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Governance Structures for Nanotechnology Regulation in the European Union

by Geert van Calster

Editors' Summary: The United States is not the only government facing the challenges of nanotechnology regulation. The European Union (EU) is also contemplating a regulatory mechanism for this new technology. Prof. Geert van Calster discusses the EU approach in this Article. He begins with an overview of regulation in the EU, and explains how the growing trend toward co- and self-regulation might be applied to nanotechnology. He then describes the impact that the Aarhus Convention may have on regulation, including access to information. The Article concludes with the prediction that the growth of nanotechnology will not lead to radically new regulation mechanisms in the EU.

I. Introduction: Governance and Law Making in the European Union

Many readers of this Article will understand "governance" as a synonym for "regulation."[1] However, governance rings a specific bell in European minds. The European Commission (EC) has suggested its own concept of governance in its April 2001 White Paper on European Governance, in which the term "European governance" refers to "rules, processes and behaviour that affect the way in which powers are exercised at [the] European level, particularly as regards openness, participation, accountability, effectiveness and coherence."[2] In the White Paper, the EC also revisited the issue of regulatory instruments. While the White Paper is meant to be a general review of better governance through increased accountability and transparency, it also includes a chapter on better law making, which is currently the focus of much discussion.[3]

In particular, the White Paper singles out the environmental sector as a prime candidate for what it terms "self-regulation" and "co-regulation." Under the self-regulation formula, industry itself would suggest a solution for a given environmental challenge, and the EC would acknowledge this initiative through a recommendation coupled with a monitoring regime. The co-regulation formula would be more akin to a true contract between the Community and industry. Previously, this type of instrument was known as an "environmental agreement."[4] The White Paper foresaw that these co-regulations would be characterized by increased involvement of the European Parliament and the Council of Ministers (the Council), as well as by a stricter monitoring mechanism.

The White Paper in general, and self-regulation and co-regulation in particular, have received much attention from industry. However, I doubt whether these concepts will make much of an impact on European Union (EU) regulatory practice. The EC itself acknowledges that there are few candidate sectors in which it would like to promote self- and co-regulation: polyvinyl chloride, waste, and climate change are the only identified priority areas. In 2001, when the White Paper was written, nanotechnology regulation was not quite on the horizon. Hence, it is unlikely that nanotechnology was meant to be included in this shortlist. However, it is clear that the EC does not intend for self- and co-regulation to replace its traditional regulatory approach. Moreover, the European Parliament has expressed skepti-

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1. This Article profited from the discussions at the May 2006 workshop held by the Environmental Law Institute (ELI) at the Vanderbilt Center for Environmental Management Studies and the Owen School of Management at Vanderbilt University. *See* http://www2.eli.org/research/events/nanotech5.19.06.htm.
2. European Commission, European Governance—A White Paper 428 n.1 (COM 2001) [hereinafter 2001 White Paper], *available at* http://europa.eu.int/eur-lex/encom/cnc/2001/com2001_0428en01.pdf. That the concept should be defined in a footnote is somewhat surprising, given its importance. It is, in itself, not the best example of good governance.
3. The goal of more effective regulation is also part of the Lisbon Agenda, a process begun by the 2000 Lisbon European Council, which resolved to make the European Union (EU) the leading knowledge-based economy by 2010.
4. *See* Geert van Calster, *The Use of Voluntary Agreements in the European Community's Environmental Policy*, *in* Environmental Contracts: Comparative Approaches to Regulatory Innovation in the United States and Europe 199-246 (Eric Orts & Kurt Deketelaere eds., Kluwer Law Int'l 2001) (with Kurt Deketelaere).

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cism about these approaches, citing a number of disadvantages to co- and self-regulation.[5]

I propose that other factors besides self- and co-regulation will have an impact on nanotechnology regulation in the EU. These include the Aarhus Convention,[6] which empowers citizen groups as well as environmental nongovernmental organizations (NGOs), both at the EU and Member State level, and the attempts—relatively unsuccessful so far—to better involve nonindustry actors in the standardization process.

