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Functional Participation in EU Delegated Regulation: Lessons from the United States at the EU's “Constitutional Moment”

STIJN SMISMANS*

INTRODUCTION

“Delegated regulation,” “delegated legislation,” “administrative rulemaking,” or “regulatory implementation” are well-known phenomena in modern democracies. Given the complexity of contemporary societies and the broad range of issues (often of a technical nature) in which the state intervenes, regulation cannot entirely be assured by normal legislative procedure, as this is too cumbersome, not flexible enough to adapt to rapidly changing conditions, and often not able to integrate the necessary technical expertise. Legislation will, therefore, delegate part of the regulatory process to less cumbersome bodies. Yet while delegated regulation is a general practice, and while its necessity is generally acknowledged, it has not been an easy task to make it fit with the dominant understanding of democracy in which parliament would adopt all measures of a generally binding nature, whereas a “neutral bureaucracy” would ensure the application of the general rule to the specific case.

There are considerable differences in the way the United States and the European Union (EU) deal with delegated regulation and how they conceptualize the legitimacy of such regulatory procedures beyond the normal legislative road. In the United States, delegated regulation is the resort of independent regulatory agencies, and the legitimacy of such administrative rulemaking has been thought of mainly in terms of legislative mandate, due process, and participatory rights guaranteed by judicial review. In the EU, delegated regulation is mainly adopted through the so-called comitology procedures, where regulatory powers are not delegated to independent agencies, but are exercised by the European Commis-

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sion¹ in interaction with a comitology committee that is composed of representatives from the national administrations, with, in certain cases, the final option that the Council may decide the issue.² Comitology has raised questions from a democratic point of view, in particular because it takes part of the regulatory process out of the hands of the European Parliament. Yet, in contrast to their place in the United States, the ideas of participatory rights, due process, and judicial review have not found a prominent place in European political and institutional discourse regarding the legitimacy of comitology and delegated regulation. Rather, it is argued that the legitimacy of European delegated regulation resides in the fact that indirect, territorial representation by way of Member States' representatives in the comitology committee, and the Council, could compensate for the lack of parliamentary involvement. However, participatory processes for civil society organizations, stakeholders, or interest groups can and, to a certain extent, already do play a role in EU delegated regulation. Moreover, in the context of the reforms introduced by the Constitutional Treaty (still to be ratified), such functional participation³—combined with judicial review—may become more important in guaranteeing the legitimacy of delegated regulation.

1. Implementation of European legislation is primarily the task of the Member States. CONSOLIDATED VERSION OF THE TREATY ESTABLISHING A EUROPEAN COMMUNITY art. 10, Dec. 24, 2002, O.J. (C 325) 33 (2002) [hereinafter EC TREATY]. According to Article 202 of the treaty, the Council may only “in specific cases” reserve the right to directly exercise implementing powers. Most implementation by Community Institutions thus results from the other option of Article 202, namely that the Council can confer on the Commission the power to implement legislation and may impose certain requirements with respect to the exercise of this power. *Id.* art. 202.

2. There are different comitology procedures, as set out in the Comitology Decision 87/373/EEC as replaced by Council Decision 1999/468/EC, laying down the procedures for the exercise of implementing powers conferred on the Commission. 1999 O.J. (L 184/23), *corrigendum* in 1999 O.J. (L 269/45). One can mainly distinguish between advisory committee procedure, management committee procedure, and regulatory committee procedure (including, though, different variants). On the basic features of comitology, see Ellen Vos, *EU Committees: The Evolution of Unforeseen Institutional Actors in European Product Regulation*, in EU COMMITTEES: SOCIAL REGULATION, LAW AND POLITICS 19, 19–22 (Christian Joerges & Ellen Vos eds., 1999) [hereinafter EU COMMITTEES]; Georgh Haibach, *The History of Comitology*, in DELEGATED LEGISLATION AND THE ROLE OF COMMITTEES IN THE EC 185 (Mads Andenas & Alexander Türk eds., 2000); Koen Lenaerts & Amaryllis Verhoeven, *Towards a Legal Framework for Executive Rule-Making in the EU? The Contribution of the New Comitology Decision*, 37 COMMON MKT. L. REV. 645–86 (2000).

3. To overcome the opposition between concepts such as interest groups, civil society organizations, and stakeholders, I use the concept of “functional participation.” As opposed to “territorial representation,” on the basis of a territorially defined electoral mandate, “functional participation” refers to the participation of organized groups in policymaking. For a more detailed justification of mmm

This article is divided into four parts. In the first section, I will show that there is a gap between the discourse on the democratic (or undemocratic) nature of comitology and the more recent European institutional discourse on the relevance of civil-society participation in European policymaking. In the second section, I will analyze how—despite the lack of attention in institutional and academic discourse on this issue—in some cases civil-society participation has been institutionalized in delegated regulation, and will argue that this may function as an additional source of legitimacy. In the third section, I will analyze whether, according to the case law of the European Court of Justice (ECJ), there is a place for judicial review ensuring such functional participation. Finally, in section four, I will describe how the current constitutional debate may change the picture of delegated regulation. I will argue that, if the proposals made by the Constitutional Treaty are implemented, there may be a further increasing role for functional participation as an additional source of legitimacy in delegated regulation, including a desirable, stronger judicial review by the Court on such participation, which could bring the EU model of delegated regulation closer to the U.S. version.

I. COMITOLGY AND CIVIL-SOCIETY PARTICIPATION: TWO SEPARATE DISCOURSES

The legitimacy of comitology was initially questioned by the European Parliament, which saw itself bypassed in its regulatory procedures. As early as 1984, the European Parliament (EP) adopted a resolution⁴ that strongly criticized the procedures for adaptation to technical and scientific progress based on comitology. According to the report of the Legal Affairs Committee⁵ preparing that resolution, such procedures allow the Commission “to enact measures of considerable economic and political importance without Parliament’s being given any

the use of this concept building on theories of functional democracy and functional representation, see STIJN SMISMANS, *LAW, LEGITIMACY AND EUROPEAN GOVERNANCE: FUNCTIONAL PARTICIPATION IN SOCIAL REGULATION* 42–48 (2004). I limit the concept to the participation of interest groups or associations and do not include other forms of participation beyond territorial representation, such as participation of “independent experts” or of representatives from national administrations.

4. Resolution on Committees for the Adaptation of Directives to Technical and Scientific Progress, 1984 O.J. (C 172/76).

5. Report of the Legal Affairs Committee on Committees for the Adaptation of Directives to Technical and Scientific Progress, EUR. PARL. DOC. (1-205/84) (1984).

opportunity to exercise its Treaty-enshrined duty of supervision; in effect, the [comitology] committees exercise powers which in the general scheme of the Treaties are conferred on the European Parliament.” The EP consequently proposed that it be involved in the implementation procedure, and requested that the Commission and Council should refrain from setting up additional committees. Several factors, however, pushed the Community in the other direction. The single-market project on the one hand, and dissatisfaction with the “harmonization strategy” and the limits of mutual recognition on the other hand, contributed to an intensive European regulatory strategy in which legislation often sets out only the general principles, whereas implementation measures—via comitology procedures—deal with the technical details.⁶

Also, in the academic literature, the normative debate on comitology has mainly been phrased with reference to parliamentary representation and accountability. Thus, scholars have primarily focused on comitology as an issue that raises problems of delegation and institutional balance.⁷ In addition, the political science literature on the role of committees in EU policymaking more broadly increased awareness of the lack of transparency of delegated regulation. Against this gloomy picture, Christian Joerges and Michelle Everson developed their model of “deliberative supranationalism.”⁸ This model counters the dominant negative image of comitology procedures and instead sees comitology as a deliberative structure that, on the one hand, ensures that risk regulation in a multilevel polity takes into account “national concerns,” and on the other hand, strips the defense of national sectarian interests by replacing negotiation with a process of persuasion and argument. The legitimacy of the comitology proce-

6. See Josef Falke, *Achievements and Unresolved Problems of European Standardization*, in *INTEGRATING SCIENTIFIC EXPERTISE INTO REGULATORY DECISION-MAKING* 187, 187 (Christian Joerges et al. eds, 1997) (discussing the “new approach” and standardization).

