# THE NEW APPROACH TO THE NEW APPROACH: THE JURIDIFICATION OF HARMONIZED STANDARDS IN EU LAW

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## ABSTRACT

*In July 2012, the Court of Justice rendered the judgment in Fra.bo, a case about the liability of a German private standards body under the free movement of goods. In October 2012, the European Parliament and Council adopted Regulation 1025/2012 on European Standardization, the long awaited formal legal framework for the cooperation between the Commission and the European Standards Organizations. It is very unlikely that either the Court or the Union legislators were planning in these instances to affect a radical overhaul of the New Approach to technical harmonization. And yet, that is exactly what they did. The result of Fra.bo and the new Regulation is to subject European harmonized standards to judicial challenge by any disgruntled manufacturer of products excluded or adversely affected by the contents of such a standard.*

*To have each and every manufacturer or importer complain in each and every court of the Union about each and every harmonized standard that adversely affects its position on the market, however, is much more likely to lead to wholesale paralysis than it is to increase the procedural integrity of European standardization.*

**Keywords:** Court of Justice; European governance; free movement of goods; product safety; technical standards



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## §1. INTRODUCTION

In July 2012, the Court of Justice rendered the judgment in *Fra.bo*, a case about the liability of a German private standards body under the free movement of goods.[1] In October 2012, the European Parliament and Council adopted Regulation 1025/2012 on European Standardization, the long awaited formal legal framework for the cooperation between the Commission and the European Standards Organizations.[2] It is very unlikely that either the Court or the Union legislators were planning in these instances to affect a radical overhaul of the New Approach to technical harmonization. And yet, that is exactly what they did. The result of *Fra.bo* and the new Regulation is to subject European harmonized standards to judicial challenge by any disgruntled manufacturer of products excluded or adversely affected by the contents of such a standard.

While there is a lot to be said for judicial review of private standards, it is not without its issues. A deliberate new approach to the New Approach might have addressed these issues and might have struck a sensible settlement. But as it has come about, it may be feared that it will create more problems than it solves. This article will first rehearse a short history of the New Approach and the importance for its development of the lack of legal status of harmonized standards. It will then, in section 3, analyse *Fra.bo* and its – largely unnoticed – consequences. Section 4 will discuss the possibilities for judicial review opened up, unwittingly, by the new Regulation in combination with the Lisbon Treaty's amendments of Article 263 TFEU, with concluding remarks in section 5.



## §2. A CONCISE HISTORY OF THE NEW APPROACH

The 'New Approach' to technical harmonization and standards was launched in 1985 as a policy response to two major interrelated problems.[3] On the one hand, the plethora of divergent national private standards had proved a major obstacle to the completion of the internal market. Being 'private', they were widely held to be beyond the scope of what is now Article 34 TFEU; by the same token, they were also out of the reach of Community harmonization measures for lack of competence.[4] This could, of course, have been solved by a major legislative effort to replace all private standards with technical specifications laid down in public Community law. But that enterprise, known in retrospect as the 'old approach', was doomed to failure: product-by-product, hazard-

1 Case C-171/11 *Fra.bo*, Judgment of 12 July 2012, not yet reported.

2 Regulation 1025/2012 of the European Parliament and of the Council on European Standardisation, [2012] OJ L 316/12.

3 See generally H. Schepel, *The Constitution of Private Governance – Product Standards in the Regulation of Integrating Markets* (Hart, Oxford 2005).

4 Authoritative frustration in A. Mattera, 'Les nouvelles formes de protectionnisme économique et les Articles 30 et suivants du Traité CEE', 26 *Revue du Marché Commun* (1983), p. 252.

by-hazard harmonization through Community decision-making resulted in fantastically complicated and detailed directives on matters of sometimes questionable importance which, moreover, took so long to be adopted that they were often outdated long before they entered into force.[5] With negative integration out of the reach of Union law and positive integration unable to break the deadlock, the internal market seemed to be an impossible project.

