SOFT LAW OVERSIGHT MECHANISMS FOR NANOTECHNOLOGY

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ABSTRACT: Few observers doubt that regulatory oversight is now or will ultimately be necessary for at least some nanotechnology products and processes. Yet oversight need not take the form of mandatory command-and-control regulation: regulation increasingly follows a more flexible governance paradigm that incorporates private and public-private arrangements. This article reviews eleven public and private soft law oversight mechanisms for nanotechnology operating within the United States, the European Union and transnationally. It then provides a framework for assessing such mechanisms, considering the characteristic strengths and weaknesses of public and private approaches as well as the impact of specific design choices. We find that the existing mechanisms have a mixed record: many incorporate shallow commitments, few actively promote implementation, and none engage in significant monitoring or provide strong incentives for compliance. Accordingly, we call on public authorities—as well as industry groups, research bodies, and other stakeholders—to actively promote the emergence of new more effective soft law oversight mechanisms for nanotechnology and work to strengthen existing mechanisms.

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Few observers doubt that more substantial regulatory oversight for nanotechnology products, applications and processes will be necessary in the future, if not immediately:[1]

> First, some nanotechnologies, if left unregulated, are likely to pose very real if currently unknowable risks of significant health or environmental damage. Second, public confidence in new technologies [and in regulatory systems]

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1. Gary E. Marchant & Douglas Sylvester, *Transnational Models for Regulation of Nanotechnology*, 34 J.L. MED. & ETHICS 714, 714 (2006).

> may be permanently damaged if injurious nanomaterials are released without adequate, or at least the perception of adequate, oversight.[2]

In addition, the rapid development of nanotechnology raises issues of equity (for example, nanotechnology may cement the market position of economies and firms with head starts in research and intellectual property protection); ethics (for example, nanotechnology may contribute to human enhancement); social priorities (for example, nanotechnology may reinforce a societal focus on technological solutions to social problems); and democracy (for example, nanotechnology may develop with limited public input).[3]

Demands for nano-specific regulation based on the precautionary principle, coupled with demands for transparency and public involvement, have paralleled the explosive development of nanotechnology itself.[4] To cite just two examples, in 2007, a diverse coalition of civil society organizations (CSOs) led by the International Center for Technology Assessment (ICTA) called for adoption of "a *sui generis,* nano-specific regulatory regime" as part of their recommended "Principles for the Oversight of Nanotechnologies and Nanomaterials."[5] As recently as June 2011, the Institute for Agriculture and Trade Policy, an international CSO, called for products containing engineered nanomaterials to "be regulated and tested prior to commercial release"[6] and subject to postmarketing surveillance.[7]

To date, however, governmental responses to these demands have been limited. To be sure, regulatory authorities in the United States, the European Union and other jurisdictions have begun to take modest regulatory actions, as discussed in the accompanying article[8] and listed in the online database of nanotechnology measures some of the authors of this article recently created.[9] For example, in June 2011, the U.S. government issued three regulatory docu-

2. Gary E. Marchant et al., *A New Soft Law Approach to Nanotechnology Oversight: A Voluntary Product Certification Scheme*, 28 UCLA J. ENVTL. L. & POL'Y 123, 124 (2010) [hereinafter Marchant et al., *New Soft Law*].

3. Georgia Miller & Gyorgy Scrinis, *The Role of NGOs in Governing Nanotechnologies: Challenging the 'Benefits Versus Risks' Framing of Nanotech Innovation*, *in* INTERNATIONAL HANDBOOK ON REGULATING NANOTECHNOLOGIES 409, 414–19 (Graeme Hodge et al. eds., 2011).

4. *Id.* at 413.

5. INT'L CTR. FOR TECH. ASSESSMENT (ICTA) ET AL., PRINCIPLES FOR THE OVERSIGHT OF NANOTECHNOLOGIES AND NANOMATERIALS (2008), *available at* http://www.icta.org/files/2012/04/080112_ICTA_rev1.pdf.

6. Press Release, Inst. for Agric. & Trade Policy, Lack of Nanotechnology Regulation a Danger to Human Health, Environment (June 29, 2011), *available at* http://www.iatp.org/files/2011.06.28%20AgriNanotech%20SS.pdf.

7. For other calls for regulation, see Robert Lee & P.D. Jose, *Self-Interest, Self-Restraint and Corporate Responsibility for Nanotechnologies: Emerging Dilemmas for Modern Managers*, 20 TECH. ANALYSIS & STRATEGIC MGMT. 113, 121 (2008); Andrew D. Maynard, *Safe Handling of Nanotechnology*, 44 NATURE 267, 268 (2006); Kevin Reinert et al., *Nanotechnology Nexus—Intersection of Research, Science, Technology, and Regulation,* 12 HUM. ECOLOGICAL RISK ASSESSMENT 811, 815–817 (2006).