II. Widening the Scope of Existing Regulatory Instruments

A. Traditional Legal Instruments in the EU

Community law, adopted by the Council—or by the Parliament and Council in the framework of the co-decision procedure—may take one of the following forms: regulations, which are directly applied without the need for national measures to implement them; directives, which bind Member States as to the objectives to be achieved while leaving the national authorities the power to choose the form and the means to be used; decisions, which are binding in their entirety upon those to whom they are addressed (this could be any or all Member States, undertakings, or individuals); and recommendations and opinions, which are not binding but are issued, e.g., to clarify EC practice on a certain issue.[7]

B. From Command-and-Control to Market-Based Instruments and Self-Regulation

When seeking to protect the three constituent parts of the concept of sustainable development—social values, environmental resources, and economic welfare—States and the international community principally have a choice between two approaches.

The first approach is recourse to international cooperation and/or coordination. This school of thought is fearful of externalities vis-à-vis both environmental protection and social values, should States not be encouraged to set a minimum level of protection for both. Indeed, this approach predicts a race to the bottom, whereby States are tempted to give their industry considerable freedom in order to protect competitiveness. In the EU, this has led to what is often referred to as "deep integration," of which EU environmental policy is a good example. Deep integration assumes that trade and industry are best served with the creation of a "level playing field," a global or regional market in which the regulatory framework is coordinated and at best harmonized. The second approach, on the other hand, highlights the advantages of regulatory competition, particularly the advancement of regulatory techniques through trial and error, as well as the reward for regulatory efficiency.[8] This dichotomy could be summarized as laissez-faire v. harmonization.

A concurrent yet distinct theme, both at the national and international level, is the search for the optimal instrument in enforcing whichever level of regulation, harmonized or not, that has been established. Here there are also two potential approaches: one that relies heavily on the regulator's initiative and authority (a top-down approach), and one that seeks to engage the initiative of the market players themselves (a bottom-up approach). Rephrasing this in terms of the instruments chosen, the first approach relies on command-and-control, the most recent reflection of which is the concept of performance-based regulation. The second approach places more of the regulatory initiative with the regulated themselves.

Environmental policy is a relatively young phenomenon at the international level. Nevertheless, one can detect a recurring pattern in States' choice of policy instruments. States usually begin with a top-heavy, command-and-control approach, characterized by direct regulation. Government prescribes uniform environmental standards across large regions, mandates the methods required to meet these standards, licenses production sites that adopt the required methods, and ensures compliance through monitoring and sanctions.[9] States as well as individual organizations subsequently encounter a number of regulatory failures of this approach. These include economic inefficiency, environmental ineffectiveness, and democratic illegitimacy.[10] These lead to a shift to a bottom-up approach, focusing on specific actors rather than on regulatory mechanisms[11]; and shifting to new instruments,[12] including environmental taxes and charges, green tax reform, tradable permits, subsidies, deposit/refund systems, labels, audits, and voluntary agreements.

This shift at the EU level has led to the catch-phrase, "industry is not just part of the problem, but also of the solu-

5. *Id.* Note, however, that the EC's new approach to some of these regulatory instruments, as set out in the 2001 *White Paper*, was precisely intended to address Parliament's concerns.

6. 38 I.L.M. 3, 517 (1999).

7. In 1951, the Treaty of Paris established the European Coal and Steel Community (ECSC). In March 1957, the Treaties establishing the European Economic Community (EEC) and the European Atomic Energy Community (Euratom) were signed by the original six Member States in Rome (Treaties of Rome). The EEC Commission was established as the executive branch. The Parliamentary Assembly and the Court of Justice were made common to all three Communities (ECSC, EEC, and Euratom). In 1965, a Treaty merged the executives of the three Communities. There is now one EC and one Council of Ministers. The Treaty of Maastricht on a European Union (1992) has led to some confusion with respect to the name of the various Treaties. The EEC no longer exists; it is now called the "European Community." "European Communities" is a term used to denote the three Treaties that together form the first pillar of the Treaty on European Union, i.e., the EC, Euratom, and ECSC. The EU refers to all three pillars of the Treaty of Maastricht, including the intergovernmental elements.

