

Alternative Forms of Regulation: Are They Really ‘Better’ Regulation?

A Case Study of the European Standardization Process

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Abstract

One of the commitments of the Better Regulation Package is to consider ‘both regulatory and well-designed non-regulatory means’. Such mechanisms include co-regulation, i.e. administrative processes which involve the participation of private parties, such as the social partners or the standardization bodies, as (co-)decision makers. While the involvement of private parties in European Union (EU) administrative governance has the clear advantage of delivering policies which are based on the expertise of the regulatees themselves, private-party rule-making raises significant concerns in terms of its legitimacy. This article aims to discuss the gaps of judicial protection which exist in co-regulation mechanisms, by taking the case study of the standardization process. After an introduction to the issue of co-regulation and the rationale for the involvement of private parties in EU administrative governance, the standardization process will be examined and the mechanisms of judicial supervision will be reviewed in order to establish the possible gaps of judicial protection.

Keywords: Better Regulation, co-regulation, standardization, judicial review.

A Introduction

On 19 May 2015, the Commission published its new Better Regulation Package, setting out how it proposes to deliver its commitment to Better Regulation over the coming years.¹ The Better Regulation Package, which is aimed at designing EU policies and laws so that they achieve their objectives at minimum cost, states that when considering policy solutions the Commission will consider “both regulatory and well-designed non-regulatory means”.² This commitment to the consideration of non-regulatory means echoes the 2003 Interinstitutional Agreement on Better Law-Making between the European Parliament (EP), Council and Commission which provides for the “need to use, in suitable cases or where the

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1 Communication from the Commission, ‘Better Regulation for Better Results – An EU Agenda’, 19 May 2015, COM(2015) 215 final.

2 *Ibid.*, p. 6. See also the ‘Better Regulation Guidelines’, COM(2015) 215 final, p. 22.

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Treaty does not specifically require the use of a legal instrument, alternative regulation mechanisms".³

Such mechanisms include co-regulation, *i.e.* administrative processes which involve the participation of private parties, such as the social partners or the standardization bodies, as (co-)decision makers. At both the European and national levels, private bodies are important actors in the implementation of European Union (EU) law, and private rule-making has become an important regulatory mechanism in EU administrative governance in sectors such as financial markets, food regulation, consumer protection, product safety, data protection and environmental policy. While the involvement of private parties in EU administrative governance has the clear advantage of delivering policies which are based on the expertise of the regulatees themselves, private-party rule-making raises significant concerns in terms of its legitimacy.⁴

In particular, not only can the involvement of private parties in EU decision-making be questioned from the perspective of compliance with the *Meroni* doctrine,⁵ but also from that of the existence of an adequate set of control mechanisms to review the legality of the actions taken by private parties as administrative rule-makers.

This article aims in particular to discuss the gaps of judicial protection which exist in co-regulation mechanisms, by taking the case study of the standardization process. After an introduction to the issue of co-regulation and the rationale for the involvement of private parties in EU administrative governance, the standardization process will be examined and the mechanisms of judicial supervision will be reviewed in order to establish the possible gaps of judicial protection. It will be argued that participation and representation mechanisms which could theoretically be seen as adequate alternatives to a possible lack of effective judicial control do not adequately function in the current regulatory framework. While the *ex ante* control mechanisms of the standardization process do not work effectively, *ex post* judicial control also exhibits significant shortcomings, thereby threatening the rule of law in the EU legal order.

B The Evolution of Private Law-Making, Co-Regulation and Standardization in EU Governance

I Private Law-Making in the EU: Origins and Forms

The possibility to involve private parties in EU law-making first appeared with the so-called 'New Approach' Directives. As will be explained in more detail below,

3 European Parliament, Council and Commission, Interinstitutional Agreement on Better Law-Making, 2003/C 321/01, OJ C 321, 31 December 2013.

4 See e.g. D. Schiek, 'Private Rule-Making and European Governance – Issues of Legitimacy', *European Law Review*, Vol. 32, 2007, pp. 443-466. In general on the accountability of private-party rule-making (not limited to the European situation), see D. Curtin & L. Senden, 'Public Accountability of Transnational Private Regulation – Chimera or Reality?', *Amsterdam Centre for European Law and Governance Working Paper Series 2011 – 06*.

5 Case 9-56, *Meroni & Co., Industrie Metallurgiche, SpA v. High Authority of the European Coal and Steel Community*, ECLI:EU:C:1958:7.

these directives are characterized by a peculiar regulatory idea, in that they provide only the essential framework with which products must comply in order to benefit from free movement in the EU. Standardization bodies are entrusted with providing specific standards on the basis of these general requirements.

The EU support for the use of co-regulation was later confirmed in the Commission Communication on Subsidiarity, in which the Commission made it clear that, when choosing the appropriate form of action, a partnership with private bodies, such as businesses, associations and trade unions, had to be considered as a less restrictive regulatory option.⁶ As mentioned in the introduction, this preference has been stated on numerous occasions as part of the Better Law-Making Agenda which emphasizes the need for alternatives to legislation,⁷ and recently in the latest Better Regulation document of May 2015.⁸ The 2003 Interinstitutional Agreement on Better Law-Making establishes co-regulation as an alternative regulatory mechanism as well as an expression of subsidiarity.⁹

Apart from subsidiarity and internal market reasons, private law-making is promoted at the EU level, because of its perceived effectiveness, as "it combines binding legislative and regulatory action with actions taken by the actors most concerned, drawing on their practical expertise".¹⁰ According to the Commission, the result of private regulation is wider ownership of the policies as they have been designed by involving those most affected by them in their preparation, leading ultimately to a higher level of compliance.¹¹ The Commission also states that private regulation is a more cost-efficient method to address certain policy objectives.¹²

6 Communication from the Commission, 'The Principle of Subsidiarity', 27 October 1992, SEC(92) 1990 final, pp. 13 and 14.

7 See e.g. Report from the Commission, 'Better Lawmaking 1998: A Shared Responsibility', 1 December 1998, COM(98) 715 final, p. 7; Report from the Commission, 'Better lawmaking 1999', 3 November 1999, COM(99) 562 final, p. 3; Communication from the Commission, 'Action Plan "Simplifying and Improving the Regulatory Environment"', 5 June 2002, COM(2002) 278 final, p. 11; Communication from the Commission, 'Better Regulation for Growth and Jobs in the European Union', 16 March 2005, COM(2005) 97 final, p. 4.

8 Communication from the Commission, 'Better Regulation for Better Results – An EU Agenda', 19 May 2015, COM(2015) 215 final.

9 Interinstitutional Agreement on Better Law-Making, 2003/C 321/01.

10 Communication from the Commission, 'European Governance – A White Paper', 25 July 2001, COM(2001) 428 final, Section III.2.

11 *Ibid.*

12 Communication from the Commission, 'Implementing the Community Lisbon programme: A Strategy for the Simplification of the Regulatory Environment Brussels', 25 October 2005, COM(2005) 535 final, p. 7.

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Finally, one can see private rule-making as an exemplification of ‘new governance’.¹³ Broadly speaking, three main features distinguish ‘new governance’ from traditional forms of EU law-making: firstly, its emphasis on flexibility over strict command-and-control methods and the use of soft law over binding legislation; secondly, its collaborative nature and the inclusion of a range of private and public actors in the decision-making process; and thirdly, its responsiveness and adaptive capacity thanks to the importance attached to information and knowledge generation. Private rule-making, because of its flexible, inclusive and responsive character, can certainly be seen as way for the EU to regulate in a way which departs from the traditional ‘Community’ method.¹⁴

II *The Origins and Development of Co-Regulation in the EU*

Amongst the different forms of private-party rule-making,¹⁵ the focus of this article will be on co-regulation because it is the private law-making form where the private parties have the strongest role and, therefore, there is arguably a stronger need to check whether there is adequate judicial control.