7. Cf. Christoph Demmke et al., *The History of Comitology*, in *SHAPING EUROPEAN LAW AND POLICY, THE ROLE OF COMMITTEES AND COMITOLOGY IN THE POLITICAL PROCESS* 61, 63–65 (Robin H. Pedler & Guenther F. Schaefer eds., 1996) [hereinafter *SHAPING EUROPEAN LAW*]; Ellen Vos, *The Rise of Committees*, 3 *EUR. L.J.* 210, 213–14 (1997); Kieran St. C. Bradley, *The European Parliament and Comitology: On the Road to Nowhere?*, 3 *EUR. L.J.* 230, 238–40 (1997) [hereinafter *The European Parliament and Comitology*]; Kieran St. C. Bradley, *Institutional Aspects of Comitology: Scenes from the Cutting Room Floor* [hereinafter *Institutional Aspects of Comitology*], in *EU COMMITTEES*, *supra* note 2, at 71, 91–93.

8. E.g., Christian Joerges & Jüngen Neyer, *From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology*, 3 *EUR. L.J.* 273, 285, 298–99 (1997); Christian Joerges, “Good Governance” Through Comitology?, in *EU COMMITTEES*, *supra* note 2, at 311, 312–13.

dures depends on the “deliberative” nature of the process that is based on the “national representation” in the comitology committee and the importance of scientific argument rather than participatory involvement of interest groups or stakeholders. According to Joerges:

[T]he correctness of risk decisions cannot be guaranteed by unmediated recourse to interests or their negotiation—or in legal terms, by extending corresponding participation rights and veto positions [B]y virtue of its feedback links to Member States [compare with Member States representatives in comitology committee], comitology can, in principle, take all social concerns and interests into account while, at the same time, links with science (seen as a social body) can be shaped so as to allow for the plurality of scientific knowledge to be brought to bear.⁹

The reliance on a different, indirect form of territorial representation (national administrators in the comitology committee) and on scientific deliberation as sources of legitimacy for delegated regulation, rather than the involvement of civil society organizations, contrasts with the U.S. tradition of having participatory procedures for stakeholders in such regulation. Some European scholars did refer to the role stakeholders may play in delegated regulation,¹⁰ but this has hardly ever been taken as a core issue of research. A remarkable exception comes from a U.S. scholar, Francesca Bignami, who has placed the issue of participation in delegated regulation at the center stage of her research, and—relying on the U.S. experience—has proposed the introduction of a notice and comment procedure in EU delegated regulation.¹¹

The lack of attention paid to EU participatory procedures in delegated regulation is striking when one acknowledges that, since the end of the 1990s, Community institutions have developed a normative discourse on the importance of civil society participation in European policymaking. In particular, the Euro-

9. Joerges, *supra* note 8, at 334.

10. Vos, *supra* note 7, at 210–11; Vos, *supra* note 2, at 31; Renaud Dehousse, *Towards a Regulation of Transitional Governance? Citizen’s Rights and the Reform of Comitology Procedures*, in EU COMMITTEES, *supra* note 2, at 109, 120–21.

11. See Francesca Bignami, *The Administrative State in a Separation of Powers Constitution: Lessons for European Community Rulemaking from the United States*, available at <http://www.jeanmonnetprogram.org/papers/99/990501.html> (last visited Feb. 15, 2005).

pean Economic and Social Committee (EESC) and the European Commission (through its White Paper on European Governance) have stressed the added value of civil society participation.¹² Yet the focus has been mainly on their involvement in the drafting of new legislation, whereas little has been said about functional participation in implementation.¹³ The Commission Communication on “General Principles and Minimum Standards for Consultation of Interested Parties by the Commission” (December 2002),¹⁴ which can be considered the most important outcome of all this talk on civil society, is very illustrative of the Commission’s general attitude toward functional participation. The principles are broadly defined as “participation, openness and accountability, effectiveness and coherence,” but the document is not legally binding and the Commission stresses that “a situation must be avoided in which a Commission proposal could be challenged in the Court on the grounds of alleged lack of consultation of the interested parties.”¹⁵ Moreover, the Communication explicitly excludes comitology from its application, and thus seems mainly to aim simply at a broader use of green papers and electronic consultations on new legislative initiatives.

Yet there would be good reasons to pay particular attention to the role of functional participation in comitology procedures. First, it is precisely because of the lack of, or limited, territorial representation in comitology, that it is worth looking at functional participation as a complementary source of legitimacy. Second, the experience of the United States with the Administrative Procedure Act (APA) shows that an institutional framework for functional participation, in the broader context of due process and judicial review, can provide legitimacy for delegated regulation. Third, as will be argued below, within the EU, judicial review on “proceduralized” functional participation is more likely to develop with regard to delegated regulation than with legislation, where functional par-

12. See Stijn Smismans, *European Civil Society: Shaped by Discourses and Institutional Interests*, 9 EUR. L.J. 473, 482 (2003).

13. An exception is the normative discourse on the importance of “decentralized participation” in the nonregulatory policy regime that is constituted by the open method of coordination. See Stijn Smismans, *EU Employment Policy: Decentralisation or Centralisation through the Open Method of Coordination?*, at 4–5, available at <http://www.iue.it/PUB/law04-1.pdf> (last visited Feb. 16, 2005).

14. See *Towards a Reinforced Culture of Consultation and Dialogue: General Principles and Minimum Standards for Consultation of Interested Parties by the Commission*, COM(02)704 final.

15. Peter Bonnor, *When EU Civil Society Complains—Civil Society Organisations and Ombudsmanship at the European Level*, in CIVIL SOCIETY AND LEGITIMATE EUROPEAN GOVERNANCE (Stijn Smismans ed., forthcoming 2005) (arguing that the general principles and minimum standards may, nevertheless, be used as soft law for review by the European Ombudsman).

ticipation is ultimately always “covered” by the final word of the legislature—the EP and the Council.

II. FUNCTIONAL PARTICIPATION AS AN ADDITIONAL SOURCE OF LEGITIMACY IN REGULATORY IMPLEMENTATION

The fact that both EU legitimation discourses and the comitology literature have paid limited attention to the participation of stakeholders or interest groups in EU delegated regulation does not mean that such participation is non-existent. To be sure, such participation is not as extensive and regulated as in the United States. As far as functional participation of stakeholders *does* take place in comitology, it is mainly informal, through direct lobbying of the Commission or through contacts “back home” with the national representative in the comitology committee (as deliberative supranationalism suggests). Yet, in some cases such functional participation has also been institutionalized. This institutionalization differs strongly from the way functional participation is regulated in delegated regulation in the United States. Institutionalization also remains the exception rather than the rule. Yet, institutionalized functional participation in EU delegated regulation might function as a source of legitimacy. Moreover, as will be argued below, if the Constitutional Treaty is implemented, the legitimacy of delegated regulation may increasingly depend on the institutionalized functional participation in it.

To provide a better insight into the reality of institutionalized functional participation in delegated regulation in the EU, I will use the example of Community regulation in the field of occupational health and safety (OH&S). While one should acknowledge that patterns of participation differ strongly according to the policy sector, the field of OH&S provides an interesting case study. OH&S has been the core field of European social regulation, including an important amount of legislative Directives. Often these Directives have conferred regulatory implementation powers on the Commission, conditioned on a comitology procedure. These procedures not only involve a “comitology committee,” composed of representatives from the national administrations, but they also ensure forms of functional participation.

Two main procedures of “regulatory implementation” can be distinguished in OH&S policy: the procedure for adaptation to technical change, and the procedure for setting occupational exposure limit values (which is actually a special

type of the former procedure).¹⁶ I will analyze how functional participation might compensate for the lack of parliamentary representation in delegated regulation, or how it might counterbalance scientific expertise.

A. Functional Participation as Compensation for Lack of Parliamentary Representation

1. The Procedure "Adaptation to Technical Change"

New machinery, new chemical and biological substances, and new production processes create new types of occupational risks. Moreover, scientific development leads to new insights into the dangerous nature of certain substances and production processes and to new techniques for combating occupational risks (with lower economic costs). For the legislature, it is difficult to keep up with all these developments. Continuously enacting new legislation, for instance at the EU level by legislative directives (adopted by the Council and the EP), is a time-consuming exercise. By the time a proposal has passed the complete legislative process, new technical developments may already have seen the light of day. Moreover, territorial representatives may be overburdened with very technical issues for which they might lack the necessary expertise. A part of the OH&S regulatory process at the European level has therefore been "delegated" to implementation measures. A procedure of "adaptation to technical change" allows the Commission to enact Directives which "update" the technical aspects of existing legislation.