A solution to the first problem was pioneered by the 1983 'Information Directive'.[6] Part of the purpose of that piece of legislation was to encourage the Europeanization of standards by the standards community itself. To that end, it propped up the languishing European standards bodies CEN and CENELEC in several ways. First, it made them responsible for handling the elaborate notification system, through which national standards bodies were to communicate projects and drafts of national standards. Second, it enforced the obligations on national standards bodies arising from their statutes on a 'standstill' on any work that could prejudice harmonization efforts of standards at European level.[7] And third, it launched a procedure through which the Commission can 'request' the European standards bodies to draw up European standards. The 1985 Council Resolution on the New Approach then made a treasure of this nascent pool of European standards in order to solve the second problem. From now on, Community directives covering entire sectors would limit themselves to formulating 'essential requirements.' Conformity with these requirements, then, was to be 'presumed' for products that complied with European harmonized standards.[8]

As a tool towards the completion of the internal market, the New Approach was undeniably a masterstroke.[9] And yet, unease with the system was widespread from the outset.[10] In so far as the Community legislator seemed to delegate regulatory tasks to the private European standards bodies, the new system was clearly at odds with the Court's *Meroni* doctrine, according to which the Commission could delegate powers



5 Suffice it to refer to Directive 87/402/EEC on roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors, [1987] OJ L 220/1, which runs for 43 pages, and Directive 84/438/EEC on the permissible sound power level of lawnmowers, [1984] OJ L 183/9, adopted six years after the Commission's proposal, [1979] OJ C 86/9.

6 Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical regulations and standards, [1983] OJ L 109/8. It was replaced by the consolidated version of Directive 98/34/EC, [1998] OJ L 205/37.

7 Article 7(1) of the Directive instructed Member States 'to take all appropriate measures' to ensure that national standards bodies do not draw up or introduce standards in fields covered by work on European standards.

8 Council Resolution on a new approach to technical harmonisation and standards, [1985] OJ C 136/1.

9 Authoritative cheerleading in J. Pelkmans, 'The New Approach to Technical Harmonization and Standardization', 25 *Journal of Common Market Studies* 3 (1987), p. 249.

10 See e.g. the excellent account in J. Falke, 'Achievements and Unresolved Problems of European Standardization: The Ingenuity of Practice and the Queries of Lawyers', in C. Joerges, K.-H. Ladeur and E. Vos (eds.), *Integrating Scientific Expertise into Regulatory Decisionmaking- National Traditions and European Innovations* (Nomos, Baden-Baden 1997), p. 187.

to private parties only under very strict conditions.[11] Paradoxically, then, for a long time it was felt that the only way to ensure the legality of the New Approach was to keep the standardization system at arm's length from the legal system, and preferably a bit further still. This was achieved, in particular, by the insistence that harmonized standards remained of 'voluntary application.' A precondition for this was, of course, that the 'essential requirements' would be 'worded precisely enough in order to create, on transposition into national law, legally binding obligations which can be enforced'.[12] In other words, compliance with harmonized standards was to remain but one of the ways of showing conformity to 'essential requirements': manufacturers and importers should be free to show conformity by other means.[13]

Relations between the Commission and the European standards bodies were strictly contractual, not hierarchical: modalities of cooperation were set out in *Guidelines for Cooperation*,[14] and CEN remained perfectly free to reject 'requests' for harmonized standards. And, lastly, the Commission, for the longest time, strictly denied any responsibility or accountability for the decision to endorse the proposition that a particular harmonized standard met the 'essential requirements'. The official doctrine is well captured in this passage:

> The European standards organizations are responsible for identifying and elaborating harmonized standards and for presenting a list of adopted harmonized standards to the Commission. The technical contents of such standards are under the entire responsibility of the European standards organizations. (…) New Approach Directives do not foresee a procedure under which public authorities would verify or approve either at Community level or national level the contents of harmonized standards, which have been adopted with the procedural guarantees of the standardization process.[15]



If the New Approach was originally perceived at best as a necessary evil, it soon turned to be considered better, and respectable and better. It was taken up in the cause of

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11 Case 9/56 *Meroni* [1958] ECR 133. On the tension between new governance and the *Meroni* doctrine, see e.g. R. Dehousse, 'Misfits: EU Law and the Transformation of European Governance', in C. Joerges and R. Dehousse (eds.), *Good Governance in Europe's Integrated Market* (Oxford University Press, Oxford 2002), p. 207.

12 Section B (III), Annex II (the 'Model Directive'), Council Resolution on a new approach to technical harmonization and standards, [1985] OJ C 136/1. This turned into a rather unfunny joke when Directive 2001/95/EC on General Product Safety Directive, [2002] OJ L 11/4, turned the general safety requirement (of presenting 'only minimal risk compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of persons') into a New Approach 'essential requirement'.