Co-regulation is defined in the 2003 Interinstitutional Agreement on Better Law-Making as

the mechanism whereby a Community legislative act entrusts the attainment of the objectives defined by the legislative authority to parties which are recognised in the field (such as economic operators, the social partners, non-governmental organisation, or associations).¹⁶

An EU legislative act, therefore, defines the criteria for the use of co-regulation, while leaving the power to provide detailed rules necessary to obtain the achievement of a specific policy goal to private parties. Co-regulation is seen in the 2003 Interinstitutional Agreement on Better Law-Making as having the advantages mentioned above to reduce the legislative burden by focusing on essential

13 For further on this, see G. de Búrca & J. Scott, *Law and New Governance in the EU and the US*, London, Hart Publishing, 2006; C.F. Sabel & J. Zeitlin, ‘Learning from Difference: The New Architecture of Experimentalist Governance in the European Union’, in C.F. Sabel & J. Zeitlin (Eds.), *Experimentalist Governance in the European Union: Towards a New Architecture*, Oxford, Oxford University Press, 2010, pp. 1-28; D.M. Trubek & L.G. Trubek, ‘New Governance & Legal Regulation: Complementarity, Rivalry, and Transformation’, *University of Wisconsin Law School, Legal Studies Research Paper Series 1047*, May 2007, available at: <<http://ssrn.com/abstract=988065>>; J. Scott & D.M. Trubek, ‘Mind the Gap: Law and New Approaches to Governance in the European Union’, *European Law Journal*, Vol. 8, No. 1, 2002, pp. 1-18.

14 Further on the rationale for the use of private law-making, as well as for its different forms, see H.C.H. Hofmann, G.C. Rowe & A.H. Türk, *Administrative Law and Policy of the European Union*, Oxford, Oxford University Press, 2011, pp. 326-328.

15 For an overview of the different approaches to self- and co-regulation that can be found within the EU context (as well as in a number of Member States and international organizations), see L.A.J. Senden *et al.*, ‘Mapping Self- and Co-regulation Approaches in the EU Context: Explorative Study for the European Commission, DG Connect’, Utrecht, Utrecht University Repository, 2015, available at: <http://ec.europa.eu/digital-agenda/sites/digital-agenda/files/dae-library/mapping_self-and_co-regulation_in_the_eu_context_0.pdf>.

16 Interinstitutional Agreement on Better Law-Making, 2003/C 321/01, para. 18.

aspects, drawing from the expertise and knowledge of the private actors and to increase acceptance and compliance with the policies. However, it is also made clear in the same document that co-regulation, as an alternative form of EU regulation, needs to meet the criteria of transparency and representativeness of the parties involved.¹⁷

There are two key illustrations of the mechanisms of implementation of EU law through co-regulation, *i.e.* standardization and social policy. While quite extensive research has been carried out on the role of social partners in EU administrative governance,¹⁸ the process of standardization has been less studied.¹⁹ The judicial implications of the standardization process have also not been extensively studied.²⁰ For these reasons, the further focus of this article will be on standardization and the gaps of judicial protection arising from the use of this regulatory technique.

III The Standardization Process

1 Origin, Procedures and Actors

The origins of the use of standardization for regulatory purposes can be traced back to the efforts to achieve the internal market and remove the technical barriers to trade in the EU and, in particular, to the difficulties encountered in this process. While the Commission had originally opted for a broad harmonization package, due to the unanimity rule applicable in the Council, the adoption of directives intended to harmonize technical requirements was slow and has been considered to not be sufficiently flexible to react to technological changes.²¹ The shift in approach was approved by the Council of Ministers²² and further outlined in the White Paper in 1985 on the completion of the internal market. In this document, the Commission effectively opted for a system based on essential health and safety requirements set in EU legislation coupled with detailed stan-

17 *Ibid.*, para. 17.

18 See e.g. G. Britz & M. Schmidt, 'The Institutionalised Participation of Management and Labour in the Legislative Activities of the European Community: A Challenge to the Principle of Democracy under Community Law', *European Law Journal*, Vol. 6, No. 1, 2000, p. 45; C. Barnard, 'The Social Partners and the Governance Agenda', *European Law Journal*, Vol. 8, No. 1, 2002, p. 80; S. Smismas, *Law, Legitimacy and European Governance: Functional Participation in Social Regulation*, Oxford, Oxford University Press, 2004.

19 See, however, the comprehensive analyses of H. Schepel, *The Constitution of Private Governance – Product Standards in the Regulation of Integrating Markets*, London, Hart Publishing, 2005, and M. Egan, *Constructing a European Market*, Oxford, Oxford University Press, 2001.

20 See, however, R. van Gestel & H. Micklitz, 'European Integration through Standardization: How Judicial Review is Breaking Down the Club House of Private Standardization Bodies', *Common Market Law Review*, Vol. 50, No. 1, 2013, p. 145.

21 M. Egan, 'Regulatory Strategies, Delegation and European Market Integration', *Journal of European Public Policy*, Vol. 5, No. 3, 1998, p. 490. For a clear account of the developments, see H. Schepel, 'The New Approach to the New Approach: The Juridification of Harmonized Standards in EU Law', *Maastricht Journal of European and Comparative Law*, Vol. 20, No. 4, 2013, p. 523.

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

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dards set by the European Standardization Bodies.²³ While compliance with these standards remained voluntary, it had the advantage of creating a presumption of conformity with the essential requirements.

In this way, the first New Approach Directives were enacted.²⁴ Until recently, European standardization was governed by a specific legal framework consisting of three different legal acts, namely, Directive 98/34/EC,²⁵ Decision 1673/2006/EC²⁶ and Council Decision 87/95/EEC.²⁷ However, the current legal framework was considered to no longer be up to date with developments in European standardization over recent decades. The framework needed to be simplified and adapted in order to cover new aspects of standardization to reflect those latest developments and future challenges in European standardization.²⁸ To this end, Regulation 1025/2012 was adopted.²⁹ It contains provisions, inter alia, on transparency and stakeholder participation, and the financing of the European Standardization Bodies.

The basic procedure for the use of standards is set out in Decision 768/2008.³⁰ According to this Decision, products can be placed on the market only if they comply with the applicable European legislation (Art. 1) and, in particular, with the essential requirements aimed at protecting public interests (Art. 3(1)). According to the same provision, the essential requirements must be expressed in terms of the results to be achieved. This definition, therefore, leaves considerable room for the European Standardization Bodies to develop technical standards adapted to technical progress. The task of the European Standardization Bodies stems from a mandate from the Commission.³¹ These standards, once

23 White Paper from the Commission, 'Completing the Internal Market', 28-29 June 1985, COM(85) 310, p. 19 *et seq.* For further on this, see J. Pelkmans, 'The New Approach to Technical Harmonisation and Standardisation', *Journal of Common Market Studies*, Vol. 25, No. 3, 1987, pp. 249-269; Egan, 1998, p. 490 *et seq.*; N. Burrows, 'Harmonisation of Technical Standards: Reculer Pour Mieux Sauter?', *Modern Law Review*, Vol. 53, No. 5, 1990, pp. 597-603.

24 For a complete and updated list of harmonized standards published in the OJ, see 'New Approach Standardisation in the Internal Market', available at: <www.newapproach.org/Directives/DirectiveList.asp>.

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

26 Dec. 1673/2006/EC of the European Parliament and of the Council of 24 October 2006 on the financing of European standardisation, OJ L 315/9.

27 Council Dec. 87/95/EEC of 22 December 1986 on standardization in the field of information technology and telecommunications, OJ L 36/31.