   The Treaty on European Union (TEU) based the Union's activities on three pillars. Pillar One covers a wide range of Community policies, such as agriculture, transport, environment, energy, research, and development. The issues covered by Pillar One are subject to the entire Community framework, including the power of the European Court of Justice to interpret the legislation arising out of the Pillar's legislative process. For the other two pillars created by the TEU—Common Foreign and Security Policy (Pillar Two) and cooperation in the fields of Justice and Home Affairs (Pillar Three)—the Council is the decisionmaker as well as the promoter of initiatives.

8. Regulatory Competition and Economic Integration IX (Daniel C. Esty & Damien Geradin, eds., Oxford Univ. Press 2001).

9. New Instruments for Environmental Policy in the EU 2 (Jonathan Golub ed., 1998).

10. *Id.* at 3.

11. Environmental Governance in Europe 61 (Albert Weale, ed., Oxford Univ. Press 2000).

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tion," culminating in widespread enthusiasm in industry circles for voluntary agreements between industry and the authorities.[13] However, the bottom-up approach, too, leads to disappointment. This approach includes potentially long periods of negotiation—in the context of voluntary agreements, for example—hence denying one of the alleged advantages of the bottom-up approach. Bottom-up also inevitably requires a certain amount of organization within industry, which may lead to practical concerns such as overrepresentation of big industry. Moreover, especially now that the transparent nature of environmental law is being emphasized, there is growing concern that bottom-up leads to regulation by stealth, served by the interests of few rather than of the environment as a whole.[14]

Performance-based regulation is arguably the latest attempt to combine the advantages of both command-and-control and bottom-up regulation. A performance-based regulatory standard is a rule, regulation, or standard that specifies the desired outcome but gives firms discretion in how they meet the outcome.[15] Firms could employ any number of instruments to meet the specified standard. Some of these approaches link environmental law and policy with political theory and ethics, giving rise to some fascinating challenges in implementing environmental protection policy—corporate social responsibility, management schemes and audits, and liability come to mind.

The EC's use of directives is arguably a performance-based standard *avant la lettre*. At the very core of directives lies the intention to preserve Member States' freedom with respect to the national strategy and instruments chosen, the only yardstick being the achievement of the prescribed result. Interestingly, the use of these directives is often singled out as an explanation for the weak implementation and enforcement records of most EU Member States in the environmental area. Some sectors of industry, in particular small- and medium-size enterprises as well as industry in the new Member States, argue that traditional command-and-control actually has some advantages, including predictability and straightforwardness, which other regulatory instruments lack. However, it is outside the scope of this Article to look into these.

C. Impact of the 2001 White Paper—Increasing Co-Regulation?

As noted, the White Paper on governance identified increasing co-regulation as one of the means to achieve better regulation:

> Co-regulation combines binding legislative and regulatory action with actions taken by the actors most concerned, drawing on their practical expertise. The result is wider ownership of the policies in question by involving those most affected by implementing rules in their preparation and enforcement. This often achieves better compliance, even where the detailed rules are nonbinding.[16]