Nearly all legislative OH&S directives "delegate" implementation measures via a procedure for adaptation to technical change. The two legislative OH&S Framework Directives (of 1980 and 1989) describe this particular procedure,¹⁷ to

16. Comparable procedures can be found in sectors such as environmental policy, food safety, and product safety regulation. Detailed analyses of comitology in these sectors—although scarcely paying attention to functional participation—can be found in several sources. See Christine Landfried, *The European Regulation of Biotechnology by Polycratic Governance*, in EU COMMITTEES, *supra* note 2, at 173, 187–89; Thomas Gehring, *Bargaining, Arguing and Functional Differentiation of Decision-making: The Role of Committees in European Environmental Process Regulation*, in EU COMMITTEES, *supra* note 2, at 195, 199–201; Christoph Demmke, *Comitology in the Environmental Sector*, in DELEGATED LEGISLATION AND THE ROLE OF COMMITTEES IN THE EC, *supra* note 2, at 279, 283–84; Sabine Schlacke, *Centralization and Europeanization of Administrative Implementation: Product Safety Legislation*, in DELEGATED LEGISLATION AND THE ROLE OF COMMITTEES IN THE EC, *supra* note 2, at 303, 311.

17. Council Directive 80/1107, 1980 O.J. (L 327); Council Directive 89/391, art. 17, 1989 O.J. (L 275).

which the individual legislative directives then refer. It involves a typical comitology procedure: in order to adopt the implementation measures, the Commission has to consult a committee, which is chaired by a representative of the Commission, composed of the representatives of the Member States. More precisely, the involvement of a regulatory committee is required, as described in the Comitology Decision 87/373/EEC and revised by Decision 1999/468/EC.¹⁸ If the committee's opinion, expressed with qualified majority vote according to the terms of Article 205 of the EC Treaty, is in accordance with the proposal of the Commission, the latter shall adopt the measures. If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken and inform the EP. The Council shall act by qualified majority. If, on the expiration of three months from the date of the referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

The procedure for adaptation to technical change thus takes regulatory intervention out of the hands of territorial representatives. Even though the position of the EP in comitology has been improved by the 1999 decision, it remains merely "informed." In theory, the Council may play a prominent role in comitology, which would ensure the involvement of political territorial representatives, but, in practice, comitology rarely leads to the involvement of the Council because the deliberation between the Commission and national administrators in comitology, for the most part, ends in agreement.

The procedure for adaptation to technical change applies, according to the 1989 Framework Directive, to take account of mainly two elements:

- technical progress, changes in international regulations or specifications, and new findings, and
- the adoption of directives in the field of technical harmonization and standardization, such as product regulation concerned with OH&S.

Generally, individual legislative directives have an annex with technical specifications, and it is those annexes that can be changed with the "adaptation to technical change" procedure. However, to avoid the Commission's bypassing the Council

18. Due to space limitations, I will not be able to elucidate the subtle differences between Council Directive 87/373, 1987 O.J. (L 197), and the new Council Directive 99/468, 1999 O.J. (L 184). See Lenaerts & Verhoeven, *supra* note 2, at 675–78.

and the EP on issues that are not “strictly technical,” the 1989 Framework Directive states explicitly that other amendments to individual directives are only possible through legislation. Some individual legislative directives specify even further that legislative action is needed for certain specific amendments.¹⁹ The aim is clearly to ensure that only “purely technical adjustments” be left for implementation measures, leaving more “fundamental policy choices” to be made by legislation.

How does functional participation fit into this procedure? The treaty provisions do not provide indications on functional participation in implementation procedures. The conditions for the implementation processes are normally laid out in the delegating legislative act: in this case, the legislative directive setting up a procedure of adaptation to technical change. However, the OH&S legislative directives do not mention that any form of functional participation should take place in the process of adaptation to technical change.²⁰

Despite this lack of provisions, one institutionalized form of functional participation used in this implementation process is consultation of the tripartite Advisory Committee on Safety and Health at Work. The Advisory Committee (AC) is composed of three members for each Member State, with one representative of the national administration, one representative of a trade union, and one representative of an employers’ organization. The AC has, according to its statutes,²¹ the task of assisting the Commission in the preparation *and* implementation of *activities* in the fields of safety, hygiene, and health protection at work. Even if the Commission is not obliged to consult the AC in such implementation, it has preferred to do so. The normal procedure for adaptation to technical change is therefore as follows:

Commission initiative → AC → comitology committee → Commission directive (or → the Council)

2. Functional Participation as an Additional Source of Legitimacy

One can ask whether functional participation, for instance via a committee like the AC, can be seen as an additional source of legitimacy in the implemen-

19. For example, the Work Equipment Directive 89/655, art. 9, 1989 O.J. (L 393) states that, contrary to technical adaptations of the annexes, additions of supplementary minimum requirements to the annex can only be adopted by legislation.

20. For the exception of the particular procedure to set occupational exposure limits, see Council Decision 2003 O.J. (C 218) 1.

21. *Id.*

tation phase, especially to compensate for the lack of territorial representation. The scholarly literature has generally proposed three ways to structure comitology procedures to concerns of “good governance”:²² (1) parliamentary control; (2) scientific expertise;²³ and (3) proceduralization or institutionalization of interest group participation.²⁴

The involvement of the AC in the adaptation of Directives to technical change is a good example of the latter. The Commission drafts its “technical change” amendments not only in collaboration with the comitology committee, which represents the Member States, but also involves functional groups via the AC.²⁵ A Commission directive is thus not a “pure technocratic construct of a Commission bureaucracy” but builds on the deliberation of the comitology committee, which is supposed to draw back on national social concerns and interests,²⁶ and on the technical and interest-based deliberation of the AC.

The first option, to ensure extensive parliamentary control over comitology procedures, has actually met with serious academic skepticism,²⁷ because the EP has neither the expertise nor the time to engage in daily control over the large number of committees. However, resorting to functional participation as a way to make the implementation procedure more legitimate does not exclude the

22. See Joerges, *supra* note 8; Dehousse, *supra* note 10, at 115.

23. See Joerges, *supra* note 8, at 332 (describing the role of political and legal science in the EU’s committees); Dehousse, *supra* note 10, at 115; Michelle Everson, *The Constitutionalisation of European Administrative Law: Legal Oversight of a Stateless Internal Market*, in EU COMMITTEES, *supra* note 2, at 281 (analyzing legal oversight in European administrative law).

24. See generally Vos, *supra* note 7 (giving a general overview of EU committees and their recent growth); Vos, *supra* note 2 (analyzing the role of EU committees in European product regulation); Dehousse, *supra* note 10 (analyzing the legal status and legitimacy of comitology).

25. The normative proposals to organize interest group participation in comitology procedures generally prefer a more “pluralist” model in which transparency, a sort of general “Administrative Procedure Act” (APA), and judicial review of these procedures should guarantee equal access for all concerned interests. See generally Jürgen Schwarze, *Developing Principles of European Administrative Law*, PUB. L., Summer 1993, at 229 (giving an overview of modern European administrative law); Martin Shapiro, *Codification of Administrative Law: The US and the Union*, 2 EUR. L.J. 26 (1996) (examining parallels between U.S. and European administrative law); Carol Harlow, *Codification of EC Administrative Procedures? Fitting the Foot to the Shoe or the Shoe to the Foot*, 2 EUR. L.J. 3 (1996) (arguing that codification of EC procedures should reflect ECJ jurisprudence); Dehousse, *supra* note 10; Vos, *supra* note 2.

26. See Joerges, *supra* note 8.

27. See *The European Parliament and Comitology*, *supra* note 7 (summarizing the interactions between the European Parliament and comitology committees); Dehousse, *supra* note 10; Joerges, *supra* note 8.

possibility that some (more modest) parliamentary control could be installed, such as a right for Parliament to intervene when, in the implementation phase, issues arise that members of the EP deem fundamental,²⁸ or such as an *ex post* monitoring on the correct procedural working of committees.²⁹

It is less clear whether additional legitimacy via functional participation of interest groups could be combined with an ever increasing resort to deliberation based on rational argument and scientific expertise. Some authors, such as Joerges and Everson, point to the fact that, where the legitimacy of decisionmaking is sought in the deliberative and science-based nature of the decisionmaking procedure, there is less need for the inclusion of ever more “interests.”³⁰

Yet the question is, to what extent do comitology committees have enough “feedback links to Member States” to ensure that deliberation within these committees takes account of the social concerns that are inevitably linked to risk regulation. As made clear by the empirical part of the research of Joerges and Neyer, the national representatives in comitology committees often do not have enough time for domestic consultations with all interested parties.³¹

In more recent work, Joerges acknowledges the possibility of promoting the articulation of interests at a European level via the procedure for including experts in the comitology committee.³² The alternative to such a method of representing interests via experts attached to the comitology committee, namely an advisory committee composed of functional groups attached to the Commission, is not mentioned by Joerges.³³ Yet, my analysis of the AC shows that such an advisory committee composed of interest groups may also contribute to scientific and expert deliberation. The AC, in fact, not only provides a forum where interest groups such as labor and management can express their view, but it also provides for deliberation, in which technical arguments are often predominant. Whether one should prefer a comitology procedure with the comitology committee itself including experts (who may originate from functional groups) or a

28. See generally Dehousse, *supra* note 10.

29. See generally Joerges, *supra* note 8 (describing the role of political and legal science in the EU’s committees). See also Everson, *supra* note 23 (arguing that parliamentary committees should trigger judicial review on the deliberative nature of committees).