28 Recital 7 of Reg. 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, OJ L 316/12.

29 *Ibid.*

30 Dec. 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, OJ L 218/82. Please note that, from a legal point of view, Dec. 768/2008/EC is what is referred to as a *sui generis* decision, meaning that it has no addressees. It constitutes a political commitment on the part of the European Parliament, the Council and the Commission. This means that for its provisions to apply in EU law, they have to be either referred to expressly in future legislation or integrated into it.

31 For further on this, see European Commission, 'The "Blue Guide" on the Implementation of EU Product Rules', 2014, pp. 35-36.

a reference to them is published in the Official Journal, create a presumption of conformity with the essential requirements set in the EU legislation, but remain, strictly speaking, voluntary. However, given the time and costs involved, producers often use them, as the system offers considerable advantages from a legal and a practical point of view for operators engaging in trading goods and services. This usage thereby creates, to a certain extent, de facto binding rules adopted by private bodies.³²

The European Standardization Bodies which, under the New Approach, are in charge of creating technical standards are the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI).³³ The European Standardization Bodies, which are private organizations subject to Belgian law, receive a mandate from the Commission (pursuant to Art. 10(1) of Reg. 1025/2012), which determines the tasks that the Commission assigns to the European Standardization Bodies.

2 *Legitimacy of Co-Regulation: Meroni, Its Limits and the Mechanisms of ex ante Control*

It has been argued that co-regulation in general, and standardization in particular, despite the above-mentioned advantages, can at the very least be questioned from the perspective of the *Meroni* doctrine.³⁴ As it is well known, this ruling serves to limit the possibility of delegation of powers in the EU legal system, and it requires that, in order to be lawful, delegation must be express, it must only concern clearly defined tasks of a non-discretionary nature and it must be subject to a strict system of control.

A very legalistic view of co-regulation, supported explicitly by the EU institutions,³⁵ and the standardization bodies themselves,³⁶ would maintain the idea that no delegation of powers takes place in the standardization process. This is because standards are voluntary and therefore economic operators can choose whether to apply them or follow the essential requirements mandated by the Directive in a different way. However, in reality, economic operators will find it difficult to comply with the essential requirements without the use of these standards, given the high costs they would incur in such situations. Moreover, Mem-

32 Hofmann *et al.*, 2011, p. 593.

33 See Ann. I of Reg. 1025/2012. The Regulation confers exclusivity to these bodies to create the standards. See further Schepel, 2005, p. 104 and Egan, 2001, p. 142.

34 Hofmann *et al.*, 2011, p. 247. Schepel, 2005, pp. 226-227; for an early account of these concerns, see J. Falke, 'Achievements and Unresolved Problems of European Standardization: The Ingenuity of Practice and the Queries of Lawyers', in C. Joerges, K.-H. Ladeur & E. Vos (Eds.), *Integrating Scientific Expertise into Regulatory Decisionmaking – National Traditions and European Innovations*, Baden-Baden, Nomos, 1997, p. 187.

35 See European Commission, 2014, p. 33. See also Recital 1 of Reg. 1025/2012, which states: "The primary objective of standardization is the definition of voluntary technical or quality specifications."

36 B. Schettini Gherardini, 'Harmonised European standards and the EU Court of Justice: Beware Not to Open Pandora's box', available at: <<http://europeanlawblog.eu/?p=3212>>.

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ber States are under EU law bound to respect the presumption of conformity. European standards, therefore, can hardly be seen a merely voluntary.

The perspective of the European courts on the legal effects of standards is not entirely clear: in a 2010 case,³⁷ an operator challenged a standard on the grounds of a breach of EU competition law. The operator alleged, inter alia, that the standard was de facto binding because it was largely dominating the market while the procedure for entering the market without following the standard was “time-consuming, slow, costly and its outcome uncertain”.³⁸ The General Court, however, took a rather legalistic perspective and did not uphold the applicant’s claim. A reading by analogy of a more recent Court of Justice ruling where the Court essentially subjected a standardization body to free movement rules would however indicate that, in fact, not even the judicial instances at the EU level believe in the ‘tale’ of voluntariness anymore.³⁹ Although not taken up in the subsequent court ruling, the Opinion of the Advocate General (AG) Campos Sánchez-Bordona in the *James Elliot* case also pleads for an application of the *Meroni* doctrine and defines the standards as “a case of controlled delegation of powers in favour of a private standardisation body”.⁴⁰

From the point of departure of a de facto binding force of the European standards, the application of the *Meroni* ruling would entail that delegation to the European Standardization Bodies is only possible if the powers are the result of an explicit delegation and of a clearly defined non-discretionary nature.⁴¹ However, extensive research on the standardization process has shown that European standards are not mere technical translations of political decisions made by Commission but entail a significant room of political judgment.⁴²

If it were to be concluded that the standardization process does not remain within the limits of lawful delegation, it could be argued that the lack of legitimate delegation from a strict *Meroni* perspective can perhaps be supplemented by adequate participation, so that affected stakeholders have a chance to ex ante influence the content of the outcome of the delegated process. In particular, the ‘autonomy perspective’ put forward by Schiek suggests the standardization as form of self-governance is to be supported for its potential to enhance self-deter-

37 Case T-432/05, *EMC Development AB v. Commission*, ECLI:EU:C:2011:203.

38 *Ibid.*, para. 110.

39 Case C-171/11 *Fra.bo SpA v. Deutsche Vereinigung des Gas- und Wasserfaches eV*, ECLI:EU:C:2012:453, commented by Schepel, 2013, p. 521, and especially, p. 525 *et seq.*; and by A. Crespo van de Kooij, ‘The Private Effect of the Free Movement of Goods: Examining Private-Law Bodies’ Activities under the Scope of Article 34 of the Treaty of the Functioning of the European Union’, *Legal Issues of Economic Integration*, Vol. 40, No. 4, 2013, pp. 363-374.

40 Opinion of Advocate General Campos Sánchez-Bordona in Case C-613/14, *James Elliott Construction Limited v. Irish Asphalt Limited*, ECLI:EU:C:2016:63. An analysis of the AG opinion is offered by M. Medzmariashvili, ‘Opening The ECJ’s Door To Harmonised European Standards?’, available at: <<http://europeanlawblog.eu/2016/03/01/opening-the-ecjs-door-to-harmonised-european-standards-opinion-of-the-ag-in-c-61314-james-elliott-construction-2/>>.

41 Case 9-56, *Meroni & Co., Industrie Metallurgiche, SpA v. High Authority of the European Coal and Steel Community*, ECLI:EU:C:1958:7.

42 Schepel, 2005, p. 256.

mination, provided, however, that there are mechanisms to safeguard legitimacy by participation of all stakeholders.⁴³

Eager to ensure that it is at least making an effort towards sufficient transparency and stakeholder participation, the EU has long required that the European standardization process be organized in an open and transparent way.⁴⁴ This point has been reinstated and emphasized by Regulation 1025/2012, which, in Article 5, requires that European standardization organizations “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”, also in the phase of the technical discussion of standardization proposals, the submission of comments on drafts and the revision of existing European standards.

Beyond these principled statements, the question is whether these provisions serve to ensure adequate participation. Even though theoretically participation is and should be open to all interests involved, it is doubtful as to whether groups of consumers and environmental associations can keep pace with the expertise and resources of industry interests.⁴⁵ This finding is certainly an argument supporting the need for judicial review of the standards: as participation is not sufficient for ‘weaker’ interests to be able to promote their views in the decision-making process leading to the adoption of the standards, they should have recourse to court to challenge the legality of the standards.