In 2003, in response to the White Paper, the European Parliament, the Council, and the EC concluded an "inter-institutional agreement" on "better law making," in which they included provisions on co-regulation.[17] These provisions correspond to two concerns identified by the EC in the White Paper. The first concern is increased involvement of the Council and in particular of the Parliament. The inter-institutional agreement addresses this concern by instituting a cooling-off period after EC notification of a draft agreement. The second concern is the need for better monitoring, which was ultimately not addressed in the interinstitutional agreement, but deferred to the legislative act that eventually sanctioned the agreement. Curiously, the interinstitutional agreement gives a definition of co-regulation that shifts this regulatory model entirely to the implementation stage. It defines co-regulation as: "the mechanism whereby a Community legislative act entrusts the attainment of the objectives defined by the legislative authority to parties which are recognized in the field (such as economic operators, non-governmental organizations, or associations)."[18] Hence, in the agreement's approach, co-regulation not only implies the direct involvement of a public actor in the regulatory process, but also—unexpectedly and not necessarily following from the White Paper—it also presupposes a legislative act. Therefore, in this view, co-regulation complements legislation rather than replaces it.[19]

Today, it seems as though neither the 2001 White Paper nor the 2003 follow-up have led to an increase in co-regulation *sensu stricto*. However, that no co-regulation agreements have been notified to the European Parliament in accordance with the 2003 instrument does not mean that the Institutions have not made recourse to it *sensu lato*. As will also be argued below, there are a large number of gateways that, even if not formally classified as co-regulation, exhibit the substance of what constitutes co-regulation in practice.

D. Will It Matter for Nanotechnology?

The EC will determine the future direction of nanotechnology regulation. At this time, it is not formally involved in any type of voluntary action, unlike the U.S. Environmental Protection Agency (EPA), which is actively working on a voluntary program, the aim of which is the collection of information. EPA's Voluntary Nanomaterials Program[20] most certainly would be useful for obtaining access to hitherto internal company data. However, the scheme attracts the obvious criticism that because it is voluntary, it may not be successful in getting all data required.[21] So what is happening at the EU nanotechnology regulation level, and are there signs of a grand new regulatory scheme along the lines of co- and/or self-regulation?

The pace of development of EU regulation in the nanotechnology area will certainly not arouse suspicion of

12. Golub, *supra* note 9, at 4*ff*.
13. Orts & Deketelaere, *supra* note 4, at 201*ff*.
14. Cary Coglianese, ch. 4 *in* Orts & Deketelaere, *supra* note 4, at 97.
15. Cary Coglianese et al., Performance-Based Regulation, J.F. Kennedy School of Government, Harvard University, Regulatory Policy Program Report No. RPP-03, 3 (2002).
16. 2001 White Paper, *supra* note 2, at 21.
17. OJ [2003] C321/1.
18. 2001 White Paper, *supra* note 2, at 18.
19. *See* Linda Senden, *Soft Law, Self-Regulation, and Co-Regulation in European Law: Where Do They Meet?*, 9 Electronic J. Comp. L. 1 (2005).
20. *See*, *e.g.*, Lynn Bergeson, *Nanoscale Materials and TSCA: EPA's NPPTAC Recommends a Framework for a Voluntary Program*, 15 Envtl. Quality Mgmt. 61*ff* (2006).
21. *See*, *e.g.*, Jennifer Sass et al., *Nanotechnologies: The Promise and the Peril*, 6 Sustainable Dev. L. & Pol'y 11, 13 (2006).

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precautionary zealousness. The EC itself reportedly has rebuked some of its independent scientific committees for suggesting precautionary input in risk assessments—such a step is indeed contrary to the common practice of classifying precaution under risk management. In the United States, one can now draw upon a number of official and academic reports on the suitability of current laws to regulate nanotechnology,[22] whereas the EU has seen far fewer studies.[23] The EC has received but not yet disclosed the results of an in-house assessment of the suitability of the existing regulatory framework. Scientific studies on the risks associated with nanotechnologies are either requested from the internal independent scientific committees or tendered in accordance with usual procurement practice. In the various meetings, workshops, and similar events associated with nanoscience, the EC is certainly willing to listen to and accommodate the input of industry and of anyone who wants to make his view heard. All of this, however, is taking place without there being a grand move to a new regulatory approach in the field of nanotechnology, indeed, without a formalized consultation exercise—at least for the time being. The Brussels grapevine speculates that while the aforementioned in-house regulatory study predictably identifies some concerns with the current framework,[24] it does not suggest the development of a new, tailor-made law for nanotechnology.