8. Gary E. Marchant et al., *Big Issues for the Small Stuff: Nanotechnology Risk Management and Regulation*, 52 JURIMETRICS J. ??? (2012). **[Flagged for final pagination.]**

9. *The Nanotech Regulatory Document Archive*, ARIZ. STATE UNIV., http://nanotech.law.asu.edu/ (last visited Apr. 2, 2012).

ments on nanotechnology on the same day—a Policy Principles Guidance issued by the White House,[10] a Food and Drug Administration (FDA) draft guidance for determining whether a product involves the application of nanotechnology,[11] and a draft guidance by the Environmental Protection Agency (EPA) on policies for pesticide products containing nanotechnology.[12] The EPA has also adopted rules under the Toxic Substances Control Act (TSCA) requiring manufacturers of carbon nanotubes to report any new product or new use to EPA before marketing it.[13] EPA is also developing rules under TSCA to require reporting on nanomaterials and testing of certain nanoscale materials.[14] In the European Union, regulators have adopted nanotechnology labeling, notification and safety requirements under the regulatory framework for cosmetics,[15] and are considering regulation of nanomaterials under the REACH program for chemicals.[16] Australia has also introduced certain notification requirements on new chemicals considered to be "industrial nanomaterials."[17]

As this brief summary suggests, however, regulators have not followed the strongly precautionary, sui generis approach to nanotechnology regulation that groups such as ICTA advocate; far less have they engaged broader social and ethical issues. Rather, regulatory authorities have adopted largely preliminary or incremental measures, primarily addressing reporting and labeling, within existing regulatory frameworks, such as TSCA and the E.U. cosmetics

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10. Memorandum from John P. Holdren et al., Office of Sci. & Tech. Policy et al., Exec. Office of the President, to the Heads of Exec. Dep'ts & Agencies, Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials (June 9, 2011), *available at* http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf (describing principles for the review and oversight of nanomaterials).

11. *Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology*, FOOD & DRUG ADMIN. (June 14, 2011), http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm.

12. Environmental Protection Agency, Pesticides: Policies Concerning Products Containing Nanoscale Materials; Opportunity for Public Comment, 76 Fed. Reg. 35383 (June 17, 2011).

13. *E.g.,* Environmental Protection Agency, Multi-Walled Carbon Nanotubes: Significant New Use Rule, 76 Fed. Reg. 26,186 (May 6, 2011) (to be codified at 40 C.F.R. pts. 9 & 721).

14. *Control of Nanoscale Materials Under the Toxic Substances Control Act*, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/oppt/nano/#existingmaterials (last visited Apr. 14, 2012).

15. Diana M. Bowman et al., Letter to the Editor, *Nanomaterials and Regulation of Cosmetics*, 5 NATURE NANOTECH. 92, 92 (2010); Ned Stafford, *New European Nanotechnology Decree Requires Labelling of Nanoparticles in Cosmetics*, NANOWERK NEWS (Nov. 27, 2009), http://www.nanowerk.com/news/newsid=13723.php.

16. LINDA BREGGIN ET AL., SECURING THE PROMISE OF NANOTECHNOLOGIES: TOWARD TRANSATLANTIC REGULATORY COOPERATION 44–47 (2009), *available at* http://www.chathamhouse.org/sites/default/files/public/Research/Energy,%20Environment%20and%20Development/r0909_nanotechnologies.pdf; Diana M. Bowman & Geert van Calster, Commentary, *Does REACH Go Too Far?*, 2 NATURE NANOTECHNOLOGY 525, 527 (2007); For the most recent developments in the treatment of nanomaterials under REACH, see *Nanomaterials: Nanomaterials in REACH and CLP*, EUROPEAN COMM'N, http://ec.europa.eu/environment/chemicals/nanotech/ (last updated Feb. 23, 2012).

17. *See* NAT'L INDUS. CHEMS., NOTIFICATION & ASSESSMENT SCHEME, GUIDANCE ON NEW CHEMICAL REQUIREMENTS FOR NOTIFICATION OF INDUSTRIAL NANOMATERIALS, 1 (2010), *available at* http://www.nicnas.gov.au/current_issues/Nanotechnology/Guidance%20on%20New%20Chemical%20Requirements%20for%20Notification%20of%20Industrial%20Nanomaterials.pdf.

program. Similarly, most current measures focus on specific products, such as carbon nanotubes, chemicals or cosmetics, rather than all nanomaterials or technologies as a class.

A major reason for the tentative nature of these measures is the inherent difficulty of regulating nanotechnology.[18] Nanotechnology encompasses numerous, highly diverse forms and applications. As a result, even a definition of the word *nanotechnology* has yet to be universally agreed upon.[19] Nanotechnology is also advancing at a remarkable pace. New products and applications are constantly being developed, moving rapidly from simple nanoparticles to more complex and active materials. In addition, there remain major uncertainties and data gaps regarding health, safety and environmental risks.[20] Finally, nanotechnology promises substantial (though still not fully identified) health, environmental and other benefits; while an emphasis on such concrete benefits may distract from consideration of broader social transformations,[21] they undoubtedly provide a strong disincentive to zealous regulation.[22]

Yet regulatory oversight need not be—and for nanotechnology has not been—limited to traditional regulatory measures. "'[R]egulation' is increasingly recognized . . . as encompassing social interventions much more varied than the welfare state model of command-and-control regulation built around mandatory law, specific requirements or prohibitions, expert agencies and centralized enforcement."[23] In a wide range of fields, regulatory oversight follows a governance paradigm. It relies on information disclosure, incentives and market forces rather than command-and-control; it incorporates flexible, negotiated or nonbinding norms; and it delegates responsibility for norm development and implementation to nonstate actors, including the targets of regulation, subject to varied forms of supervision.[24] Examples from fields other than nanotechnology in the United States, European Union and international arenas respectively, include the EPA Sustainable Futures Initiative,[25] the