Apart from stakeholders’ participation in the decision-making process as such, EU institutions also have in principle several instruments at their disposal to control private rule-making in the form of standardization. The main aim of these controls is to check whether standards developed by the European Standardization Bodies comply with the essential requirements laid down in EU legislation, as well as to ensure adequate participation of the concerned parties.⁴⁶

Concerning the necessity to control the compliance of the standards with the essential requirements, the starting point, as mentioned above, is that the European Standardization Bodies receive a mandate from the Commission to draft the standards, with the actual relationship between the Commission and the European Standardization Bodies being of a contractual nature.⁴⁷ Because the Commission lacks the technical expertise to monitor the compliance of the standardization process carried out by the European Standardization Bodies with the essential requirements laid down in the Directive, it has come to rely on consul-

43 D. Schiek, ‘Private Rule-Making and European Governance – Issues of Legitimacy’, *European Law Review*, Vol. 32, No. 4, 2007, p. 456.

44 Recital 24 of Directive 98/34. On this point, see Schepel, 2005, pp. 244-246.

45 Egan, 2001, p. 211. It is interesting to note that in the case *EMC Development AB v. Commission* mentioned above, the applicant tried to plea for the recognition of a lack of sufficient participation and transparency in the standardization process. Unsurprisingly, these pleas were not upheld by the General Court which did not find sufficient evidence for these statements in the applicant’s submissions. This outcome makes one wonder whether a court is a suitable forum to judge and assess what sufficient participation and transparency are supposed to mean.

46 Hofmann *et al.*, 2011, p. 600.

47 See Art. 10(1) Reg. 1025/2012; Art. 7(1) Directive 89/106; Art. 3(2) of Dec. 768/2008; Schepel, 2005, p. 240.

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tants who monitor the works of the European Standardization Bodies and report to the Commission about possible shortcomings in the standards.⁴⁸

A reference to the technical standards produced by the European Standardization Bodies acting upon the mandate of the Commission will in the end be published in the 'C series' of the Official Journal in the form of a Commission Communication. Before the publication of the reference, the standards will not have any effect (*see* Art. R8 of Ann. I of Dec. 768/2008). Once the reference to the standards is published, it creates a presumption of conformity with the essential requirements of the relevant Directive. Between receipt of the standards and their publication, the Commission is entitled, at least in principle, to check whether "a harmonized standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation".⁴⁹ However, in practice, there is no control by the Commission, which as a rule does not review the adequacy of the standards.⁵⁰ This essentially means that the standards are not controlled by the Commission, which would seem to make the availability of judicial review all the more important as an adequate *ex ante* control by the Commission as mandate giver is not performed.

Another way to control the substance of technical standards is through the use of the so-called safeguard clauses. Article R9 of Annex I of Decision 768/2008 provides that all New Approach Directives have to provide a safeguard clause which can be invoked on the grounds that a standard does not comply with the essential requirements before or after the publication. This procedure has been recently modified by Regulation 1025/2012. Under the old regime, this procedure could be initiated by the Commission and the Member States, and it would trigger the intervention of the so-called "98/34 committee"⁵¹ which delivered an opinion on the matter after having consulted the relevant standardization body (Art. R9(1)(2)). The Commission itself could then decide

to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the Official Journal of the European Union (Art. R9(2)).

The biggest change introduced to this procedure by Article 11 of Regulation 1025/2012 is the possibility for the European Parliament, together with the Member States, to activate this procedure, taking this power away from the Commission. Furthermore, under the new regime, the committee assisting the Commission is to be set up by the corresponding Union harmonization legislation.

48 Hofmann *et al.*, 2011, p. 601.

49 Art. 10(6) of Reg. 1025/2012.

50 Schepel, 2005, p. 235. In fact, according to the Commission guidelines for the publication of references of standards in the Official Journal of the European Union "the Commission *should not* review the technical adequacy of the content of a standard" (emphasis added), D(2005) C2/MJE/IG - D (2005) 7049, p. 3.

51 This is a Committee consisting of representatives appointed by the Member States who could call on the assistance of experts or advisers; its chairman was a representative of the Commission.

Thirdly, the new Regulation separates the *ex ante* and *ex post* procedures (*i.e.* before or after the publication of a standard) according to different modalities provided for in the Comitology Regulation.⁵²

This procedure certainly does provide a certain control framework, as the publication of the standards (or their continued application as creating the presumption of conformity after the publication) can be blocked by a decision of the Commission upon application of the European Parliament or the Member States. However, first of all, the system leaves operators, consumers and consumer or environmental associations completely left out of the process, their only options being to convince their Member States to initiate the procedure. Secondly, the final decision as to the outcome of the safeguard procedure rests with the Commission, who has expressed concerns about this procedure, especially because of its limited resources. It has also suggested that an expert body be established to allow for a speedier analysis of the safeguard clauses.⁵³

C Standardization before the European Courts

I Introduction

Section B has shown that the standardization process is becoming increasingly important in the system of EU administrative governance, and, while strictly speaking not binding, it has *de facto* very important consequences for the EU operators. The analysis carried out above has also shown that *ex ante* control mechanisms in the standardization process exhibit several shortcomings. First of all, while legally mandated by the relevant legislation, it is doubtful whether *de facto* consumer or environmental organizations are able to influence the process and voice their concerns, in light of their comparative lower resources *vis-à-vis* the industry. While 'weaker' interests cannot effectively control the process, neither can the Commission, which, for lack of resources and knowledge, more often than not takes up the standards produced by the ESOs without further checks. Also during safeguard procedures, the lack of resources seems to prevent the European institutions from performing an adequate control, with operators and associations being completely left out of the process. Because of the limitations of the *ex ante* control of the standards, it seems necessary to establish whether the *ex post* judicial review of the process may compensate for these shortcomings or whether, instead, judicial review of the standardization process also presents worrisome gaps.

52 In the *ex ante* procedure, before the standards are published, the Committee gives an opinion under the advisory procedure, with the Committee taking a decision by simple majority, and the Commission being required to take 'utmost account' of the opinion. In the *ex post* procedure, once the standards are published in the Official Journal, the procedure requires the Committee to take a decision by qualified majority, and the Commission to follow that opinion. *See* Art. 11 in combination with Art. 22, Reg. 1025/2012, referring to Arts. 4 and 5 of Reg. 182/2011, OJ L 55/13.

53 Communication from the Commission enhancing the implementation of the new approach directives COM (2003) 240 final, p. 21.

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The presence of an adequate judicial review framework is important for several reasons. First of all, because the EU is a “Community based on the rule of law”,⁵⁴ of which the presence of an adequate judicial supervision is an essential corollary. Secondly, because of the principle of effective judicial protection, which is enshrined in Article 47 of the Charter of Fundamental Rights and has long been considered by the Court of Justice as a general principle on EU law, is binding on the EU and the Member States’ legal systems alike.⁵⁵ Thirdly, from the delegation of powers perspective and from the starting point that standardization entails the delegation of discretionary powers, an adequate set of judicial control mechanisms would render the standardization process compliant with the *ESMA* ruling.⁵⁶ In this case, the Court of Justice, somewhat loosening the *Meroni* requirements, concluded that the delegation of discretionary powers is allowed, if it is subject to adequate judicial supervision. Finally, one could argue that sufficient judicial control of the standardization process is necessary because the standards can affect health and the environment which are values protected by the EU and which the Court of Justice should therefore be able to protect.

In the following sections, the different acts arising out of the standardization process are set out and the possibility of judicial control is examined.

II *The Direct Challenge of a European Standard: Only for the Lucky Few?*

1 *Judicial Review before Publication in the Official Journal*

As discussed above, standards are first adopted by the ESOs and thereafter published on the Official Journal, at which point the presumption of conformity will start to apply. Regarding the possibility to challenge the standards as adopted by the ESOs and before their publication, the main hurdle will consist of the notion of ‘reviewable act’ at EU level.