There is one important area of EU legal practice that the EC characterizes as successful co-regulation: the so-called New Approach in EU standardization.[25] The original harmonization program of the Community was far too ambitious, aiming to create a single set of regulations throughout the Member States, in a variety of sectors, using the technique of so-called total harmonization. Voting procedures, as they then stood, required unanimity for legislation to be adopted. The opposition of a single Member State in a given area thus halted harmonization efforts. As a result, a large portion of the harmonization program was fruitless. The subsequent New Approach program of the EC centers on a principal role for so-called minimum harmonization. This entails defining a standard at the European level that, if it is met by products in the sector concerned, guarantees free movement of goods for these products. Member States may subject national production to stricter standards, albeit in principle only, within a purely national context. Importantly, the translation of the often embryonic minimum safety and other standards in EU legislation into more specific technical guidelines is carried out not by the EC, but rather, under mandate of the EC, by private bodies such as the European Committee for Standardization.

The New Approach also entails a greater emphasis on manufacturer's self-assessment of safety standards. This is reflected in the widely known trademark "CE," which refers to Conformité Européenne.[26] The toy sector is a prime example of reliance on manufacturers' self-inspection, rather than on lengthy and expensive procedures by national authorities. However, even in a New Approach context, national authorities still perform sample testing.

The New Approach, with its emphasis on minimum harmonization, is likely to be employed for nanotechnology, particularly for those elements of the sector that will require product regulation. However, recourse to minimum harmonization can now hardly be called revolutionary and its potential use in the nanotechnology sector would not be extraordinary.

III. The Impact of the Aarhus Process

Rarely quoted under its full name of the United Nations Economic Commission for Europe Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, the Aarhus Convention aims to establish improved environmental governance and democracy for its Signatory States,[27] using the three pillars to which its title refers. Abundant scholarship has explored and continues to explore the ins and outs of the Convention's obligations.[28] It is likely, given the increased pace of implementation of the Convention in its Member States, that the precise scope of the Convention's obligations will be tested in national courts and through the Convention's own dispute settlement mechanism before long. The expectation in the legal community is that the language employed in the Convention is such as to exclude direct effect of most of its provisions. However, in combination with some home-grown developments, such as the constitutional recognition of environmental rights in an increasing number of European countries (not just EU Member States), and with the development of environmental rights through the European Convention on Human Rights, Aarhus is exercising a supplementary role in brokering environmental governance throughout Europe.[29]

Coupled with the advanced use of information technology and the increasingly proactive use of the Internet by national and EU authorities alike,[30] the access to information provisions of the Aarhus Convention are the most likely to be adhered to in the near future. However, access to the outcome of scientific studies into the health and safety impact of nanotechnologies, for example, is subject to the hurdles that generally apply to access to science, such as the need for peer review (especially in cases of im-

22. See the most recent work from the American Bar Association Section of Environment, Energy, and Resources at http://www.abanet.org/environ/nanotech/; *see also infra* note 23.

23. *See* Geert van Calster, *Regulating Nanotechnology in the European Union*, 3 NANOTECH. L. & BUS. 359-72 (2006); also published in EUR. ENVTL. L. REV. 238-47 (2006).

24. These concerns include the shortcomings of any regulations that define their field of application in terms of size or mass; the issue of what constitutes a "new" substance or product, e.g., for chemicals regulation; the very practical difficulty of distinguishing, in the nanotechnology field, among foods, food supplements, and drugs; and the concerns associated with labelling.

25. *See* Council Resolution of May 7, 1985 on a new approach to technical harmonization and standards, OJ [1985] C136/1.

26. The Conformité Européenne is the process by which the manufacturer, whether based in the EU or not, confirms that the product conforms to the EU's safety, environmental, and other product standards.