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18. *See* Gary E. Marchant et al., *Big Issues for Small Stuff: Nanotechnology Regulation and Risk Management*, 52 JURIMETRICS J. ___. **[Flagged for final pagination.]**

19. Mélanie Auffan et al., *Towards a Definition of Inorganic Nanoparticles from an Environmental, Health and Safety Perspective*, 4 NATURE NANOTECHNOLOGY 634, 634 (2009). This poses legal problems for regulators: an agency seeking to regulate nanotechnology would find it difficult to marshal scientific evidence that nanotechnology as such poses unacceptable risks. *See* Marchant et al., *New Soft Law*, *supra* note 2, at 130.

20. Linda K. Breggin & Leslie Carothers, *Governing Uncertainty: The Nanotechnology Environmental, Health, and Safety Challenge*, 31 COLUM. J. ENVTL. L. 285, 290–92 (2008); Marcia C. Powell et al., *Bottom-Up Risk Regulation? How Nanotechnology Risk Knowledge Gaps Challenge Federal and State Environmental Agencies*, 42 ENVTL. MGMT. 426, 433 (2008).

21. Miller & Scrinis, *supra* note 3, at 415–16.

22. *See generally* DANIEL J. FIORINO, WOODROW WILSON INT'L CTR. FOR SCHOLARS, VOLUNTARY INITIATIVES, REGULATION, AND NANOTECHNOLOGY OVERSIGHT: CHARTING A PATH, 8–13 (2010), *available at* http://www.nanotechproject.org/process/assets/files/8347/pen-19.pdf.

23. Kenneth W. Abbott et al., *Transnational Regulation of Nanotechnology: Reality or Romanticism?*, *in* INTERNATIONAL HANDBOOK ON REGULATING NANOTECHNOLOGIES 525, 532 (Graeme Hodge et al. eds., 2011).

24. *Id.*

25. The Initiative offers expedited review under TSCA for manufacturers that agree to screen newly developed chemicals under EPA-approved methodologies. FIORINO, *supra* note 22, at 18.

E.U. Eco-Management and Audit Scheme (EMAS),[26] and the U.N. Global Compact.[27]

In parallel, arrangements for oversight by private organizations—including industry groups, CSOs and business-CSO collaborations—and by public-private partnerships have proliferated, in fields ranging from worker rights to climate change.[28] Examples include the chemical industry's Responsible Care program,[29] the CSO Gold Standard for carbon offset projects,[30] and the multi-stakeholder Forest Stewardship Council.[31]

For the purpose of this article, we refer to both public and private arrangements of these kinds as *soft law oversight mechanisms*.[32] Given the challenges

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26. Under EMAS, the European Union certifies and authorizes use of a logo by firms and other organizations that voluntarily make environmental commitments, adopt qualified environmental management systems, carry out environmental reviews and audits, and publicly report environmental performance. EMAS incorporates ISO standards for environmental management systems (ISO 14001). *See Main Features*, EUROPEAN COMM'N, http://ec.europa.eu/environment/emas/about/summary_en.htm (last updated Apr. 4, 2012).

27. The Global Compact—established by the U.N. Secretary-General and the U.N. agencies responsible for environmental, human rights, labor and corruption policies—calls on firms and other organizations to adopt and implement 10 principles drawn from widely adopted interstate treaties and declarations, and provides tools and resources to assist participating organizations to implement sustainable business models. *Overview of the U.N. Global Compact*, UNITED NATIONS GLOBAL COMPACT, http://www.unglobalcompact.org/AboutTheGC/ (last updated Dec. 1, 2011).

28. *See* FIORINO, *supra* note 22, at 14–23; Kenneth W. Abbott & Duncan Snidal, *Strengthening International Regulation Through Transnational New Governance: Overcoming the Orchestration Deficit*, 42 VAND. J. TRANSNAT'L L. 501, 555–56 (2009) [hereinafter Abbott & Snidal, *Transnational New Governance*]**;** Kenneth W. Abbott, *The Transnational Regime Complex for Climate Change*, ENV'T & PLANNING C: GOV'T & POL'Y (forthcoming) (manuscript at 2) (on file with authors) [hereinafter Abbott, *Transnational Regime Complex*].

29. Responsible Care is a voluntary industry initiative that incorporates environmental management and product stewardship systems, third-party verification, and company-level reporting. FIORINO, *supra* note 22, at 20

30. The Gold Standard sets sustainable development standards for projects designed to generate offset credits for voluntary and mandatory (for example, Clean Development Mechanism) carbon markets, operates a registry for project credits, and certifies credits for sale. *Gold Standard FAQs*, THE GOLD STANDARD FOUND., http://www.cdmgoldstandard.org/frequently-asked-questions/gold-standard-foundation (last visited Apr. 2, 2012).

31. The Forest Stewardship Council sets standards for sustainable forest management, certifies forests, certifies chains of custody from certified forests to markets, and authorizes use of the Forest Stewardship Council logo. *About FSC*, FOREST STEWARDSHIP COUNCIL, http://www.fsc.org/about-fsc.html (last visited Apr. 1, 2012).