30. See Joerges, *supra* note 8, at 334; Everson, *supra* note 23, at 307.

31. Joerges & Neyer, *supra* note 8, at 290.

32. Joerges, *supra* note 8, at 335.

33. The “bad experience” with an advisory committee in the foodstuff sector, upon which the empirical research of Joerges and Neyer is based, might be the basis of discarding this option in their normative proposal. See Joerges & Neyer, *supra* note 8, at 279.

procedure which combines a comitology committee with a separate advisory committee would need to be tested by using both procedures in practice. On the one hand, one can question, in the latter case, how the deliberation of the comitology committee would relate to the deliberation of the advisory committee. On the other hand, in the former case, the “experts” may intervene directly into the deliberation of the comitology committee, but one can question whether the inclusion of “some” experts would be as representative as the “balanced” representation sought in the AC, involving one “expert” from each of the three groups from each country.

B. Functional Participation to Counterbalance Scientific Expertise

1. The Procedure to Adopt Occupational Exposure Limits

Some OH&S legislative directives require a particular regulatory implementation procedure in order to adopt “occupational exposure limit values” (OELs), which refer to the maximum amount of a certain agent a worker can be exposed to. The definition of OELs requires particular scientific expertise, and should keep pace with the ongoing discovery of new agents. The procedure to adopt OELs was first introduced in 1988³⁴ to deal with exposure to chemical, physical, and biological agents at work, but it is mainly used in the field of chemical agents, according to the procedure set out in the 1998 Council Directive on chemical agents.³⁵

The Chemical Agents Directive distinguishes two types of OELs: binding OELs and indicative OELs.³⁶ Binding OELs have to be adopted via legislation.³⁷

34. Council Directive 88/642, 1988 O.J. (L 356) 74, is an amendment to Council Directive 80/1107, 1980 O.J. (L 327).

35. See Council Directive 98/24, 1998 O.J. (L 131) 11 (discussing the protection of the health and safety of workers from the risks related to chemical agents at work). This Directive repeals the 1980 Council Directive, *supra* note 17, and its amendment by Directive 88/642, O.J. (L 356) 74, *supra* note 34. Yet, the 1998 Directive only deals with chemical agents, whereas the other also dealt with physical and biological agents. Subsequently, a separate Directive on biological agents has been adopted, as have two on physical agents (one on vibration, another on noise), but without introducing a procedure for the adoption of OELs.

36. In the case of indicative OELs the “Member States shall establish a national occupational exposure limit value, taking into account the Community limit value, determining its nature in accordance with national legislation and practice.” *Id.* art. 3(3). However, in the case of binding OELs the “Member States shall establish a corresponding national binding occupational exposure limit value based on, but not exceeding, the Community limit value.” *Id.* art. 3(5).

37. *Id.* art. 3(4).

Indicative OELs can be adopted by Commission Directive via a procedure comparable to the “adaptation to technical change” procedure.

Both in the case of binding OELs (legislation) and indicative OELs (adaptation to technical change), the first stage of the procedure is identical and can be described as follows:

Commission initiative (scientific dossier) → Scientific Committee for Occupational Exposure Limits (SCOEL) → notice and comment procedure → SCOEL

This first step of the procedure has not been exhaustively described in the Chemical Agents Directive, which is limited: “[T]he Commission shall evaluate the relationship between the health effects of hazardous chemical agents and the level of occupational exposure by means of an independent scientific assessment of the latest available scientific data.”³⁸ However, as early as 1993, the Commission had already adopted a guidance note³⁹ on the procedure for setting OELs within the context of the (now repealed) 1988 directive.

The procedure begins with the preparation of a “scientific dossier” by the European Commission, who will subcontract to private organizations or experts, or will rely on the expertise of national expert bodies or international organizations. Subsequently, the Commission will send the scientific dossier to the SCOEL.⁴⁰ The SCOEL is composed of scientific experts that represent the range of specialist expertise in chemistry, toxicology, epidemiology, occupational medicine, and hygiene. The SCOEL evaluates data from different sources (and thus not only the scientific dossier). Moreover, an announcement is made in the Official Journal to request further data.⁴¹ On the basis of the scientific dossier and the supplementary data, the SCOEL formulates a short document which describes the recommended OELs. The Commission reveals the recommended OELs to

38. *Id.* art. 3(1).

39. Health and Safety Commission, Establishment of Occupational Exposure Levels in the European Community, Guidance Note on the Procedure for Scientific Review and Evaluations, and Arrangements for Consultation, Doc. 803-2/93 (Nov. 11, 1993).

40. The SCOEL has been formally constituted by a Commission Decision of July 12, 1995. Commission Decision 95/320, art. 1, 1995 O.J. (L 188) 14–15. However, it actually replaces an older informal “Scientific Expert Group,” which was established to prepare the first Commission Directive setting OELs. Commission Directive 91/322, 1991 O.J. (L 177) 22–24.

41. *E.g.*, 1994 O.J. (C 094) 3–4.

the interested parties along with a request for health-based scientific comments, and eventually, further data. After a comments period of about six months, the SCOEL reviews the document again in light of the comments received, and adopts the final version.

The procedure differs according to whether it has to be a binding OEL or an indicative OEL. In the case of a binding OEL, the procedure would be the following:

Recommended OEL by SCOEL → (AC →) formal Commission proposal → EESC → EP → Council (directive).

The consultation of the EESC and the joint decision of the EP and the Council result from the legislative basis of Article 137 of the EC Treaty. There is no explicit requirement to consult the AC, but the 1993 Guidance Note promises its consultation. Moreover, nonconsultation would be a strong deviation from the established practice to consult the AC on all legislative proposals in the OH&S field.

In the case of an indicative OEL, the procedure would be the following:

Recommended OEL by SCOEL → AC → comitology → Commission directive (or → Council directive)

Contrary to the procedure for binding OELs (via legislation), the 1998 Chemical Agents Directive explicitly requires the consultation of the AC for the setting of indicative OELs. After consultation of the AC, the Commission adopts its formal proposal for indicative OELs, which has to pass the comitology procedure for “adaptation to technical change.”

To date, no binding OELs have been adopted, either under the (now repealed) 1988 Directive, or under the 1998 Chemical Agents Directive. All OELs have been adopted by Commission Directives setting indicative OELs.⁴²

The Commission seems to prefer the procedure for indicative OELs rather than going the long way, through legislation, to obtain binding OELs. Actually, in

42. Two Commission Directives have adopted OELs in the context of the now repealed 1988 Directive. See Commission Directive 91/322, *supra* note 40; Commission Directive 98/24, 1998 O.J. (L 131) 11–23. One Commission Directive is in the context of the Chemical Agents Directive. Commission Directive 2000/39, 2000 O.J. (L 142) 47–50.

its initial proposal for the Chemical Agents Directive, the Commission tried to retain only one procedure (leading to Commission Directives)⁴³ while the EP⁴⁴ (and the EESC)⁴⁵ stressed that binding OELs should pass through legislation. The final Chemical Agents Directive does provide a double procedure, but as long as the Commission weighs the advantage of the “adaptation to technical change procedure” more heavily than the disadvantage of having “merely” indicative OELs, the procedure to adopt binding OELs via legislation may remain unused.

2. *Functional Participation as Additional Source of Legitimacy*

On the one hand, the setting of OELs is a very technical issue that requires the involvement of those familiar with chemistry, toxicology, epidemiology, occupational medicine, and hygiene. The SCOEL and the procedure established in the Guidance Note of 1993 should remedy this need. On the other hand, the protection of workers’ health and safety often stands or falls with the allowed level of exposure to certain agents.⁴⁶ Because OELs often determine the core of OH&S protection, these decisions cannot entirely be left over to technical experts. Technical experts can define how dangerous agents are and express their opinion on the necessity and feasibility of avoiding certain levels of exposure, but the social acceptance of certain risks should be expressed by a democratic process. Moreover, scientists are not “untouchable” and they have to work under conditions of scientific uncertainty.⁴⁷ A certain level of democratic control and a

43. See Proposal for a Council Directive on the Protection of the Health and Safety of Workers from the Risks Related to Chemical Agents at Work, 1993 O.J. (C 165) 4.