Pursuant to Article 263 of the Treaty on the Functioning of the European Union (TFEU), which sets out the appropriate action (*i.e.* the action for annulment) in case of a possible challenge against a European standard, the Court may review the legality of acts ‘other than recommendations and opinions’. Under the case law developed before the Lisbon Treaty (and concerning the predecessor of Article 263 TFEU, *i.e.* Art. 230 EC), the scope of reviewability of EU measures was extended to “all measures adopted by the institutions, whatever their nature or

54 Case 294/83, *Les Verts v. Parliament*, ECLI:EU:C:1986:166, para. 23.

55 See *e.g.* Case C-279/09, *DEB Deutsche Energiehandels- und Beratungsgesellschaft mbH v. Bundesrepublik Deutschland*, ECLI:EU:C:2010:811; Case C-12/08, *Mono Car Styling SA, in liquidation v. Der-vis Odemis and Others*, ECLI:EU:C:2009:466, para. 49 (“whilst it is, in principle, for national law to determine an individual’s standing and legal interest in bringing proceedings, [EU] law nevertheless requires, in addition to observance of the principles of equivalence and effectiveness, that the national legislation does not undermine the right to effective judicial protection”). Further on this principle and its implications, see S. Prechal & R. Widdershoven, ‘Redefining the Relationship between “Rewe-effectiveness” and Effective Judicial Protection’, *Review of European Administrative Law*, Vol. 4, No. 2, 2011, pp. 31-50.

56 Case C-270/12, *United Kingdom of Great Britain and Northern Ireland v. European Parliament and Council of the European Union*, ECLI:EU:C:2014:18.

form, which are intended to have legal effects".⁵⁷ As far as private parties are concerned, they also need to prove that "the measure is binding on, and capable of affecting the interests of, the applicant by bringing a distinct change in his legal position".⁵⁸

The notion of 'reviewable act' will create an insurmountable hurdle for the challenge of a standard before its publication, firstly because a standard is not adopted by an EU institution, but is a document produced by a private party. Moreover, even if a broad notion of 'EU institutions' would be adopted, arguing that standardization bodies, although not being EU institutions, have received a clear mandate to act by a European institution, it would not be possible to claim that a such a measure is intended to have legal effects. The authority for this statement is contained in the *IBM* case in which the Court of Justice held that a measure is reviewable only if it is "definitively laying down the position of the Commission or the Council in the conclusion of [that] procedure, and not a provisional measure intended to pave the way for a final decision".⁵⁹

As the standards, once adopted, need to be referred to in a Commission Communication and published in the Official Journal, in application of the *IBM* case law, standards will not constitute reviewable acts under Article 263 TFEU and will, therefore, not be challengeable before the European courts, neither by Member States nor by natural and legal persons.

2 Judicial Review after Publication in the Official Journal

As discussed above, a reference to the standards is published in the Official Journal in the form of a Commission Communication, at which point the presumption of conformity and the duty for the Member States to respect it starts to apply. Therefore, in application of the *IBM* case law discussed above, it would be possible to state that the standards constitute a reviewable act as they are intended to produce legal effects, namely, to impose the presumption of conformity onto the Member States.⁶⁰ However, it is far from self-evident that a standard will be considered as an act of the European institutions for the purposes of review under Article 263 TFEU, as they are, technically, still acts of private bodies, although 'endorsed' by the European Commission through a publication of the reference to the standards in a Commission Communication.

This is because, as noted by Scott in the context of post-legislative guidance, in order to be reviewable, a measure needs to be an act adopted by the European institutions pursuant to Article 263 TFEU, and it is likely that guidance documents, which have been adopted jointly by the Commission and the Member

57 Case 22-70, *Commission of the European Communities v. Council of the European Communities*, (ERTA) ECLI:EU:C:1971:32, para. 42.

58 Case 60/81, *International Business Machines Corporation v. Commission of the European Communities*, ECLI:EU:C:1981:264, para. 9.

59 *Ibid.*, para. 10.

60 For the same conclusion but a different line of reasoning, see Schepel, 2013, p. 531.

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States, will not meet this criterion.⁶¹ This line of reasoning can also be extended to the standardization process, as in this case the Commission publishes the references to the standards in a Communication, but is in essence not the author of the content of the measure.⁶²

In the recent *James Elliot* case, the AG advised in favour of the Court's jurisdiction to rule on the interpretation of a standard as an 'act of the EU institutions' on the basis of the links between the New Approach Directives and the ensuing standards, as well as the links between the ESOs and the Commission.⁶³ If this opinion had been followed by the Court, there would have been a much more certain case to make for reviewability of standards also under Article 263 TFEU, as an equal line of reasoning could have been applied to the reviewability of standards in direct actions. Instead, the Court reached the same conclusion but through a different line of reasoning: the Court indeed rejected the possibility to attribute the standards to any European institutions and admitted the reviewability of the standards because they "are by their nature measures implementing or applying an act of EU law".⁶⁴ This statement, in combination with the fact that the supporting case law cited is only applicable to preliminary rulings of interpretation under Article 267 TFEU, seems to close the door on the direct reviewability of standards.

Even if the reviewable act test was to be met, automatic standing will only be granted to the Member States as they are, under Article 263 TFEU, privileged applicants and therefore capable of challenging any EU measure without the need to prove any specific link the measure itself. It has been argued that, in practice, this is not likely to happen.⁶⁵

With regard to a private party, pursuant to Article 263 TFEU, he may be able to gain standing in an action for annulment only in three situations, *i.e.* if he is the addressee of the measure, if the measure is of individual and direct concern to him or if he is challenging a regulatory act which does not entail implementing measures and which is of direct concern to him. The concept of 'regulatory act' is not defined in the list of instruments contained in Article 288 TFEU. The European courts have defined it to be a non-legislative measure of general application,⁶⁶ *i.e.* a measure which is not adopted following the ordinary or special

61 J. Scott, 'In Legal Limbo: Post-Legislative Guidance as a Challenge for European Administrative Law', *Common Market Law Review*, Vol. 48, No. 2, 2011, p. 337; *see also* E. Korkea-aho, *Adjudicating New Governance*, London, Routledge, 2015, pp. 173-174.

62 For a different opinion, *see* H. Schepel, who instead maintains that "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 Art. 263 TFEU". *See* Schepel, 2013, p. 531.

63 Case C-613/14, *James Elliott Construction Limited v. Irish Asphalt Limited*, ECLI:EU:C:2016:63.

64 *Ibid.*, para. 34.

65 Hofmann *et al.*, 2011, p. 603.

66 *See* case C-583/11 P, *Inuit Tapiriit Kanatami and Others v. European Parliament and Council of the European Union*, ECLI:EU:C:2013:625. For a discussion of the case law leading up to this ruling, *see* H. Roer-Eide & M. Eliantonio, 'The Meaning of Regulatory Act Explained: Are There Any Significant Improvements for the Standing of Non-Privileged Applicants in Annulment Actions?', *German Law Journal*, Vol. 14, 2013, available at: <www.germanlawjournal.com/index.php?pageID=11&artID=1581>.

legislative procedures within the meaning of paragraphs 1 to 3 of Article 289 TFEU, whether adopted by the Commission or not.⁶⁷

The Communication which contains the reference to a standard can be considered a regulatory act, as it is a measure adopted following a different decision-making process than those contained in Article 289 TFEU. However, it is doubtful whether the direct challenge of a standard by a private party would fall within the third situation mentioned above, because of the existence of 'implementing measures'.⁶⁸ In the light of the case law of the European Courts,⁶⁹ an implementing measure is any measure taken by the Member States and which is linked to the European measure at stake. As the standards always need to be 'translated' into national standards for their definitive application, it is highly doubtful that the Court would admit a claim against a European standard as a 'regulatory act not entailing implementing measures'.