32. A growing body of legal and policy scholarship discusses soft law approaches to nanotechnology, most often favorably. *See, e.g.,* Gary E. Marchant et al., *Transnational New Governance and the International Coordination of Nanotechnology Oversight*, *in* THE NANOTECHNOLOGY CHALLENGE: CREATING LEGAL INSTITUTIONS FOR UNCERTAIN RISKS 179 (D. Dana ed., 2012) (discussing regulating nationally nanotechnology); Diana Bowman & Graeme Hodge, *"Governing" Nanotechnology Without Government?,* 35 SCI. PUB. POL'Y 476, 479–84 (2008) [hereinafter Bowman & Hodge, *"Governing" Nanotechnology*]; Vladimir Murashov & John Howard, *Essential Features for Proactive Risk Management*, 4 NATURE NANOTECHNOLOGY 467, 467 (2009); Gurumurthy Ramachandran et al., *Recommendations for Oversight of Nanobiotechnology: Dynamic Oversight for Complex and Convergent Technology*, 13 J. NANOPARTICLE RES. 1345, 1348–50 (2011). For more critical assessments, see Jennifer Kuzma & Aliya Kuzhabekova, *Nanotechnology, Voluntary Oversight, and Corporate Social Performance: Does Company Size Matter?*, 13 J. NANOPARTICLE RES.1499 (2011) (examining voluntary oversight programs for nanotechnology in the context of corporate social performance in order to

of traditional regulation, a number of public and private actors have turned to soft law oversight mechanisms to address nanotechnology.[33] At least eleven such mechanisms, described below, are currently or have recently been in operation within the United States, the European Union, and transnationally.[34] Considering these mechanisms along with the limited public measures summarized above provides a more complete picture of nanotechnology regulation and suggests a broader range of potential responses for the future.[35] Yet these mechanisms vary in important ways in their structure, governance, and substantive activities, making analysis complex.[36]

These mechanisms also raise important normative questions: To what extent can voluntary oversight arrangements influence the conduct of a dynamic global industry? Which types of mechanisms are likely to be most effective? Are soft law oversight arrangements desirable only as precursors to mandatory regulation, or are they valuable in their own right as ongoing supplements, or alternatives to mandatory regulation?

In this article we present a framework for approaching these issues. Part I introduces soft law and describes the eleven current and recent mechanisms that address nanotechnology. Part II presents a typology of soft law mechanisms based on the identity of the actors, public and private, that create and govern them. Part III considers the characteristic advantages and disadvantages of public and private soft law as tools for oversight, including for nanotechnology. Part IV assesses specific design choices for soft law mechanisms, including the stages of the regulatory process they address and the scope and depth of their norms. Finally, in a brief conclusion, we call for public authorities to promote appropriate soft law oversight mechanisms and work to strengthen those that already exist.

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better understand the drivers, barriers, and forms of company participation in such programs); Timothy Malloy, *Nanotechnology Regulation: A Study in Claims Making*, 5 ACS NANO 5, 7 (2011).

33. FIORINO, *supra* note 22, at 28–37.

34. *See infra* Part I.B.

35. Elsewhere, some of the authors have associated such mechanisms, domestic and transnational, with the broad approach to regulation known as "new governance," in which "regulatory authority is distributed among public, private and public-private actors and institutions, and regulation takes the form of public and private 'soft law' as well as legally-binding rules." Marchant et al., *supra* note 32, at 180.

36. For example, one recent analysis breaks nanotechnology soft law programs into four categories: (i) voluntary reporting schemes, (ii) voluntary risk management systems, (iii) codes of conduct, and (iv) guidelines and auxiliaries. Christoph Meili & Markus Widmer, *Voluntary Measures in Nanotechnology Risk Governance: The Difficulty of Holding the Wolf by the Ears*, *in* INTERNATIONAL HANDBOOK ON REGULATING NANOTECHNOLOGIES 446, 448 (Graeme A. Hodge et al. eds., 2011).

I. SOFT LAW AND NANOTECHNOLOGY

A. Soft Law Generally

The term *soft law* has no precise technical meaning and its definition is contested. We do not attempt to resolve those debates here, but use "soft law" as a shorthand term to cover a variety of nonbinding norms and techniques for implementing them. Discussions of soft law are especially common in international law,[37] but the term and its underlying concepts are equally relevant to domestic law.