27. Including a high number of former Soviet Republics.

28. Indeed, the "outs" seem often more crucial than the "ins," as a variety of Signatory States have tried their best to limit exposure to the Convention at the time of negotiations.

29. *See*, *e.g.*, Stephen Sec, *'Aarhus Environmental Rights' in Eastern Europe*, *in* YEARBOOK OF EUROPEAN ENVIRONMENTAL LAW 1 (Oxford Univ. Press 2005).

30. On the impact of the information society, see Daniel C. Esty, *Environmental Protection in the Information Age*, 79 N.Y.U. L. REV. 115-211 (2004).

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mediate publication of results for media and research funding purposes), and intellectual property issues in cases of privately funded studies.[31] Moreover, the uninhibited, immediate publication of research on the impact of nanosciences may offer activists, the general public, and public authorities such a piecemeal view of nanoscience that the sector as a whole will be tarnished as a result of concerns raised by individual applications.[32]

It is also noteworthy that authorities often require a process of a general nature, such as the Aarhus Convention, to drive a particular initiative through the organization, regardless of the exact legal force of the instrument. For instance, Brussels often heaves with cries to increase transparency and Parliament input into the many technical committees which guide the implementation of and follow-up to EU legislation once it is adopted; these cries are often accompanied by references to the Aarhus Convention, even though strictly speaking, a lot of the goings-on in these committees would not be covered by the Convention's provisions.

While the Aarhus Convention and its implementation at the EU and national level may empower existing organizations, it does not—nor was it meant to—address the existing imbalance in the EU, as elsewhere, between the representation of industry's interests and those of civil society. Whether this is to be remedied by increased public funding of NGOs (in the absence of an established culture of philanthropy in the EU), or by the creation of something akin to a "Science Watch" at the EU level,[33] it certainly ought to be part of the governance process.

Related to the previous heading is the topic of better involvement of environmental and other NGOs in the translation of minimum standards into technical requirements.[34] Part of the debate on this issue undoubtedly is linked to the straightforward but onerous concerns of funding. More intricate challenges, however, include the lack of involvement of stakeholders in conformity assessment of environmental standards and of the environmental aspects of other standards; as well as the training of relevant staff to ensure proper follow-up on these standards. Simply throwing money at environmental and consumer NGOs at the European and international levels will not suffice to address these concerns. To ensure the proper delivery of the environmental promise of standards requires penetration of health, safety, and environmental concerns from the design stage through to production, use, and disposal.

IV. Conclusion

This Article has reviewed the regulatory context in which EU law on nanotechology is to be developed. At this preliminary stage of regulation, there are no indications that the development of regulation of nanotechnologies will be as rapid as the development of the technologies themselves. There are no indications that the European authorities view nanotechnology as a sector where radical new types of regulation will be implemented. Rather, in some parts of industry and often within the new Member States, a return to more classic command-and-control structure is advocated.

That said, the EC is not neglecting the need for development of health, safety, and environmental legislation for the nanotechnology area. It is aware of the importance of the development of nanotechnology regulation for the general debate on the precautionary principle and, as a consequence, is not going to be rushed into developing legislation for the sector.

31. See generally the debate on the publication of science. *See, e.g.*, EUROPEAN COMMISSION, STUDY ON THE ECONOMIC AND TECHNICAL EVOLUTION OF THE SCIENTIFIC PUBLICATION MARKETS IN EUROPE: FINAL REPORT (2006), *available at* http://ec.europa.eu/research/science-society/pdf/scientific-publication-study_en.pdf.

32. See similar concerns with respect to the more general debate on the precautionary principle in CASS SUNSTEIN, LAWS OF FEAR (Cambridge Univ. Press 2005).

33. A suggestion made by Bruce Ballantine. *See Enhancing the Role of Science in the Decisionmaking of the European Union* (European Policy Centre, Working Paper No. 17, 9) (2005).

34. See in particular the European Commission Communication on "The Integration of Environmental Aspects Into Standardisation," COM 130 (2004).