has argued that the category of applicants which might be willing to take an action for annulment against the publication of HSs broadens. Despite this, it is suggested that the space for judicial intervention in standardisation through Art. 263 TFEU would remain limited in practice. The argument builds around five hypotheses, each of these considering a different group of prospective applicants empowered to take an action for annulment. First, the MSs for issues of conformity between a HS and the essential requirements. Second, the NSBs for challenging the goodness of the HSs they are obliged to implement but disagree with. Third, the Annex III stakeholders for the breach of their participatory rights. Fourth, the ESOs for the rejection or withdrawal of a HS, as well as for inaction of the Commission. Fifth, the manufacturers negatively affected by the

market imbalances caused by a HS. In this latter case, competition law and free movement law have been considered as possible grounds for action. In each of the five hypotheses, a mix of normative and factual elements have been taken into account. From the overall analysis emerges that the intersection of European judiciary and HSs through the judicial remedy under Art. 263 might be complicated and quite sporadic. In addition, more general issues are touched upon, which affect any hypothesis of judicial involvement in technical standardisation considered. The substantive powers that the Court enjoys under Art. 263 TFEU are deemed insufficient for grasping the complex issues underpinning technical standardisation. At the same time, the Court does not seem to have the technical apparatus for dealing with the merit of HSs. A meaningful appraisal of the soundness of the Commission's decision to publish a HS seems therefore to unlikely, as unlikely seems to be a major role of the Court in the standardisation arena.