Soft law lacks the mandatory, enforceable character of hard law. This may be because soft law instruments are framed in hortatory terms—for example, recommendations or guidelines issued by a regulatory agency[38]—or because they are adopted by institutions that lack authority to create binding law—for example, resolutions of the U.N. General Assembly. Privately generated norms, like those of Responsible Care[39] and the Forest Stewardship Council,[40] typically fall in the second category, because private organizations are seldom authorized to adopt legally binding rules; such norms may also be framed in hortatory terms, and in any case apply only to actors that voluntarily accept them.[41] Private schemes may best be described as engaging in "'regulatory standard-setting.'"[42] Their norms are "regulatory" because they apply in situations where actors' incentives normally call for mandatory, enforceable state regulation. They involve "standard setting" because their voluntary character

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37. *See, e.g.*, COMMITMENT AND COMPLIANCE: THE ROLE OF NON-BINDING NORMS IN THE INTERNATIONAL LEGAL SYSTEM (Dinah Shelton ed., 2000) (investigating the impact of soft law nonbinding legal proposals and suggestions on state behavior); Kenneth W. Abbott & Duncan Snidal, *Hard and Soft Law in International Governance*, 54 INT'L ORG. 421, 434–450 (2000); Kenneth W. Abbott et al., *The Concept of Legalization*, 54 INT'L ORG. 401 (2000) [hereinafter Abbott et al., *The Concept of Legalization*] (explaining "legalization"); Andrew T. Guzman & Timothy L. Meyer, *International Soft Law*, 2 J. LEGAL ANALYSIS 171 (2010) (explaining why states use soft law and advocating the adoption of "international common law").

38. International organizations sometimes adopt hortatory norms aimed at business firms or other private entities because they lack authority to adopt legally binding rules for nonstate actors. For example, both the OECD and ILO have adopted guidelines for behavior by multinational enterprises: the OECD Guidelines for Multinational Enterprises, first adopted in 1976, and the ILO Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy, first adopted in 1977. ORG. FOR ECON. CO-OPERATION & DEV., OECD GUIDELINES FOR MULTINATIONAL ENTERPRISES (2011), *available at* http://www.oecd.org/dataoecd/43/29/48004323.pdf (guiding enterprises to operate within governmental policy to foster confidence between enterprises and society); INT'L LABOUR ORG., TRIPARTITE DECLARATION OF PRINCIPLES CONCERNING MULTINATIONAL ENTERPRISES AND SOCIAL POLICY (2006), *available at* http://www.ilo.org/wcmsp5/groups/public/---ed_emp/---emp_ent/---multi/documents/publication/wcms_094386.pdf (urging multinational enterprises to bear in mind international labor conventions).

39. *Responsible Care*, AM. CHEMISTRY COUNCIL, http://responsiblecare.americanchemistry.com/ (last visited Apr. 8, 2012) [hereinafter *Responsible Care*].

40. FOREST STEWARDSHIP COUNCIL, http://www.fsc.org/ (last visited Apr. 8, 2012).

41. At least one group of scholars defines soft law as encompassing only norms primarily created by private actors. John J. Kirton & Michael J. Trebilcock, *Introduction: Hard Choices and Soft Law in Sustainable Global Governance*, *in* HARD CHOICES, SOFT LAW: VOLUNTARY STANDARDS IN GLOBAL TRADE, ENVIRONMENT AND SOCIAL GOVERNANCE 9 (John J. Kirton & Michael J. Trebilcock eds., 2004).

42. Abbott & Snidal, *Transnational New Governance*, *supra* note 28, at 506–08.

and private procedures are more typical of technical product standards than of legal rules.

At the same time, soft law is understood to shape expectations of appropriate behavior more strongly than mere political or social undertakings. Because of its relatively formal, institutionalized character, moreover, soft law differs from morality and other normative systems.[43] While soft law is contrasted with both legal rules and "nonlaw," neither dividing line is clearly drawn.

Many scholars view soft law not as a sharply defined category, but as part of a continuum—from hard law through soft law, to political and social undertakings, and finally to the absence of any obligation.[44] A similar continuum extends within soft law itself. For example, a mechanism like the EPA's former National Environmental Performance Track[45]—which offered fewer inspections, expedited permitting and other benefits for firms that voluntarily committed to enhance their environmental performance, adopt an approved environmental management system and engage with the public—may seem more "lawlike" than a vague, freestanding code of conduct. Similarly, elaborate norm systems like Responsible Care and the Forest Stewardship Council, which entail external monitoring as well as negative or positive sanctions,[46] shape expectations more strongly than norms that lack such procedures.[47]

B. Nanotechnology Soft Law Programs

Soft law programs for nanotechnology have proliferated rapidly over the past several years because of the challenges in formulating meaningful mandatory regulation in this rapidly emerging and diffuse field. The soft law mechanisms that are currently (or have recently been) in operation in the United States, the European Union, and transnationally are briefly summarized below. We introduce these programs in the order in which they first engaged in nanotechnology oversight.

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43. Soft law is thus often treated as a residual category, which includes any norms that fall outside the more easily defined categories of "law" and "nonlaw." Guzman & Meyer, *supra* note 37, at 172.

44. Abbott et al., *The Concept of Legalization*, *supra* note 37, at 404; Guzman & Meyer, *supra* note 37 at 172.

45. *National Environmental Performance Track*, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/performancetrack/ (last updated Jan. 12, 2011).

46. Firms that refuse to participate in Responsible Care may not become members of the American Chemistry Council. *Responsible Care*, *supra* note 39. Firms that comply with Forest Stewardship Council rules and procedures may display the FSC logo and take advantage of market demand for certified forest products. *FSC Certification*, FOREST STEWARDSHIP COUNCIL, http://www.fsc.org/certification.html (last visited Apr. 8, 2012).

47. BENJAMIN CASHORE ET AL., GOVERNING THROUGH MARKETS: FOREST CERTIFICATION AND THE EMERGENCE OF NON-STATE AUTHORITY 245–47 (2004).