13 See also Recital 11, Decision 768/2008 on a common framework for the marketing of products, [2008] OJ L 218/82.

14 The first version of these, stemming from 1984, was not even published in the Official Journal. That changed with the 2003 version, General guidelines for the cooperation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association, [2003] OJ C 9177.

15 Commission, *Guide to the implementation of Directives based on the New Approach and the Global Approach* (Opoce, Luxembourg 2000), p. 28.

subsidiarity in the early 1990s as an instance of devolving regulatory responsibility to where it belonged.[16] It was consecrated as a model for European governance in the 2001 White Paper on Governance which called for a wider use of 'frameworks of co-regulation', drawing on the practical expertise of the actors most concerned, which should result in 'wider ownership of the policies in question by involving those most affected'.[17] As a fore-runner of 'new governance' arrangements,[18] the New Approach had come of age by the late 2000s as an example – for better or for worse – of 'integration through de-legalisation'.[19] In 2012 all of that – for better or for worse – changed radically.

## §3. HARMONIZED STANDARDS AND THE FREE MOVEMENT OF GOODS

Had the Court decided *Fra.bo* 30 years ago, then the New Approach would likely never have happened. By holding a national private standards body liable under Article 34 TFEU, the Court has now solved the problem of the reach of the regime on the free movement of goods to standards that are both private and 'voluntary'. By deciding this in 2012, however, the Court has not provided a solution to a problem, but has posed a problem for the solution. To understand the implications of the case, it is best to start with another judgment, the obscure 2008 decision in *Commission v. Belgium*.[20] There, the Commission complained about regulatory arrangements in Belgium whereby a presumption of conformity with legislative requirements was conferred on products bearing the mark of the IBN, the Belgian standards body. The Court recalled its case law to the effect that the mere fact that an importer might be 'dissuaded' from introducing or marketing a product in the Member States concerned constitutes a 'restriction' on the free movement of goods.[21] It then went so far as to hold that a Member State infringes Article 34 TFEU even when it 'encourages' economic operators to obtain national marks



16 See e.g. Commission Communication, On a Broader Use of Standardisation in Community Policy, COM (1995) 412 final, p. 4 ('Recourse to standardization could, in principle, replace regulatory action with voluntary standardization action in sectors of Community activity. Since it is based on consensus, and relies on acceptance of the results by those who will use them, standardization follows the principle of subsidiarity to a high degree').

17 Commission White Paper, European Governance, COM (2001) 428, p. 21.

18 See e.g. K. Armstrong, 'The Character of EU Law and Governance: From "Community Method" to New Modes of Governance', 64 *Current Legal Problems* 1 (2011), p. 179, and M. Dawson, 'Three Waves of New Governance in the European Union', 36 *European Law Review* (2011), p. 208.

19 C. Joerges, 'Integration Through De-legalisation?', 33 *European Law Review* 3 (2008), p. 291.

20 Case C-227/06 *Commission v. Belgium*, Judgment of 13 March 2008. Summary publication in [2008] ECR I-46. The full text of the judgment is available (in French only) from the Court's website.

21 Case C-286/07 *Commission v. Luxembourg*, Judgment of 24 April 2008, para. 2. Summary publication in [2008] ECR I-63. The full text of the judgment is available, only in French, from the Court's website.

of conformity for products lawfully marketed in another Member State.[22] Now, the Commission complained both about legislative and regulatory measures and about the activities of IBN itself. Given the legal status of IBN, however, the Court had little trouble classifying its standardization and certification activities as 'State measures'.[23]

In *Fra.bo*,[24] the Court had to do with the *Deutsche Vereinigung des Gas – und Wasserfaches* (DVGW), a non-profit body governed by private law, which sets technical standards for the water industry and certifies compliance with those standards. Certification by the DVGW lends a presumption of conformity with the general requirement that only products that follow 'the acknowledged rules of technology' may be used in the industry. That requirement in turn, is found in the Regulation on General Conditions for Water Supply (the *AVBWasserV*), which lays down general sales conditions for water supply undertakings and their customers, from which parties are free to depart. *Fra.bo*, an Italian producer of copper fittings, found itself in trouble when the DVGW amended the relevant standard to include the requirement to withstand a test of immersion for 3,000 hours in boiling water. Unable to produce test results to the satisfaction of the DVGW,[25] *Fra.bo* had its current certificate cancelled and a new one refused. It then brought proceedings against DVGW for impeding its access to the German market in contravention of its rights under Article 34 TFEU. Contrary to the IBN, however, the DVGW is a private-law body which the state does not finance nor has decisive influence over.[26] The Court framed the question it faced as follows:

> 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.[27]

That analysis, in turn, took the form of an anti-formalist reading of the *AVBWasserV*. First, the Regulation leaves the option open of verifying compliance with the 'acknowledged rules of technology' by a different procedure than certification by the DVWG. The Court refused to recognize this as a viable alternative, however, in light of the administrative difficulties and additional costs associated with it.[28] Second, the Regulation merely lays down general sales conditions from which parties are free to depart: in other words, there is no binding legislative requirement to adhere to the 'acknowledged rules of technology',

22 Case C-227/06 *Commission v. Belgium*, para. 69.
23 Ibid., para. 37.
24 Case C-171/11 *Fra.bo*, para. 24.
25 There was an issue in the case about the refusal by the DVWG to recognize as equivalent the inspection reports issued by an Italian laboratory. Though potentially important in the larger scheme of things, the matter was of no consequence for the issues discussed here: as far as is evident from the judgment, *Fra.bo* never put its fittings to the 3,000 hours test.
26 Case C-171/11 *Fra.bo*, para. 24.
27 Ibid., para. 26.
28 Ibid., para. 29.

let alone to bear a DVGW mark. This, too, the Court dismissed, noting that, '*in practice*, almost all German consumers purchase copper fittings certified by the DVGW'.[29] The Court then concluded that the DVWG, 'by virtue of its authority to certify the products, in reality holds the power to regulate the entry into the German market' of products such as copper fittings.

In the blinding light of Advocate General Trstenjak's grandiose Opinion,[30] to many commentators *Fra.bo* seems to be a case about the horizontal direct effect of Article 34 TFEU.[31] According to this view, it is odd and wilfully obscure that the Court refuses to engage in *Walrave*-like reasoning and omits the citation of a single relevant case from the *Bosman-Wouters-Viking* range.[32] Even stranger, the Court doesn't seem to be particularly interested in the actual 'activities' of the DVWG, concentrating instead exclusively on the 'legislative and regulatory context' in which it operates. The better view is probably hidden in the dead angle of the preliminary reference procedure. The referring Court asked about the compatibility of the DVGW's measures; what the Court of Justice is answering is really a question about the compatibility of the German regulatory framework.

In the light of *Commission v. Belgium*, the Court *must* be of the view that the *AVBWasserV* falls foul of Article 34 TFEU: as does the Belgian regulatory framework, it 'encourages' operators to seek certification by a standards body even if it doesn't formally impose it. Against that background, *Fra.bo* stands for a fairly limited proposition: if state measures are infringing the free movement of goods by encouraging economic operators to comply with standards, the mere fact that the standards and certificates concerned are private measures will not render those state measures suddenly lawful. And against the same background, it makes perfect sense for the Court not be interested at all in the actual activities of the DVWG: if the offence lies in the act of 'encouraging' operators to seek certification, it is really of no consequence whether that certification is based on the *Fra.bo*'s fittings resisting 3,000 hours or just 5 minutes in boiling water.

In order to gauge the implications of *Commission v. Belgium* and *Fra.bo* for European standards, it should be remembered that the Court considers it settled case law that Article 34 TFEU applies to the institutions of the European Union in the same way as



29 Ibid., para. 30. Emphasis added.

30 Opinion of Advocate General Trstenjak in Case C-171/11 *Fra.bo*, delivered on 28 March 2012, not yet reported.

31 See e.g. the exuberant editorial by N. Shuibhne, 'The Treaty is going to get you…', 37 *European Law Review* (2012), p. 367; W.-H. Roth, 'Die "horizontale" Anwendbarkeit der Warenverkehrsfreiheit (Art. 34 AEUV)', *Europäisches Wirtschafts- und Steuerrecht* (2013), p. 16, and H. Van Harten and T. Nauta, 'Towards direct horizontal effect for the free movement of goods?', 38 *European Law Review* 5 (2013), p. 677.