Nor will it be possible to argue that the national standards constitute a mere 'copy-paste' of the European standards, as the Court of Justice has remarked on several occasions that

the question whether the contested [measure] leaves any discretion to the national authorities entrusted with the task of implementing it is not relevant for the purposes of determining whether the contested [measure] entails implementing measures.⁷⁰

As a consequence, private parties wishing to challenge European standards in an action for annulment need to prove that they are individually and directly concerned.

The Court of Justice has consistently held that a measure is of direct concern only if it affects the applicant's legal position directly and it leaves no discretion to the addressees of the measure who are entrusted with its implementation. In other words, a direct link between the challenged measure and the loss or damage that the applicant has suffered must be established.⁷¹ Moreover, the implementation must be automatic and result from EU rules without the application of other intermediate rules. If the measure leaves national authorities of the Member

67 Case T-93/10, *Bilbaina de Alquitranes, SA, and Others v. European Chemicals Agency*, ECLI:EU:T:2013:106, paras. 55-59.

68 Harm Schepel is, in my view, neglecting this point when concluding that European standards will be able to profit from the 'regulatory act' exception in a direct action. See Schepel, 2013, pp. 531-532.

69 C-274/12 P, *Telefónica SA v. European Commission*, ECLI:EU:C:2013:852.

70 Case T-134/10, *Fédération européenne de l'industrie du sport (FESI) v. Council of the European Union* ECLI:EU:T:2014:143; case T-381/11 *Eurofer v. Commission*, ECLI:EU:T:2012:273, para. 59; case T-551/11 *BSI v. Council of the European Union*, ECLI:EU:T:2012:273, para. 56.

71 Cases 41-44/70 *NV International Fruit Company and others v. Commission of the European Communities* ECLI:EU:C:1971:53; case 207/86 *Asociación Profesional de Empresarios de Pesca Comunitarios (Apesco) v. Commission of the European Communities*, ECLI:EU:C:1988:200, para. 12. More recently, case C-417/04 P *Regione Siciliana v. Commission of the European Communities* ECLI:EU:C:2006:282.

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States a degree of discretion as to how the measure should be implemented, the applicant will not be considered directly concerned.⁷²

Direct concern will likely not be an issue in a direct challenge against European standards, at least for operators, since the publication of these standards and the presumption of conformity this publication creates are certainly capable of affecting the legal sphere of an operator. However, what certainly stands in the way of any challenge of a European standard by any private party is the requirement to show individual concern.

The definition of individual concern was first given in the *Plaumann* case⁷³ and is still the reference for determining 'individual concern'. In this case, the Court of Justice established that private parties are able to seek judicial review of decisions not expressly addressed to them only if they can distinguish themselves from all other persons, not only actually but also potentially. In other words, the applicants must show that the decision

affects them by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and by virtue of these factors distinguishes them individually just as in the case of the person addressed.⁷⁴

As a result, individual concern cannot be established when the applicant operates a trade which could be engaged in by any other person at any time. In particular, the applicant has to show, according to the case law developed by the Court of Justice, that, at the time when the decision was adopted, it belonged to a so-called 'closed class', which is differently affected by the EU measure than all other persons.⁷⁵

72 See e.g., case 69/69 *SA Alcan Aluminium Raeren and others v. Commission of the European Communities*, ECLI:EU:C:1970:53; case 222/83 *Municipality of Differdange and Others v. Commission of the European Communities*, ECLI:EU:C:1984:266.

73 Case 25-62, *Plaumann & Co. v. Commission of the European Economic Community*, ECLI:EU:C:1963:17.

74 *Ibid.*, p. 107.

75 E.g. *Joined cases 106 and 107-63, Alfred Toepfer and Getreide-Import Gesellschaft v. Commission of the EEC*, ECLI:EU:C:1965:65.

The *Plaumann* test constitutes a very restrictive approach to individual standing, which has sparked a vast amount of academic debate and criticism,⁷⁶ and has been challenged even from within the EU courts.⁷⁷

Concerning specifically claims brought by associations, these actions have only been considered admissible in three cases:⁷⁸ (a) when a legal provision grants procedural rights to these associations;⁷⁹ (b) where every single member of the association would be directly and individually concerned;⁸⁰ and (c) where the association's interests, and especially its position as a negotiator, is affected by the measure.⁸¹

These requirements have made it almost impossible for associations to ever succeed in showing individual concern given that the cases under (a) are rare and the cases under (b) are as difficult (if not more so) to be successful as cases con-

- 76 For criticism on the standing requirements of individual applicants, *see, ex multis*, A. Ward, 'Locus Standi under Article 230(4) of the EC Treaty: Crafting a Coherent Test for a Wobbly Polity', *Yearbook of European Law*, Vol. 22, No. 1, 2003, p. 45; A. Arnulf, 'Private Applicants and the Action for Annulment since Codorniu', *Common Market Law Review*, Vol. 38, No. 1, 2001, p. 7; J.M.M. Cortés, 'Ubi ius, Ibi Remedium? Locus Standi of Private Applicants under Article 230(4) EC at a European Constitutional Crossroads', *Maastricht Journal of European and Comparative Law*, Vol. 11, 2004, p. 233; A. Abaque de Parfouru, 'Locus Standi of Private Applicants under the Article 230 EC Action for Annulment: Any Lessons to be Learnt from France?', *Maastricht Journal of European and Comparative Law*, Vol. 14, No. 4, 2007, p. 361; A. Cygan, 'Protecting the Interests of Civil Society in Community Decision-making: The Limits of Article 230 EC', *International and Comparative Law Quarterly*, Vol. 52, No. 4, 2003, p. 995; X. Lewis, 'Standing of Private Claimants to Annul Generally Applicable European Community Measures: If the System is Broken, where Should it be Fixed?', *Fordham International Law Journal*, Vol. 30, No. 5, 2006-2007, p. 1496; A. Albors-Llorens, 'Sealing The Fate of Private Parties in Annulment Proceedings? The General Court and the New Standing Test on Article 263(4) TFEU', *Cambridge Law Journal*, Vol. 71, No. 1, 2012, p. 52.
- 77 Opinion of Advocate General Jacobs in case C-50/00 P *Unión de Pequeños Agricultores v. Council of the European Union* ECLI:EU:C:2002:197; Case T-177/01 *Jégo-Quéré & Cie SA v. Commission of the European Communities* ECLI:EU:T:2002:112.
- 78 Case C-321/95 P *Stichting Greenpeace Council (Greenpeace International) and Others v. Commission of the European Communities* [1998] ECLI:EU:C:1998:153; Case T-122/96 *Federazione nazionale del commercio oleario (Federolio) v. Commission of the European Communities* [1997] ECLI:EU:T:1997:142.
- 79 Case C-191/82 *EEC Seed Crushers' and Oil Processors' Federation (FEDIOL) v. Commission of the European Communities* [1983] ECLI:EU:C:1983:259; Case T-12/93 *Comité Central d'Entreprise de la Société Anonyme Vittel and Comité d'Etablissement de Pierval and Fédération Générale Agroalimentaire v. Commission of the European Communities* [1995] ECLI:EU:T:1995:78.
- 80 Joined Cases T-447/93, T-448/93 and T-449/93 *Associazione Italiana Tecnico Economica del Cemento and British Cement Association and Blue Circle Industries plc and Castle Cement Ltd and The Rugby Goup plc and Titan Cement Company SA v. Commission of the European Communities* [1995] ECLI:EU:T:1996:174; Case T-380/94 *Association internationale des utilisateurs de fils de filaments artificiels et synthétiques et de soie naturelle (AIUFFASS) and Apparel, Knitting & Textiles Alliance (AKT) v. Commission of the European Communities* [1996] ECLI:EU:T:1996:195; Case T-229/02 *Osman Ocalan acting on behalf of Kurdistan Workers' Party (PKK) v. Council of the European Union* [2008] ECLI:EU:T:2008:87.
- 81 Joined Cases C-67/85 R, 68/85 R and 70/85 R *Kwekerij Gebroeders van der Kooy BV and others v. Commission of the European Communities* [1985] ECLI:EU:C:1985:173; Case T-84/01 *Association contre l'horaire d'été (ACHE) v. Council of the European Union and European Parliament* [2002] ECLI:EU:T:2002:5.