1. *Foresight Institute Guidelines*

The Foresight Institute was created in 1986 as a think tank and CSO dedicated to promoting the benefits and managing the risks of nanotechnology and other emerging technologies.[48] One of its earliest activities was to draft "guidelines" for the management of nanotechnology, aimed particularly at discouraging creation and deployment of autonomous replicating nano-systems.[49] The Foresight Institute Guidelines have been updated six times, most recently in 2006.[50] The Guidelines are premised on the belief that professional ethics and soft law measures can be at least as effective as traditional regulation in promoting safe practices for a rapidly evolving global technology, while remaining more flexible.[51] One innovative feature of the Guidelines is the inclusion of separate self-assessment scorecards for industry, professionals, and government agencies.

By focusing on molecular nanotechnology, the Guidelines attempted to establish ground rules for a technology that did not yet exist. Because that technology has still not been developed, the Guidelines have had little direct regulatory impact, but have been highly effective in raising issues and fostering deliberation. In particular, they have helped build a strong ethical consensus against the development of self-replicating autonomous nanodevices.[52] More recently, the Institute has turned to other projects, such as creating roadmaps for productive molecular nanosystems.[53] Yet the Guidelines remain an enduring guidepost for the ethical development of nanotechnology.

2. *NIOSH*

The National Institute of Occupational Safety and Health (NIOSH), a U.S. government research institute based in the Centers for Disease Control and Prevention (CDC), focuses on worker health and safety. Although it has no regulatory authority, NIOSH has been proactive in addressing safety and risk management for nanotechnology.[54] In addition to conducting research on issues such as toxicity, exposure levels, and technical exposure controls, NIOSH has worked with employers to help safely manage nanotechnology in the work

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48. FORESIGHT INST., http://www.foresight.org/ (last visited Apr. 1, 2012).

49. Neil Jacobstein, *Foresight Guidelines for Responsible Nanotechnology Development,* FORESIGHT INST. (Apr., 2006), http://www.foresight.org/guidelines/current.html.

50. *Id.*

51. *Id.*

52. For example, a recent study of potential designs for self-replicating nanomachines conducted by General Dynamics for the National Aeronautics and Space Administration (NASA)—one of the first such studies sponsored by the United States in many years—took care to propose designs consistent with the Foresight Guidelines. TIHAMER TOTH-FEJEL, MODELING KINEMATIC CELLULAR AUTOMATA: FINAL REPORT 31–32 (2004), *available at* http://www.niac.usra.edu/files/studies/final_report/883Toth-Fejel.pdf.

53. *Technology Roadmap for Productive Nanosystems*, FORESIGHT INST., http://www.foresight.org/roadmaps/index.html (last visited Apr. 1, 2012).

54. *See generally Nanotechnology Guidance and Publications*, NAT'L INST. OF OCCUPATIONAL SAFETY & HEALTH, http://www.cdc.gov/niosh/topics/nanotech/pubs.html (last visited Apr. 8, 2012) (listing NIOSH publications that give guidance on workplace safety practices and nanoparticle exposure levels).

place. Its flagship vehicle for this effort is *Approaches to Safe Nanotechnology*, a hands-on practical guide to workplace nanotechnology management. The guide was initially issued in 2005; the most recent version appeared in 2009.[55]

In addition to this general guidance, NIOSH has developed Recommended Exposure Levels (RELs) and work practice recommendations for specific nanomaterials, such as carbon nanotubes[56] and titanium dioxide.[57] While its recommendations are voluntary, they fill a vacuum left by the absence of mandatory regulations. NIOSH also engages in substantial outreach and collaboration with companies and other stakeholders.[58]

3. *ISO and Other Standard-Setting Bodies*

Consensus-based standard-setting bodies have played an early and important role in nanotechnology oversight. At the forefront has been the International Organization for Standardization (ISO), which in 2005 created technical committee TC-229 to consider nanotechnology standards.[59] TC-229 has established subcommittees on consumer and societal dimensions of nanotechnology, sustainability, terminology and nomenclature, measurement and characterization, material specifications, and health, safety and environmental issues.[60] Since its inception, TC-229 has published 23 standards.[61]

As the range of the TC-229 subcommittees suggests, ISO has begun to expand beyond its traditional focus on terminology, test methods and interoperability standards; it now focuses on quasi-regulatory rules, such as its standard on environmental, health, and safety (EHS) management of nanomaterials in occupational settings.[62] As the chair of TC-229 has stated, ISO standards now serve three objectives: "1. To support commercialisation and market

55. NAT'L INST. OF OCCUPATIONAL SAFETY & HEALTH, DHHS (NIOSH) PUB. NO. 2009-125, APPROACHES TO SAFE NANOTECHNOLOGY: MANAGING THE HEALTH AND SAFETY CONCERNS ASSOCIATED WITH ENGINEERED NANOMATERIALS (2009), *available at* http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf (describing and defining different types of nanoparticles, providing guidance on risk assessment, exposure levels, health concerns, and safety hazards, and establishing guidelines for working with nanoparticles in the workplace).