32 On the doctrine generally, 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', 18 *European Law Journal* 2 (2012), p. 177.

it applies to Member States:[33] in other words, any measure taken by the Commission that 'dissuades' operators from marketing their products in the internal market will be subjected to the discipline of the free movement of goods. The similarities between the regulatory arrangements at issue in these two cases and the New Approach will not be lost on anyone: under the New Approach, too, certification to harmonized standards is formally voluntary, but *de facto* it is prohibitively expensive and complicated to prove conformity with the essential requirements by alternative means. Under the New Approach, too, consumers purchase, *in practice*, only products bearing CE marks. The European standards body, CEN, too, 'in reality' holds the power to regulate entry into the internal market of products covered by the New Approach. And so it is hard to think of a good reason why harmonized standards and the regulatory arrangement of the New Approach itself should not be held to fall within the reach of Article 34 TFEU. And it would be hard to think of a plausible reason why any disaffected producer whose products are excluded by a harmonized standard – and *every* standard excludes certain products and favours others – could not, now, seek judicial review in any court in the European Union of national standards transposing harmonized standards. Whether the issue even came to the Court's mind or not, the judgment in *Fra.bo* seems to have made one thing clear: measures under the New Approach will not escape judicial review any longer on the theory that harmonized standards are 'private' and 'voluntary'.



Having been brought within the scope of the free movement of goods does not, of course, spell the end of the New Approach. The 'essential requirements' in directives will generally be considered to be within the reach of the grounds for justification in Article 36 TFEU and under the Court's doctrine of 'mandatory requirements'.[34] But CEN may now well have a case to make in explaining how a harmonized standard is necessary – and proportionate – for the achievement of those public interests. And the Commission will now have a case to make in explaining how and why it considers particular harmonized standards to be compatible with the 'essential requirements' in the first place.

## §4. HARMONIZED STANDARDS AND LEGALITY REVIEW

As originally conceived under the system of the New Approach, harmonized standards were not adopted, endorsed, or even recognized by the Commission. The grandmother

[33] See e.g. Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health* [2005] ECR I-6451, para 49. See e.g. K. Mortelmans, 'The Relationship between the Treaty Rules and Community Measures for the Establishment and Functioning of the Internal Market- Towards a Concordance Rule', 39 *Common Market Law Review* 6 (2002), p. 1303, and K. Sørensen, 'Reconciling Secondary Legislation with the Treaty Rights of Free Movement', 36 *European Law Review* 3 (2011), p. 339.

[34] See generally e.g. C. Barnard, 'Derogations, Justifications and the Four Freedoms: Is State Interest Really Protected?', in C. Barnard and O. Odudu (eds.), *The Outer Limits of European Union Law* (Hart, Oxford 2009), p. 273.

of all New Approach Directives, the Low Voltage Directive of 1973, announced innocently:

> *For purposes of information*, the list of harmonized standards and their references shall be published in the Official Journal.[35]

In line with this, the acts of publication of the references are consistently called Commission 'communications', and are found in the C series of the Official Journal.[36] Under the New Approach proper, the publication lost some of its innocence where it was firmly established that the presumption of conformity was bestowed only to those standards 'the references of which have been published in the Official Journal'.[37] The act of publication thus has considerable consequences, as Member States are barred by standing case law from introducing any requirements additional to those contained in such harmonized standards.[38] And yet, until very recently, the Commission denied that the act of publication implied a prior assessment of the standard's compatibility with the essential requirements,[39] and doubts remained whether it constituted a contestable decision under Article 263 TFEU.[40]

By design or not, the 2012 Regulation on Standardization now makes it clear that the act of publication of the references to harmonized standards is an act susceptible to legality review in direct actions. The development is perhaps best explained by tracing the evolution of the so-called formal objection procedure first. In its most common form in early New Approach Directives, the relevant clause reads as follows:

> Where a Member State or the Commission considers that the harmonized standards (…) do not entirely meet the essential requirements (…) the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Directive 83/189/EEC, giving the reasons therefor.



35 Article 5, Low Voltage Directive 73/23/EEC, [1973] OJ L 77/29. Emphasis added. Shockingly, the clause has survived the recast; see Article 5, Low Voltage Directive 2006/95, [2006] OJ L 374/10.

36 See e.g. Commission Communication in the framework of the implementation of Directive 2009/48 on the safety of toys, [2013] OJ C 149/2.

37 Article R8, Annex to Decision 768/2008.

38 See e.g. Case C-112/97 *Commission v. Italy* [1999] ECR I-1821, Case C-100/00 *Commission v. Italy* [2001] ECR I-2785; Case C-103/01 *Commission v. Germany* [2003] ECR I-5369, and Case C-6/05 *Medipac-Kazantzidis* [2007] ECR I-4557.