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cerning individuals, given the strict interpretation of the *Plaumann* formula. Successful cases under (c) are also not very common since the Court of Justice has held that the test to be met is that the position of the association as negotiator is clearly defined and must be related to the subject matter of the contested act, and that that position must have been affected by the adoption of the contested act.⁸² The fact that an association has communicated information to an EU institution or has tried to influence the position adopted by the national authorities in the EU legislative procedure has been regarded to not suffice in itself to show that the act adopted affects an association in its position as a negotiator.⁸³

In the application of the *Plaumann* test, and the case law concerning associations, it is highly doubtful that private parties, such as a legal person or an operator, as well as associations purporting to protect consumers or environmental interests, would be considered individually concerned. As far as natural or legal persons are concerned, it will be very hard for them to prove that they are affected by a certain European standard differently than all other individuals engaged in the same trade, as standards are indistinctly applicable to all the traders in a certain field.

Similarly, associations of operators, consumers or environmental associations alike will not be able to prove individual concern, as their members, in application of the *Plaumann* doctrine, cannot be considered individually concerned. Moreover, they will not be able to show that the relevant provisions leading to the adoption of a standard grant them a special position as negotiators nor specific procedural rights, as Article 5 of Regulation 1025/2012 only requires that European standardization organizations 'encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders'. These conclusions are supported by the *Schmoldt* case, in which a private individual, a company active in the sector of the challenged standard and an association protecting the interests of the operators in that sector were all denied individual concern in a claim against a safeguard decision of the Commission. Although concerning a different type of decision adopted in the context of the standardization process, the considerations made by the Court on the concept of individual concern are equally applicable to a case of direct challenge against a standard. This case law is analysed in the next section.

III *The Direct Challenge of a Safeguard Decision of the Commission: No More Than the Lucky Few*

Member States, as well as natural and legal persons, may also want the challenge the Commission decision taken at the end of a possible safeguard procedure.

82 Case C-106/98 P *Comité d'entreprise de la Société française de production, Syndicat national de radio-diffusion et de télévision CGT (SNRT-CGT), Syndicat unifié de radio et de télévision CFDT (SURT-CFDT), Syndicat national Force ouvrière de radiodiffusion et de télévision and Syndicat national de l'encadrement audiovisuel CFE-CGC (SNEA-CFE-CGC) v. Commission of the European Communities* ECLI:EU:C:2000:277, para. 45.

83 Case T-391/02 *Bundesverband der Nahrungsmittel- und Speiseresteverwertung eV and Josef Kloh v. European Parliament and Council of the European Union* ECLI:EU:T:2004:138; T-264/03 *Jürgen Schmoldt and Others v. Commission of the European Communities* ECLI:EU:T:2004:157.

On the basis of the *IBM* case law, this decision will constitute a reviewable act, as it is intended to produce legal effects, and could therefore be challenged under Article 263 TFEU. Member States will consequently be able to challenge it in their position as privileged applicants.

Natural and legal persons, however, will not be able to challenge this Commission decision for lack of individual concern. While it is true that, in application of the *Inuit* case law, the Commission decision qualifies as a 'regulatory act' for the purposes of Article 263(4) TFEU, private parties will not be able to be dispensed from the need to prove individual concern. Indeed, similarly to what has been concluded above concerning the publication of the standards, also with regard to a possible challenge against a safeguard decision, the Court of Justice will likely find that the contested measure entails implementing measures (in the form of the national – modified, if applicable – standards), therefore individual concern will need be proven. The *Schmoldt* case law⁸⁴ discussed below shows that this is quite likely an insurmountable obstacle for private parties.

In this case, the Commission had adopted a Decision⁸⁵ not to withdraw a set of standards on the basis that they did not fail to meet essential substantive requirements laid down in a New Approach Directive. The contested Decision stated that information received in the course of consultations with the CEN, which was responsible for drawing up the standards in question, and with the relevant Standing Committee, disclosed no evidence of the alleged risk associated with the standards in question.

The first applicant, Mr. Schmoldt, was chair of that part of CEN, which is responsible for the adoption of the standards in question. Nonetheless, he disagreed with the Commission's Decision not to withdraw these standards and attempted to challenge the legality of that Decision. The General Court denied standing, based on the fact that the applicant could not prove to be individually concerned. The Court reasoned that the decision at stake was a measure of general application, as it concerned "all producers and users of construction products within the European Union".⁸⁶ Concerning the specific position of the applicant, in relation to the *Plaumann* criterion, the Court stated that the fact that a person participates, in one way or another, in the process leading to the adoption of a Community act does not distinguish him individually in relation to the act in question unless the relevant Community legislation has laid down specific procedural guarantees for such a person. However, in the present case, procedural guarantees were laid down for the benefit of the CEN and the relevant Standing Committee, not personally for specific members or the chairmen of those bodies.⁸⁷

84 Case T-264/03, *Jürgen Schmoldt and Others v. Commission of the European Communities* ECLI:EU:T:2004:157.

85 Commission Decision 2003/312/EC of 9 April 2003 on the publication of the reference of standards relating to thermal insulation products, geotextiles, fixed fire-fighting equipment and gypsum blocks, OJ L-114/50.

86 Case T-264/03, *Jürgen Schmoldt and Others v. Commission of the European Communities*, ECLI:EU:T:2004:157, para. 93.

87 *Ibid.*, paras. 100-101.

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A second applicant, one of the major operators in the field, was also considered by the General Court not to have individual concern, as it was concerned by the contested Decision only by reason of its objective status as an economic operator manufacturing the products to which the standards related, in the same way as any other economic operator in the same situation. The Court concluded, on the basis of its prior case law, that that status alone is not sufficient to establish that the company was individually concerned by the contested Decision.⁸⁸ The Court did not accept either the proposition that the applicant is more distinguished individually by the fact that it was one of an identifiable number German undertakings which would be affected by the standards.⁸⁹

Having considered Mr. Schmoldt and the company he was the manager of to not be individually concerned for the purposes of Article 264(3) TFEU, the third question answered by the General Court was whether a national association representing the relevant industry sector in Germany could be considered individually concerned. Also in this case, the Court considered that there was no individual concern. First of all because, in the Court's view, an association cannot be considered individually concerned if its members are not individually concerned: since neither the second applicant (*i.e.* the company Mr. Schmoldt was the head of) nor other members of the national association could be considered individually concerned, neither could the association.⁹⁰

Moreover, the Court argued that while it is true that, according to the European Courts' case law, an association which is not the addressee of a contested act has a particular interest in bringing an action for annulment of the act, even where its members may not do so individually, in the present case, the procedure at stake does not require that national associations could exercise any rights or even be entitled to be heard. Therefore, the association could not rely on an individual interest distinct from that of its members to justify its entitlement to bring proceedings nor on its position as negotiator in the process.⁹¹

This case clearly shows that, because of the strict interpretation of individual concern, the standardization process remains, as of today, immune from judicial review at the EU level. This could be regarded not only as a threat to the rule of law and the principle of effective judicial protection but also a missed opportunity for the European Courts to emphasize the importance of participation in the standardization process.⁹²

IV The Indirect Route to the Challenge of a European Standard and Its Limitations

In the system of remedies created by treaties, EU measures can, in principle, be challenged not only directly through an action for annulment provided under Article 263 TFEU but also indirectly, *i.e.* through a question of validity, by bringing an action against a national measure and challenging the validity of the

88 *Ibid.*, para. 110.