56. NAT'L INST. OF OCCUPATIONAL SAFETY & HEALTH, CURRENT INTELLIGENCE BULLETIN: OCCUPATIONAL EXPOSURE TO CARBON NANOTUBES AND NANOFIBERS (2011), *available at* http://www.cdc.gov/niosh/docket/review/docket161A/pdfs/carbonNanotubeCIB_PublicReviewOfDraft.pdf (establishing guidelines for working with carbon nanotubes in the workplace).

57. NAT'L INST. OF OCCUPATIONAL SAFETY & HEALTH, DHHS (NIOSH) PUB. NO. 2011-160, CURRENT INTELLIGENCE BULLETIN 63: OCCUPATIONAL EXPOSURE TO TITANIUM DIOXIDE (2011), *available at* http://www.cdc.gov/niosh/docs/2011%2D160/pdfs/2011-160.pdf (establishing guidelines for working with titanium-dioxide nanoparticles in the workplace).

58. *Partnerships and Collaborations*, NAT'L INST. OF OCCUPATIONAL SAFETY & HEALTH, http://www.cdc.gov/niosh/topics/nanotech/partners.html (last visited June 4, 2012).

59. *TC 229, Nanotechnologies*, INT'L ORG. FOR STANDARDIZATION, http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983 (last visited Apr. 7, 2012).

60. *Id.*

61. *Id.*

62. *ISO/TR 12885:2008, Nanotechnologies—Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies*, INT'L ORG. FOR STANDARDIZATION, http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=52093 (last visited Apr. 7, 2012).

development; 2. To provide a basis for procurement through technical, quality and environmental management; 3. To support appropriate legislation/regulation and voluntary governance structures."[63]

In support of the third objective, ISO's EHS standard provides detailed guidelines for managing occupational and environmental risks in the production, handling, use and disposal of a broad range of manufactured nanomaterials. In 2011, ISO adopted a new Nanomaterial Risk Evaluation standard expressly based on the Environmental Defense-DuPont Nano Risk Framework, discussed below.[64] Other organizations have also adopted nanotechnology standards; these include the British Standards Institute (BSI), Institute of Electrical and Electronics Engineers (IEEE), and ASTM International.[65]

4. *NanoRisk Framework*

The NanoRisk Framework is the product of a partnership between DuPont and Environmental Defense (ED) that began in 2005.[66] This collaboration between a leading multinational and a leading environmental CSO was intended to promote responsible development of nanoscale materials, develop mechanisms to share information with stakeholders, facilitate public understanding, and provide input for government policy.[67] It grew out of a Wall Street Journal op-ed jointly authored by the heads of the two organizations, which argued that securing the benefits of nanotechnology will require safe, responsible and collaborative development.[68]

The Framework was drafted by a multidisciplinary team of experts using real time assessment analysis over the product life cycle. Following public comments, the final version was released in 2007. It is intended to offer a "systematic and disciplined process" for evaluating and addressing the risks of nanoscale materials.[69] The process consists of six steps: (1) describe material and application; (2) profile lifecycle(s); (3) evaluate risks; (4) assess risk management; (5) decide, document, and act; and (6) review and adapt.[70] The

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63. Peter Hatto, Chairman, ISO TC 229 & BSI NTI/1 Nanotechnologies Standardization Comms., Presentation at The George Washington University Law School Nanogovernance 2008 (Innovative Approaches to Nanotechnology Environmental Governance): Standardization-In Support of "Nanogovernance" (Feb. 12, 2008), *available at* http://www.nanogovernance.com/images/Hatto.pdf.

64. Andrew Maynard, *International Standards Organization Guidelines for Evaluating Nanomaterial Risks—Are They Any Good*, 2020 SCI. BLOG (May 26, 2011), http://2020science.org/2011/05/26/international-standards-organization-guidelines-for-evaluating-nanomaterial-risks-%E2%80%93-are-they-any-good/.

65. *ASTM E2535—07 Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings*, ASTM INT'L, http://www.astm.org/Standards/E2535.htm (last visited May 8, 2012).

66. ENVTL. DEFENSE-DUPONT NANO P'SHP, NANO RISK FRAMEWORK 7 (2007) [hereinafter NANO RISK FRAMEWORK], *available at* http://apps.edf.org/documents/6496_nano%20risk%20framework.pdf.

67. *See id.* at 7–8.

68. Fred Krupp & Chad Holliday, Op-Ed., *Let's Get Nanotech Right*, WALL ST. J., June 14, 2005, at B2.

69. NANO RISK FRAMEWORK, *supra* note 66, at 7.

70. *Id.* at 8–10.

Framework allows a user "to organize, document, and communicate what information the user has about the material; to acknowledge where information is incomplete; to explain how information gaps were addressed; and to justify the rationale behind the user's risk management decisions and actions."[71]

DuPont and ED have actively promoted the NanoRisk Framework through presentations and training sessions.[72] As a result, the Framework has been widely considered. As of March 2011, it had been reviewed online by some 21,000 unique visitors and downloaded approximately 10,000 times.[73] A number of companies, trade associations, insurers and government agencies have endorsed the Framework or cited it favorably.[74] The ISO has recently incorporated the Framework into its nanotechnology risk management standard.[75] Notwithstanding these accomplishments, however, little information is publicly available about the implementation of the Framework and its practical effects.