44. Legislative Resolution Embodying the Opinion of the European Parliament on the Proposal for a Council Directive on the Protection of the Health and Safety of Workers from Risks Related to Chemical Agents at Work, EUR. PARL. DOC. (AP-0185), 1994 O.J. (C 128) 167 [hereinafter *Legislative Resolution Embodying the Opinion*].

45. Opinion on the proposal for a Council Directive on the Protection of the Health and Safety of Workers From the Risks Related to Chemical Agents at Work, EESC Opinion, 1994 O.J. (C 034) 42, § 3.12.1.

46. The same, for instance, applies in the case of environmental law, where the core of the matter centers around the limit values. Schaefer argues that, in this context, the comitology committees dealing with the definition of such limit values are “in some respects . . . the most far-reaching legislative type of committee.” Guenther F. Schaefer, *Committees in the EC Policy Process: A First Step Towards Developing a Conceptual Framework*, in *SHAPING EUROPEAN LAW*, *supra* note 7, at 18.

47. “Uncertainty is rarely due to a simple need to do more research. Rather the phrase is shorthand for a whole series of methodological, epistemological, and even ontological problems inherent in determining the level of danger.” Elizabeth Fisher, *Drowning by Numbers: Standard Setting in Risk Regulation and the Pursuit of Accountable Public Administration*, 20 OXFORD J. LEGAL STUD. 109, 115 (2000).

balance between different discourses beyond the scientific are desirable. Therefore, the first list of binding OELs was adopted through legislation in the 1998 Council Directive on Chemical Agents; the directive requires that future binding OELs will also have to travel the same legislative road. Consequently, territorial representatives in the EP and the Council, and functional groups in the EESC and in the AC can have their say on the definition of binding OELs.

However, bearing in mind that there are more than 100,000 existing chemical substances,⁴⁸ as well as many complex mixtures arising from work processes, it is evident that the Community cannot adopt OELs for all of them, especially not through the slow legislative process. The possibility of adopting indicative OELs via a Commission directive may slightly facilitate the impressive (but by definition eternally incomplete) task.

The procedure aims at a balanced deliberation, first of a scientific nature within the context of the SCOEL; second via the technical and interest-based deliberation of the AC; and third in the context of the comitology committee representing national interests. The entire process is guided by the Commission representing the general interest of the Community.⁴⁹

Two particular remarks regarding functional participation should be made. First, the initial stage of the procedure focuses on scientific deliberation and the notice and comment procedure introduced by the 1993 Guidance Note does not have the same function as notice and comment under the APA in the United States. Unlike notice and comment under the APA—where it is a general principle for delegated legislation—the notice and comment procedure analyzed here is established ad hoc, for this particular directive. Moreover, it aims at gathering “purely” scientific data, in contrast to the plurality of voices and interests permitted in the notice and comment procedure under the APA.

Second, according to the Guidance Note, it is only at the level of the AC that it is necessary to take account of both technical and socioeconomic and interest-based information. As in the case of the procedure of adaptation to technical change described above, it can be argued that the AC has a particular role as an

48. This is identified in the European inventory of existing commercial chemical substances, quoted by the 1993 Commission's Guidance Note on the procedure for scientific review and evaluations, and arrangements for consultation. Health and Safety Commission, *supra* note 39.

49. For a comparable “balance among committees,” see Andreas Bucker et al., *Social Regulation through European Committees: An Interdisciplinary Agenda and Two Fields of Research*, in *SHAPING EUROPEAN LAW*, *supra* note 7, at 50.

additional source of legitimacy to compensate for the lack of territorial representation via the EP (and the Council).

In the case of the 1998 Chemical Agents Directive, this is exemplified by the fact that the consultation of the AC is required explicitly in the procedure for the adoption of indicative OELs through Commission directives, whereas there is no such explicit requirement for the adoption of binding OELs through legislation.⁵⁰

It is also worth remembering that, in general, legislative directives providing implementation procedures do not require the consultation of the AC (although in practice the AC is nearly always consulted). That the Chemical Agents Directive does explicitly require consultation of the AC may be linked to the “quasi-legislative nature” of the process of defining the acceptable levels of exposure,⁵¹ even if “merely” indicative. Moreover, it may also be seen as a particular recognition of the AC as the best forum to counterbalance and control the “purely scientific deliberation” of the SCOEL.

III. JUDICIAL REVIEW

As analyzed in the preceding section, institutionalized functional participation could be a source of legitimacy in EU delegated regulation, compensating, to a certain extent, for weak territorial representation and to counterbalance scientific expertise. If this is the case, one can ask whether judicial review can play a role in ensuring such functional participation, for instance, by requiring the consultation of committees such as the tripartite Advisory Committee on Safety and Health at Work, or by requiring that such committees should be “representative” of the interests in that sector. Yet, whereas judicial review on functional participation in delegated regulation is well developed in the United States, there are strong limits on such review in the EU. This can be illustrated again with the case of OH&S delegated regulation.

50. In the original Commission proposal for the Chemical Agents Directive, there was no explicit requirement to consult the AC. It was under the pressure of those institutions that are excluded from the procedure for setting indicative OELs, namely the EP and the EESC, that the requirement to consult the AC was finally included. See Council Directive 98/24, *supra* note 35, at 4; Legislative Resolution Embodying the Opinion, *supra* note 44, at 167; Proposal for a Council Directive on the Protection of the Health and Safety of Workers from the Risks Related to Chemical Agents at Work, *supra* note 43.

51. Thus the debate in the AC on setting of OELs appears more politically sensitive than most issues of adaptation to technical change. Personal interviews with AC members.

A. Ensuring Consultation

If the tripartite advisory committee is supposed to be a source of legitimacy in the implementation phase, which can compensate for the lack of involvement of parliamentary representation, can judicial review then ensure such “legitimizing input”?

The statutes of the AC define the task of that committee, but do not impose an obligation on the Commission to consult it. The EC Treaty does not mention the AC at all, and most delegating OH&S Directives do not require the consultation of the AC either. As a consequence, although in practice consultation of the AC is the general rule, the Commission has on some rare occasions presented its formal proposal, or made its decision, without having heard the opinion of the AC.

In the case of the 1993 Working Time Directive, on which the AC had not been consulted, the Court of Justice has confirmed the absence of a requirement to consult the tripartite committee.⁵² The United Kingdom contested the legal basis of the Working Time Directive, arguing that the issue of working time should not be considered as an occupational health and safety issue. To obtain the annulment of the Working Time Directive before the Court, the United Kingdom argued that, unlike the tradition of elaborating Council Directives based on Article 118a of the treaty, this time the AC had not been consulted. This cast doubt on the link between the directive and the health and safety of workers and constituted a procedural defect sufficiently serious to render the directive invalid.⁵³ The Court, however, replied that under Article 2(1) of the AC Statutes “such consultation is intended only [to assist] the Commission in the preparation and implementation of activities in the fields of safety, hygiene and health protection at work,” and does not therefore constitute a condition precedent for action by the Council.⁵⁴ It follows that a Council directive cannot be annulled for lack of consultation with the AC.⁵⁵ This judgment is in line with

52. Case C-84/94, *United Kingdom v. E.U. Council*, 1996 E.C.R. I-5755.

53. *Id.* para. 34, at 152.

54. *Id.* para. 41, at 684.