39 See e.g. Commission Report, Efficiency and Accountability in European Standardization under the New Approach, COM (98) 291 final, para. 7 ('public authorities have committed themselves to not insisting on approving the technical content of harmonized standards; no positive decision is required by which authorities approve the standards, even if previously such technical aspects were subject to regulation').

40 See e.g. R. Lauwaars, 'The "Model Directive" on Technical Harmonization', in R. Bieber et al. (eds.), *1992: One Internal Market?* (Nomos, Baden-Baden 1988), p.151.

> The Committee shall deliver an opinion without delay. In the light of the Committee's opinion, the Commission shall *inform* the Member State whether or not it is necessary to withdraw those standards from publication.[41]

In this formulation, the procedure is clearly meant as an *ex post* emergency brake, to deal with problems arising from the application of harmonized standards after their references had been published. In practice, however, the procedure was triggered on various occasions *before* publication.[42] The 2008 Decision acknowledges that reality, and proposes the following standard formulation of the second sentence of the clause:

> In the light of the Committee's opinion, the Commission shall *decide* to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonized standards concerned in or from the *Official Journal*.[43]

The *ex ante* application of the procedure makes it impossible to maintain, as the Commission has done for a very long time, that the act of publication of the references to harmonized standards is a mere matter of 'information'. Implicitly, the shift from 'inform' to 'decide' in the second sentence confirms this. More confirmation is found in the new Regulation, which recasts the procedure once more and amends several directives accordingly.

The new text gives Member States *and the European Parliament* the right to object, but not the Commission itself. According to the old conception of the act of publication as an act of providing information, the anomaly of the Commission objecting to an act of the Commission could be explained away. Now, however, it seems accepted that the Commission has to *take a decision* to publish the references, based on a prior assessment: in that case, it is only right and proper that the Commission should not be allowed to object to itself.

The new Regulation separates the *ex ante* and *ex post* procedures according to different modalities provided for in the Comitology Regulation. The Standing Committee hence gives an opinion under the advisory procedure whether 'to publish, not to publish or to publish with restrictions' the references to harmonized standards: this involves the Committee taking a decision by simple majority, and the Commission taking 'utmost account' of the opinion. The Committee gives its opinion whether 'to maintain, to maintain with restriction or to withdraw' the references to harmonized standards already published in the *Official Journal* under the examination procedure: this involves the Committee taking a decision by qualified majority, and the Commission being bound by that opinion.[44]

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41 See e.g. Article 6, Simple Pressure Vessels Directive 87/404/EEC, [1987] OJ L 220/48. Emphasis added.

42 See e.g. 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.

43 Article R9 (2), Decision 768/2008. Emphasis added.

44 See Article 11 *juncto* Article 22, Regulation 1025/2012, referring to Articles 4 and 5 of Regulation 182/2011, [2011] OJ L 55/13. The procedure is used sparingly. In its report over 2009 and 2010, the

Against this background, the formulation in the 2012 Regulation leaves little room for serious debate:

> *Where a harmonized standard satisfies the requirements* which it aims to cover and which are set out in the corresponding Union harmonisation legislation, the Commission shall publish a reference of such harmonized standard without delay in the Official Journal.[45]

With this, it seems beyond doubt that the act of publication of the references is an act that can be challenged in a direct action before the European Courts under Article 263 TFEU. The subsequent question is then about standing.

Before the Treaty of Lisbon, what was then Article 230(4) EC demanded from private parties that they show that the contested act was of 'direct and individual concern' to them. This was notoriously difficult under the so-called *Plaumann*-test of the Court of Justice as regards the latter limb of the test. 'Individually' concerned were those parties that are affected by the act 'by reason of attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons'.[46]

The Treaty of Lisbon has famously abolished the test of 'individual concern' in Article 263(4) TFEU for private parties where they challenge the legality of 'a regulatory act which is of direct concern to them and which does not entail implementing measures'.[47] A 'regulatory act' has been defined by the Court as 'all acts of general application apart from legislative acts',[48] a category that includes at least all acts of general application adopted by the Commission 'in the exercise of implementing powers and not in the exercise of legislative powers'.[49] It is therewith beyond doubt that the Commission's decision to confer the presumption of conformity on certain harmonized standards can in principle be challenged by private parties, provided they can show that the act is of 'direct' concern to them. The category of persons whose legal situation is 'directly affected' by the fact that a presumption of conformity is bestowed on certain standards seems fairly substantial. It would include national standards bodies who, even if they were outvoted in CEN, are still obliged to transpose harmonized standards as their own. It would include the stakeholders that the new Regulation gives determined procedural rights to.[50] After *Fra.bo*, the category has become enormous. If we take that judgment seriously, the theory of viable alternatives to compliance with 'voluntary