89 *Ibid.*, paras. 111-112.

90 *Ibid.*, paras. 127-130.

91 *Ibid.*, paras. 131-139.

92 J. Scott & S.P. Sturm, 'Courts as Catalysts: Rethinking the Judicial Role in New Governance', *Columbia Journal of European Law*, Vol. 13, No. 3, 2007, p. 581.

underlying EU measure in the national proceedings. In the case of the standardization process, EU standards could be indirectly challenged before national courts through the use of Article 267 TFEU.

As a matter of fact, in the *Schmoldt* case considered above, after having dismissed the admissibility of a direct action, the Court went further and considered whether the lack of standing would create a gap in the system of judicial protection of the EU legal system. In this context, the EU reiterated the usual 'mantra' of the existence of a 'complete system of remedies', according to which, where natural or legal persons cannot directly challenge EU measures of general application, they are able to plea the invalidity of such acts before the national courts and ask them, since they have no jurisdiction themselves to declare those measures invalid,⁹³ to make a reference to the Court of Justice for a preliminary ruling in this regard.

This means that an operator or association would, in principle, be able to challenge a national standard before a national court and, thereby, ask the national court to refer a question of validity of the underlying European standard. The Court of Justice, in the recent *James Elliot* case, appears to have cast doubt on whether this system is actually workable in practice. As mentioned above, the Court of Justice seems to only have opened the door to preliminary questions of interpretation under Article 267 TFEU, and not to questions of validity.

Moreover, even if the Court had followed the reasoning of the AG in that standards ought to be considered as acts of the EU institutions and may therefore be subject to a preliminary question of validity under Article 267 TFEU, the system of indirect challenges cannot be considered an adequate substitute for a direct action under Article 263(4) TFEU. This can be best explained by reference to AG Jacobs' opinion on the *UPA* case.⁹⁴ In particular, he recalled that access to the Court of Justice via the preliminary reference procedure is not available to applicants as a matter of right, since national courts (with the exclusion of courts of last instance) may refuse to refer a question of validity of an EU measure to the Court or might err in their assessment of the validity of the measure and decline to refer a question to the Court on that basis.⁹⁵ Furthermore, even where a reference is made, the preliminary questions are formulated by the national courts, with the consequence that applicants' claims might be redefined or that the questions referred might limit the range of measures whose validity is being challenged before the national court.⁹⁶ Finally, the AG considered that proceedings brought before a national court are more disadvantageous for individuals compared to an action for annulment under Article 263 TFEU, since they involve delays and extra costs.⁹⁷

93 Case 314/85, *Foto-Frost v. Hauptzollamt Lübeck-Ost*, ECLI:EU:C:1987:452.

94 Opinion of AG Jacobs in Case C-50/00 P, *Unión de Pequeños Agricultores v. Council of the European Union*, ECLI:EU:C:2002:197.

95 *Ibid.*, para. 42.

96 *Ibid.*

97 *Ibid.*, para. 44.

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D Conclusion

“European standardisation is a voluntary activity of building consensus in order to create technical specifications that is carried out by, and for, all interested parties.” “Industry is a key player.” “The participation of ‘societal’ stakeholders in the standardisation process brings a strong and important dimension of accountability. ANEC, ETUI and ECOS play important roles in European standardisation. These parties represent consumer, trade union and environmental interests.”⁹⁸ These quotes, extracted from the Commission website, exemplify the way in which the EU institutions wish to portray the standardization process: entirely voluntary and fairly participative.

“ECOS welcomed the adoption of Regulation (EU) No 1025/2012 on European standardisation, which aims to modernise and improve the European standards’ setting process, speeding it up and making it more transparent and inclusive.” “In reality however, ECOS regrets that the system does not currently guarantee such effective participation of societal stakeholders, neither at European nor national level.” “ECOS advocates for a truly inclusive and transparent standards’ setting process which delivers standards reflecting societal and environmental interests most appropriately.”⁹⁹ Quite clearly, the view of the organization protecting environmental interests begs to differ from the Commission’s view of inclusiveness and participation.

Indeed, the analysis carried out above has shown that, although co-regulation in general and standardization in particular have become important regulatory instruments in EU administrative governance in many policy fields and represent an effective method to harmonize the technical barriers hindering free movement of goods, the system does not ensure adequate participation of all relevant stakeholders. This lack of effective *ex ante* control makes the availability of judicial review all the more important. This is also true in light of the requirements set in the *ESMA* ruling for the existence of a ‘controlled’ process of delegation, and, in general, the EU need to respect the rule of law and comply with the principle of effective judicial protection.

However, this article has shown that judicial review of European standards is hindered by considerable hurdles. Before publication, standards are not reviewable before the European courts, because they do not qualify as a ‘reviewable act’ for the purposes of Article 263 TFEU. After publication, it is not entirely straightforward to see standards as acts of the European institutions, since, although a reference to the standards is included in a Commission Communication and published in the C series of the Official Journal, they remain the product of a private organization. If this test was nevertheless to be met, as suggested by the AG in

98 The quotes in this paragraph are retrieved from <http://ec.europa.eu/enterprise/policies/european-standards/key-players/index_en.htm>. See also Art. 5 of the General Guidelines for the cooperation between the ESOs and the Commission of 28 March 2003, which portrays the standardization systems as a “a transparent legal and political framework for European standardisation as an independent, consensus-oriented and voluntary activity”, available at: <ftp://ftp.cencenelec.eu/EN/EuropeanStandardization/Guides/4_CENCLCGuide4.pdf>.

99 The quotes in this paragraph are available at: <<http://ecostandard.org/?cat=123>>.

the *James Elliot* case, standards would in principle be reviewable because they are intended to produce legal effects, and can be challenged by the Member States. The same conclusion can be drawn for Commission decisions adopted in the end of a safeguard procedure. However, the Court's ruling does not seem to suggest that this is a viable option.

Furthermore, a direct challenge by private parties of either a standard or a safeguard decision will not be admissible for lack of individual concern, as the *Plaumann* criterion requires a private applicant to show that it is affected by the challenged measure in a unique fashion. The more relaxed standing test applicable to 'regulatory acts' (which does not require the proof of individual concern) will not help direct challenges because regulatory acts can only profit from the more liberal standing test if they do not entail 'implementing measures'. As European standards always require to be translated into national standards, the European courts will likely consider the latter to be implementing measures for the purposes of Article 263(4) TFEU and consequently declare the challenge by a private party as inadmissible.

The only judicial review avenue left for operators or associations would then be a challenge of a national standard before a national court, coupled with a preliminary question of validity (of the underlying European standard) sent by that national court to the Court of Justice under Article 267 TFEU. However, the *James Elliott* case does not seem to make this alternative a viable one. Furthermore, a preliminary question of validity cannot be considered an effective remedy in light of the additional time and costs it would entail and the discretion left to national courts to actually send the question.

In conclusion, despite the clear advantages offered by co-regulation in terms of effectiveness of delivery of European policy and its institutional support provided by the Better Regulation Agenda, the participatory possibilities of stakeholders in the standardization process does not ensure sufficient ex ante control and the current system of judicial protection does not fully respect the principle of effective judicial protection.