55. The Court did not state this explicitly, probably because (contrary to the Advocate General) it treated the United Kingdom’s argument on the AC as only one factor in proving the non OH&S character of the Working Time Directive and not as a plea on infringement of procedural requirements. The Court therefore limits its observation to saying that “the failure to consult that committee cannot be relied on to cast doubt on the link between measures laid down by the directive and the protection of the health and safety of workers.” *Id.* para. 41, at 715.

the Court's general reluctance to review legislation. The Court leaves broad discretion to the Council, and will not annul its legislative acts if there is no strict legal requirement for consultation.⁵⁶

However, the Court is more open to judicial review in implementation procedures, and has begun to develop a jurisprudence enforcing strictly the procedural rules governing the functioning of committees in the implementation phase.⁵⁷ In the *Angelopharm* case,⁵⁸ for instance, the Court decided an amendment to the Cosmetics Directive⁵⁹ was invalid because the Scientific Committee for Cosmetology had not been consulted. The Cosmetics Directive provided that adaptations to technical progress could be realized via a comitology procedure. The procedure not only involved a comitology committee, composed of Member State representatives, but also provided that the amendments necessary for adapting to technical progress be adopted "after consultation of the Scientific Committee for Cosmetology at the initiative of the Commission or of a Member State" (Art. 8(2) Cosmetics Directive). According to the Commission and the intervening governments, this stipulation leaves it to the discretion of the Commission and the Member States to decide whether they want to consult the Scientific Committee. The Court, however, noted that "the article can also be interpreted as meaning that it is for the Commission or the Member States to take the initiative to convene the Scientific Committee, which must be consulted in all cases."⁶⁰ Given the ambiguity of the wording, the Court argued that, to determine whether the consultation of the Scientific Committee is mandatory, it is necessary to refer to the Committee's role in the procedure for adaptation to technical change.⁶¹

The Court then referred to the preamble of the Cosmetics Directive, which states that cosmetics product regulation should be founded on scientific and technical assessments. Because neither the Commission nor the Comitology

56. See Joined Cases 281, 283, 284, 285, & 287/85, *Germany v. Comm'n*, 1987 E.C.R. 3203 (giving a restrictive interpretation of the Treaty provision requiring consultation of the Economic and Social Committee).

57. Case C-269/90, *Hauptzollamt München-Mitte v. Technische Universität München*, 1991 E.C.R. I-5469; Case C-244/95, *Moskof v. Ethnikos Organismos Kapnou* 1997 E.C.R. I-6441; Case C-263/95, *Germany v. Comm'n* 1998 E.C.R. I-441.

58. Case C-212/91, *Angelopharm GmbH v. Freie und Hansestadt Hamburg*, 1994 E.C.R. I-171.

59. Council Directive on the Approximation of the Laws of the Member States Relating to Cosmetic Products, 76/768/EEC, 1976 O.J. (L 262) 169, *amended by* Council Directive 82/368/EEC 1982, O.J. (L 167) 1.

60. *Angelopharm GmbH*, 1994 E.C.R. at I-179.

61. *Id.* at I-180.

Committee is in a position to carry out such assessments, the Scientific Committee has been set up to ensure this function. Therefore, its consultation must be mandatory in all cases, and nonconsultation leads to the invalidity of the adaptation directive.

The *Angelopharm* case might be an inspiration for the few OH&S implementation procedures in which the consultation of the AC is explicitly required. However, while the Court might strictly enforce procedural rules with regard to scientific committees because it believes that the scientific quality of arguments might compensate for the lack of political debate on risk regulation, it is not clear that the Court is likely to develop a comparable argument for functional participation. Strict screening of consultation requirements for scientific committees might just be part of a broader tendency toward the development of a general principle of requiring that risk regulation be based on a certain level of scientific assessment.⁶²

There is, to date, no sign in the case law that the Court attributes an equal importance to functional participation or balanced interest group participation in risk regulation.⁶³ Cases such as *Angelopharm* and *Technische Universität München*⁶⁴ deal with scientific committees, whereas most other cases strictly enforcing procedural rules governing the functioning of committees deal with comitology committees composed of Member States representatives.⁶⁵ While it seems to be recognized that national representation via comitology committees, and scientific argument via scientific committees can compensate for the lack of

62. On the relevant case law and the debate on how far the ECJ is likely to develop the criterion of scientific expertise as a “meta-positive principle” in risk regulation, see generally INTEGRATING SCIENTIFIC EXPERTISE INTO REGULATORY DECISION-MAKING, *supra* note 6; Joerges & Neyer, *supra* note 8; *Institutional Aspects of Comitology*, *supra* note 7. See also Case T-13/99 Pfizer Animal Health v. Council, 2002 E.C.R. II-3305; Case LT-70/99 Alparma v. Council, 2002 E.C.R. II-3495.

63. See Lóic Azoulay, *The Court of Justice and the Administrative Governance*, 7 EUR. L.J. 425–41 (2001). Azoulay sees in the *UEAPME* case the potential for a more general procedural requirement calling for the creation of “consultative forums” or “contradictory and representative procedures” (other than procedural requirements for “adversarial expertise” on the basis of scientific knowledge). In my view this would require a very strong *saut qualitatif* given that the *UEAPME* case conceived of the importance of functional participation only in a well-established (pseudo-) legislative procedure where social partners are said (still, according to the Court) to replace the democratic representation of the European Parliament. See Case T-135/96, *Union Européenne de l’Artisanat et des Petites et Moyennes Entreprises (UEAPME) v. Council*, 1998 E.C.R. II-2338. For a detailed analysis, see SMISMANS, *supra* note 3, at 339–55.

64. *Technische Universität München*, 1991 E.C.R. at I-5502.

65. See, e.g., *Moskof*, 1997 E.C.R. at I-6493; *Germany*, 1998 E.C.R. at I-478.

involvement of the EP and Council in implementation measures, the role that functional participation can play in that sense is less apparent.

There are three ways to require consultation of advisory committees such as the AC on the basis of the established case law such as *Angelopharm* and *Technische Universität München*. First, the Court can simply stress the importance of respecting procedural requirements. Yet such judicial review can only take place when there is a clear obligation to consult such an advisory committee. European delegating legislation should, therefore, take more care in setting out the procedural requirements for functional participation in implementation. Second, the Court could recognize the contribution of the AC in providing scientific expertise, which could require the AC's consultation on the basis of *Angelopharm* and *Technische Universität München*, even if the legal obligation for consultation is not so explicitly established. Yet it remains to be seen whether advisory committees composed of functional groups would be recognized as part of the requirements to ensure the correct "scientific assessment" of implementation measures. In *Technische Universität München*, the Court acknowledged that technical expertise is not only a qualification of "scientific experts" but that the concerned party "is best aware of the technical characteristics" and should therefore be heard. Obviously, there is still a gap between recognizing that the concerned party (addressed by an individual decision) is a bearer of technical expertise and recognizing that a functional group (which may be representative of a concerned party) has such a qualification.

Third, the Court could explicitly recognize the importance of functional participation in its own right, implying a strict enforcement of procedural rules governing the consultation of advisory committees composed of concerned parties, in the same way as it has recognized the importance of national representation via comitology committees and scientific argument via scientific committees in implementation procedures.

B. Ensuring a Representative Nature

In addition to ensuring that consultative procedures are respected, can judicial review play a role in ensuring the representative nature of such procedures? In the United States, the representative nature of participatory procedures in delegated regulation is assumed by the fact that everybody has the same right of access. In the EU, on the other hand, functional participation is structured more by political or administrative intervention, that is, who can participate depends

on the decision of the Commission or Council. Can the Court intervene in this process?

In *Hauptzollamt München-Mitte v. Technische Universität München*, the Court of Justice ruled invalid an implementing Commission decision (among others) because the scientific committee consulted by the Commission to make that decision was not considered “representative,” that is, the members of that committee did not possess the technical knowledge they could be expected to have to adequately perform their technical task. In order to obtain duty-free importation of a scientific instrument, Regulation No. 2784/79 requires the Commission to set up a group of experts composed of representatives of all the Member States to examine whether the instrument fulfills the conditions. Although the regulation did not specify the qualifications of the members of such a scientific committee, the Court stated that “the group of experts cannot properly carry out its task unless it is composed of persons possessing the necessary technical knowledge in the various fields in which the scientific instruments concerned are used or the members of that group are advised by experts having that knowledge.”⁶⁶ Because these conditions were not met in the case at hand, the Court ruled that the Commission decision was invalid. Under certain conditions, the Court is thus in favor of judicial review of committee procedures in the implementation phase for what could be called reasons of “representativity.” However, it does not follow that the same reasoning could be applied to ensure the representativity of functional participation, that is, of civil society organizations, in delegated regulation.

First, as argued above, the *Technische Universität München* case can be placed into an emerging category of ECJ case law that values scientific expertise as a procedural requirement for legitimate risk regulation.⁶⁷ The representativity of a scientific committee consists in its members’ having the necessary technical expertise enabling an “objective” technical decision. The representativity of the AC, on the other hand, consists of an equal representativity of the concerned functional groups (management and labor) and national interests. The Court’s willingness to develop review of implementation measures to ensure the scientific value of risk regulation does not imply that the Court would be equally willing to develop such review of the “representativity” of functional participation in such risk regulation.

66. *Technische Universität München*, 1991 E.C.R. para. 22.