Commission mentions 7 cases over two years: in three cases the presumption of conformity was maintained, in four cases it was restricted or withdrawn. See Commission report, The Operation of Directive 98/34/EC in 2009 and 2010, COM (2011) 853 final, p. 9.

45 Article 10 (6), Regulation 1025/2012. Emphasis added.

46 Case 25/62 *Plaumann v. Commission* [1963] ECR 95.

47 See generally e.g. L. Gormley, 'Access to Justice: Rays of Sunshine on Judicial Review or Morning Clouds on the Horizon?', 36 *Fordham International Law Journal* 5 (2013), p. 1169.

48 See Case C-583/11 P *Inuit Tapiriit Kanatami*, Judgment of 3 October 2013, not yet reported, para. 60.

49 See Case T-262/10 *Microban v. Commission* [2011] ECR II-7697.

50 Article 5 Regulation 1025/2012.

standards' for proving conformity to the legislative requirements will no longer bar each and every disaffected manufacturer or importer whose products are excluded from harmonized standards from seeking judicial review. The final result, then, is a paradox: whereas technical specifications laid down in 'old approach' directives would be safe from judicial review under Article 263(4) TFEU as 'legislative acts', the act of recognition of private standards by the Commission are open to challenge by almost anyone who has an axe to grind.

## §5. CONCLUSION

In *Latchways*,[51] a mischievous Dutch judge asked the Court of Justice to interpret the terms of harmonized standard EN 795 – 'Protection against falls from a height – Anchor devices – Requirements and testing'. One of the issues at stake was whether a certain product could legitimately bear the CE mark for conformity with the Personal Protective Equipment Directive even if it had failed a test under EN 795, that of resisting, under certain heat conditions, a static force of 10kN. The Court was quick to point out that the publication of the reference to EN 795 carried an explicit warning to the effect that the presumption of conformity did not extend to the requirements on the product in question. Gratefully, the Court could then regard EN 795 for the purposes of the dispute in question as 'a technical standard laid down by a private standards organization and unconnected to Directive 89/686'. It could, then, in turn, decline the referring Court's invitation by holding that, 'without there being any need to consider the legal nature of the harmonized standards', the standard *in this case* did not constitute a provision of EU law.[52]

*Latchways* was always going to be a narrow escape, as the Court opened itself up for *a contrario* reasoning: would it, in slightly different circumstances, consider technical requirements in standards covered by the presumption of conformity on products covered by a specific directive as part of Union law? Would it 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 kiloNewton is?

It is to be doubted whether the Court, here as in *Fra.bo*, or the Union legislators when they passed the new Regulation, were fully aware of the consequences of their actions. Had this been a conscious, concerted effort to 'break down the club house' of European standardization,[53] we might feel a little more positive about it all. But this



51 Case C-185/08 *Latchways* [2010] ECR I-9983.

52 Ibid., para. 32–36.

53 R. van Gestel and H.-W. Micklitz, 'European Integration Through Standardization: How Judicial Review is Breaking Down the Club House of Private Standardization Bodies', 50 *Common Market Law Review* (2013), p. 145.

recent juridification spree is, frankly, rather likely to do more harm than good. Yes, it is intuitively attractive to open up private standardization to judicial review. Standards bodies are dominated by private interests and yield enormous power; they exercise that power largely behind closed doors and are accountable to no one in particular. The legal imperative is clearly to require and monitor a high level of expertise, transparency, balance and fairness in standardization. To have each and every manufacturer or importer complain in each and every court of the Union about each and every harmonized standard that adversely affects its position on the market, however, is much more likely to lead to wholesale paralysis than it is to increase the procedural integrity of European standardization. Moreover, to withstand scrutiny by judges who probably fail to grasp even the basics of the technical questions involved, CEN will have to draw on legal resources it doesn't have, and the Commission on technical resources it doesn't have. There may be a lot wrong with European standardization, but it is hard to see how clogging up the system with litigation will remedy much of it.