67. *See id.*

Second, the *Technische Universität München* case deals with an individual implementation decision addressed to a private party. The Court stresses that, in such cases, the rights guaranteed by the Community legal order in administrative procedures should be respected, such as the “duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case and the right of the person concerned to make his views known and to have an adequately reasoned decision.”⁶⁸ However, it is confirmed case law of the Court to apply less procedural rigor with respect to regulatory implementation than to administration directly addressed to individuals, or, in the words of the Court, judicial review must be less the more “the act concerned is of general scope.”⁶⁹ Put differently, judicial review on delegated regulation will be less rigorous than on individual decisions but is likely to be more rigorous than on legislation.

Third, although there may be more space for judicial review on the representation of an advisory committee that is to be consulted in the drafting process of a Commission directive through comitology than on such consultation in a legislative process, there remains a risk of conflict between the judgment by the court and that by political representatives. Namely, the composition of an advisory committee may have been decided by Council decision, as is, for instance, the case with the tripartite Advisory Committee on Safety and Health at Work. So even in a case where the representation of the committee would be contested in the context of a regulatory implementation procedure, intervention by the Court would mean replacing the political judgment on representation given by political representatives in the Council with the judgment by unelected judges. The ECJ is reluctant to interfere in this way, and judicial review on representation, if developing at all, will most likely be limited to committees set up by the Commission.

C. General Limits of Judicial Review on Functional Participation

As shown in my example in the field of OH&S, judicial review on functional participation in EU governance appears fairly limited. The reluctance to use judi-

68. *Id.* para. 14.

69. See Case C-150/94, *United Kingdom v. Council* [11] E.C.R. I-7235 (1998); Case T-521/93, *Atlanta v. Comm'n* [10/11/12] E.C.R. II-1707 (1996); Case T-122/96, *Federolio v. Comm'n* [9/10] E.C.R. II-1559 (1997); Case T-199/96, *Bergadem v. Comm'n* [7/8] ECR II-2805 (1998); see also L^oic Azoulay, *The Judge and The Community's Administrative Governance*, in *GOOD GOVERNANCE IN EUROPE'S INTEGRATED MARKET* 118 (Christian Joerges & Renaud Dehousse eds., 2002).

cial review as a way to ensure functional participation in legislative procedures, or in relation to committees set up by Council decision can easily be understood by the fear of replacing the judgment of political representatives with the decision of judges. However, in relation to regulatory implementation and participatory structures set up by administrative decision, judicial review on functional participation is desirable. Two general characteristics of the EU institutional setting—that contrast with the United States—make it difficult for such review to develop today. First of all, there is a lack of strong institutionalization of, and procedural requirements for, functional participation. Second, there are strong limits on *locus standi* for interest groups before the ECJ.⁷⁰ If functional participation is taken seriously as a source of legitimacy in regulatory implementation and administration, the requirements for such participation should be institutionalized and the position of interest groups before the Court should be strengthened.

IV. DELEGATED REGULATION AND THE CONSTITUTIONAL TREATY

On October 29, 2004 the Heads of State of the newly enlarged European Union signed the EU's Constitutional Treaty,⁷¹ the outcome of a deliberative and negotiative process that took place first in the European Convention and subsequently in the Intergovernmental Conference. If the Constitutional Treaty is ratified, it will replace the current Treaty establishing the EC and the Treaty on the European Union. The enlargement of the EU made such a constitutional revision necessary, but other objectives inspired this reform, such as the idea that a simplification of the EU's instruments and procedures would make the EU more comprehensible to its citizens and thus increase its legitimacy. One of the central ideas was to provide the EU with a clear hierarchy of norms and a clearer delineation between the legislative and executive branches of government. We cannot provide here a detailed assessment as to what extent these objectives have been reached.⁷² Yet, when looking at regulatory implementation, one should conclude that the Constitutional Treaty is not free of ambiguity.

70. For a recent analysis, see Olivier De Schutter, *Group Litigation Before the European Court of Justice*, in *CIVIL SOCIETY AND LEGITIMATE EUROPEAN GOVERNANCE*, *supra* note 15.

71. TREATY ESTABLISHING A CONSTITUTION FOR EUROPE, Dec. 16, 2004, O.J. (C 310) 47 (2004), available at <http://europa.eu.int/eurlex/lex/JOHtml.do?uri=OJ:C:2004:310:SOM:EN:HTML> (last visited Feb. 11, 2005).

72. See Paul Craig, *The Constitutional Treaty: Legislative and Executive Power in the Emerging Constitutional Order* (European University Institute 2004), available at <http://ideas.respec.org/p/erp/euillaw/p0007.html> (last visited Feb. 11, 2005).

The Constitutional Treaty contributes to simplification and transparency as far as legislation is concerned. European legislation is now clearly defined with the terms “European laws,” which are of general application, binding in their entirety, and directly applicable in all Member States, corresponding to current regulations, and “European framework laws” that are binding on the Member States as to the result to be achieved, but leaving them the choice of means of achieving the result, corresponding to current directives,⁷³ characterized by the ordinary legislative procedure (with some exceptions) that is based on co-decision and qualified majority vote and places the Council and the European Parliament on an equal footing.⁷⁴

Article I-37 confirms that the implementation of such European legislation is primarily the responsibility of the Member States. Yet, “where uniform conditions for implementing binding Union acts are needed, those acts may confer implementing powers on the Commission, or, in specific cases . . . on the Council of Ministers.” Union implementing acts shall take the form of European implementing regulations⁷⁵ or European implementing decisions.⁷⁶ Article I-37 also states that “European laws shall lay down in advance the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers.” This phrasing clearly recalls the current basis for comitology provided in Article 202 of the EC Treaty. One would therefore expect that European regulatory implementation may take the same form as is currently the case, mainly through delegation to the Commission, controlled by comitology procedures.

However, the nature of comitology is likely to be revised. Article I-37 of the Constitutional Treaty requires that the mechanisms for control by Member States of the Commission implementing acts (comitology) must be laid down in

73. See TREATY ESTABLISHING A CONSTITUTION FOR EUROPE, *supra* note 71, art. I-33.

74. *Id.* art. III-396.

75. The Treaty Establishing a Constitution for Europe states:

A European regulation shall be a non-legislative act of general application for the implementation of legislative acts and of certain provisions of the Constitution. It may either be binding in its entirety and directly applicable in all Member States, or be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.

Id. art. I-33.

76. “A European decision shall be a non-legislative act, binding in its entirety. A decision which specifies those to whom it is addressed shall be binding only on them.” *Id.* art. I-33.

European laws, adopted by the ordinary legislative procedure, and no longer by the Council of Ministers alone, acting unanimously, as has been the case for the current Comitology Decision. Since the EP will thus have a co-decision role in defining the comitology procedures in a new European law, it is likely that the position of the Parliament in these procedures will be strengthened.⁷⁷

Moreover, the picture becomes more complicated because the Constitutional Treaty provides a new category of norms, defined as “delegated European regulations” (Article I-36). European laws and framework laws may delegate to the Commission the power to adopt delegated European regulations to supplement or amend certain nonessential elements of the law or framework law. The Constitutional Treaty requires that “the objectives, content, scope and duration of the delegation of power shall be explicitly defined in the European laws and framework laws.” It also stresses that “the essential elements of an area shall be reserved for the European law or framework law and accordingly shall not be the subject of a delegation of power.”

According to Article I-36, such

European laws and framework laws shall explicitly lay down the conditions to which the delegation is subject; these conditions may be as follows: (a) the European Parliament or the Council may decide to revoke the delegation; (b) the delegated European regulation may enter into force only if no objection has been expressed by the European Parliament or the Council within a period set by the European law or framework law.

The introduction of the category of “delegated European regulations” is a reply to the critique that European legislation is too detailed. As things stand, the legislator has no satisfactory mechanism to delegate the technical aspects or details of legislation while still retaining control over such delegation. He is obliged either to go into minute detail in the provisions he adopts, or to entrust to the Commission the more technical or detailed aspects of the legislation as if they were implementing measures, in which case, control is entrusted to the Member States via comitology, but not satisfactorily to the European legislator.

77. Herwig C.H. Hofmann, *A Critical Analysis of The New Typology of Acts in The Draft Treaty Establishing a Constitution for Europe*, 7 EUROPEAN INTEGRATION ONLINE PAPERS 8 (2003), available at <http://eiop.or.at/eiop/texte/2003-009a.htm> (last visited Feb. 10, 2005).

The introduction of such a category of delegated regulations has been strongly supported by the European Commission, premised on the hope that it would lead to a dismantling or weakening of comitology. In that case, regulatory implementation by the Commission would not be conditioned by the control of the Member States through comitology committees.

The introduction of “delegated European regulations” may thus imply a shift in conceiving the legitimacy of regulatory implementation. The legitimacy of comitology procedures resides in the *ex ante* input through deliberation by Member State representatives in the comitology committees. In contrast, the legitimacy of delegated European regulations would reside in the *ex ante* definition in the law, by the Council and the EP, of the conditions for delegation, combined with some control *ex post* if the measure should not be to the liking of the Council or the EP.⁷⁸

Conceiving the legitimacy of European regulatory implementation in this way would bring us closer to the U.S. system of delegated regulation.⁷⁹ However, one should acknowledge all elements of the U.S. system of delegated regulation. As discussed above, it is not only a question of having a more clearly defined legislative mandate. The legitimacy of the system also depends on the judicial review of such delegation and on a regulated system of participatory procedures for stakeholders, again with judicial review.

If the EU were to do away with comitology, it may not be enough to ensure legitimacy of regulatory implementation by simply improving how the conditions of delegation in the law are set out. Judicial review of such delegation is desirable. Moreover, if the input *ex ante* of Member State representatives were lacking, it would be desirable to strengthen and regulate the input *ex ante* by stakeholders.

As analyzed in this paper, the participation of stakeholders in European regulatory implementation is partially institutionalized, and to a certain extent, the

78. See Craig, *supra* note 72, at 32.

79. The system would remain in any case considerably different because delegation is conceived of only in favor of the European Commission. European laws and European framework laws cannot delegate the power to enact delegated European regulations to other agencies and bodies. The Constitutional Treaty in fact “constitutionalises a strict understanding of limitations to delegation under what is known as the ‘Meroni-doctrine.’” Hofmann, *supra* note 77, at 6. While this constitutional phrasing may be in tension with some tendencies in EU governance, it clearly confirms a limit on the establishing of multiple agencies which would have considerable decision-making power. See TREATY ESTABLISHING A CONSTITUTION FOR EUROPE, *supra* note 71, art. I-36.

ECJ could build on current case law to strengthen judicial review of such participation. If comitology were to lose importance as a control mechanism on delegated regulation, the ECJ may be ready to strengthen judicial review of the participation of stakeholders. Yet, as seen in our analysis above, stronger judicial review can only go hand in hand with a stronger institutionalization of participatory rights. Whether such institutionalization should take the form of a more pluralist system of interest intermediation like in the United States, or could build on a corporatist pattern more common within Europe, remains undiscussed. Space precludes such a debate here, but some food for thought can be found elsewhere.⁸⁰

In any case, whether the U.S. experience with functional participation in delegated regulation may be an inspiration for the EU will depend on whether the introduction of the category of delegated European regulations in the Constitutional Treaty implies a real step back from comitology. The Constitutional Treaty is ambiguous on this point.

Two factors play an important role here. First, Article I-36 gives two examples of conditions to which delegation is subject. Yet this list is not exhaustive.⁸¹ One could imagine that also for delegated European regulations under Article I-36, the European law or framework law would require the respect of a comitology procedure, with or without a callback option by the EP or the Council.

However, during the discussion preparing the Constitutional Treaty, it appeared that at least the European Commission considers the use of a regulatory or management committee of comitology in contradiction with the nature of a delegated European regulation.⁸² A callback procedure (i.e., either the power of the legislator to withdraw the delegation of competence conferred to the Commission or the veto by the legislator against the adoption by the Commission of a concrete measure on that basis) would not be compatible with maintaining a comitology committee procedure that allows only the Council to quash the Commission's measure following a negative opinion issued by the committee of Member State representatives. According to the Commission, this would be contrary to its aim to place both legislative branches on an equal footing with re-

80. See SMISMANS, *supra* note 3, at 447–56.

81. In an earlier draft of the article discussed in the Convention, the list of options was longer but exhaustive. See Hofmann, *supra* note 77, at 12.

82. See European Commission, Working Group IX on Simplification, *The European Convention, Working Document*, at 27 (PP/mm-D (2002) 700167), Nov. 18, 2002, available at <http://european-convention.eu.int/docs/wd9/5419.pdf> (last visited Feb. 13, 2005).

gard to the Commission's executive activity (at least as far as acts adopted by co-decision are concerned). Consequently, a callback procedure could only function with purely consultative committees that would supply the Commission with expertise and opinions concerning the concrete application of executive measures at the national level.

Second, the relation between delegated European regulations and European implementing regulations is ambiguous. Delegated European regulations are based by definition on a European law or a European framework law. A European implementing act (which can be a regulation or a decision) implements a binding Union act, which can be the Treaty itself, a legislative act (law or framework law), or a delegated European regulation.⁸³ A European implementing regulation can thus be used to implement a law or framework law, or to implement a delegated European regulation.⁸⁴ In the first case, it will be up to the legislator to decide whether he prefers to leave detailed regulation to a delegated European regulation or to a European implementing regulation.

Put differently, it is entirely up to the European law or European framework law to define the conditions for regulatory implementation, whether by relying more on the legitimacy of the EP and the Council in defining delegation and providing a callback option, or by simply referring to a comitology procedure, or by a combination of these. While the "maximum control option," combining, for instance, a callback option with a regulatory comitology committee seems exaggerated, one should also be aware that doing entirely away with comitology and relying on the control mechanisms mentioned in Article I-36 may be too minimal. As Craig argues, it may often be difficult for the Council and the EP to specify with any exactitude the criteria that should guide the exercise of power by the Commission. Moreover, if comitology is dismantled, then it may not be easy for the Council or the EP to decide whether to exercise their powers relating to revocation of the delegation, and/or entry into force, because they might not have the requisite information with which to make this decision.⁸⁵ Therefore, the more one

83. See Chairman of the Working Group IX on Simplification, *Final Report of Working Group IX on Simplification*, at 9 (CONV 424/02), Nov. 29, 2002, available at <http://register.consilium.eu.int/pdf/en/02/cv00/00424en2.pdf> (last visited Feb. 15, 2005).

84. The reading of the Constitutional Treaty theoretically allows for a law delegating to a delegated European regulation which subsequently leaves regulatory measures to European implementing regulations. This further complicates the possible combinations of control mechanisms on regulatory implementation.

85. See Craig, *supra* note 72, at 33.

dismantles comitology, the more it is desirable to provide participatory procedures for stakeholders and ensure judicial review of such procedures.

The debate on the Constitutional Treaty has left these questions unresolved. Yet they have very important consequences on the democratic nature of European policymaking as they draw the line between legislation and administrative regulation, and conceive participation in, and democratic control over, regulation.

CONCLUSION

The legitimacy of delegated regulation is conceived of quite differently in the EU and in the United States. In the United States, such legitimacy resides in the combination of a clear legislative mandate, participatory procedures, and judicial review. In contrast, the legitimacy of European regulatory implementation is largely ensured by the “control *ex ante*” by Member State representatives in comitology committees. Yet comitology procedures have been criticized for their lack of transparency and lack of parliamentary involvement.

Strangely enough, the role of stakeholder participation in European regulatory implementation has never been a hot topic in European political and academic debate. While the issue of civil society participation has pervaded EU institutional discourses over the last years, this has surprisingly not been the case regarding a stage of policymaking where such participation may prove to be particularly important in terms of legitimacy and democratic control, namely regulatory implementation. Moreover, in reality, functional participation does, to a certain extent, take place in European regulatory implementation. As the example of occupational health and safety regulation shows, such participation can be a source of legitimacy in regulatory procedures where parliamentary participation is weak or as a way to counterbalance scientific expertise. Yet to date, functional participation is weakly institutionalized and the possibilities for judicial review are limited.

The new Constitutional Treaty may give rise to a reconceptualization of the legitimacy of European regulatory implementation and strengthen the importance of functional participation therein. The category of European delegated regulation seems to take a step back from control by Member States through comitology committees and to go into the direction of the U.S. style of delegated legislation which combines legislative mandate with participatory procedures and judicial review. However, whereas the constitutional text is ambiguous on whether there is some real intention to withdraw (partially) from comitology,

the consequences for the importance of participatory procedures and judicial review in regulatory implementation did not even enter the constitutional debate. Put differently, the EU's "constitutional moment" that took form around the European Convention and the Intergovernmental Conference preparing the Constitutional Treaty has lost an important occasion to discuss an important question each modern democracy must deal with: how to organize administrative regulation in a democratic way.