5. *OECD Working Party*

The Organization for Economic Co-operation and Development (OECD) has facilitated intergovernmental coordination on the development of standardized data and test methods for nanomaterials, information sharing, and harmonizing regulatory and risk management approaches. OECD established a Working Party on Manufactured Nanomaterials (WPMN) in 2006 to consider their EHS implications.[76] The Working Party consists of delegates from member government agencies responsible for public health and safety.[77] A number of nonmember nations, including China, Russia and India, participate as observers.[78]

The Working Party has undertaken projects including (1) establishing a database of environmental information on manufactured nanomaterials; (2) developing a coordinated and standardized test program for priority nanomaterials; (3) promoting cooperation on voluntary and mandatory regulatory programs; (4) developing guidance on exposure measurement and mitigation; and (5) promoting the environmentally sustainable use of nanotech-

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71. *Id.* at 8. The framework has been criticized as too onerous for smaller firms. FIORINO, *supra* note 22, at 31–32.

72. *Id.* at 32.

73. Presentation by Terrence Medley, Global Director of Regulatory Affairs, DuPont, to conference on The Biggest Issues for the Smallest Stuff: Risk Management and Regulation of Nanotechnology, Arizona State University (Mar. 21, 2011) (on file with authors).

74. *See, e.g., DuPont Nanotech Project: Government Influence*, ENVTL. DEF. FUND, http://business.edf.org/casestudies/dupont-nanotech-project-government-influence (last visited Apr. 15, 2012).

75. Maynard, *supra* note 64.

76. *Safety of Manufactured Nanomaterials*, OECD, http://www.oecd.org/about/0,3347,en_2649_37015404_1_1_1_1_1,00.html (last visited Apr. 2, 2012).

77. OECD, NANOSAFETY AT THE OECD: THE FIRST FIVE YEARS 2006–2010, at 4 (2011), *available at* http://www.oecd.org/dataoecd/6/25/47104296.pdf.

78. Jeff Morris et al., *Science Policy Considerations for Responsible Nanotechnology Decisions*, 6 NATURE NANOTECHNOLOGY 73, 75 (2011).

nology.[79] More generally, the Working Party facilitates transnational relationships and communication among regulators, building "communities of practice" that promote information sharing and harmonization.[80]

6. *CENARIOS*

CENARIOS is described as the "world's first certifiable risk management and monitoring system for nanotechnology."[81] CENARIOS is a joint project of two European organizations: The Innovation Society Ltd. and TÜV SÜD.[82] Developed in 2006, the program provides "a structured methodology for the industry and commercial enterprises to identify, analyse and assess potential risks and opportunities in products and processes" involving nanotechnology.[83] Companies that seek to use the CENARIOS label are audited and certified by TÜV SÜD.[84]

CENARIOS consists of three modules.[85] The first requires a company to conduct a comprehensive risk assessment of its nanotechnology products and processes.[86] The second is a "360º Risk Monitoring System," which helps companies scan the horizon for risk-related trends, including scientific, societal, legal, and media developments.[87] The third addresses issues concerning management and communication, providing tools for dealing with crises and other risk events.[88] Unusually, CENARIOS addresses societal, regulatory and liability risks in addition to occupational, environmental and consumer risks.[89]

CENARIOS is intended to provide

> a seal of approval which (i) comprises a certified and well-standardized process to increase product and process safety; (ii) defines a reliable standard for the safety of products and processes; (iii) documents a company's efforts and investments in product and process safety towards customers, suppliers and authorities; and (iv) significantly reduces potential liability risks.[90]

It is potentially applicable to a range of actors, from researchers to producers and retailers.[91] However, there have been no publicly available developments

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79. *Id.*

80. Morris et al., *supra* note 78, at 75. OECD has also created the Working Party on Nanotechnology (WPN) to advise on emerging policy issues concerning the responsible development and use of nanotechnology. *Working Party on Nanotechnology*, OECD http://www.oecd.org/document/36/0,3343,en_2649_34269_38829732_1_1_1_1,00.html (last visited Apr. 8, 2012).

81. THE INNOVATION SOC'Y LTD., CENARIOS®-MANAGING NANO RISKS 2, http://www.innovationsgesellschaft.ch/images/publikationen/Factsheet_CENARIOS_english_arial2.pdf (last visited Apr. 11, 2012).

82. *Id.* at 1.

83. *Id.* at 2.

84. *Id.*

85. *Id.* at 3.

86. *Id.*

87. *Id.*

88. *Id.*

89. Meili & Widmer, *supra* note 36, at 452.

90. Artur Marczewwski, *CENARIOS*, NANODIALOG.EU (Mar. 2, 2008), http://nanodialog.eu/index.php?option=com_content&task=view&id=26&Itemid=40.

91. THE INNOVATION SOC'Y LTD., *supra* note 81, at 4.

in the program since the publication of *Certification Standard CENARIOS* in 2008.[92]

7. *Nanoscale Materials Stewardship Program*

The Nanoscale Materials Stewardship Program (NMSP) was a voluntary reporting program created and managed by the EPA. The NMSP was developed through a collaborative process initiated in 2006, with interested parties invited to comment and participate at each stage of development.[93] The NMSP was launched in January 2008,[94] and terminated in December 2009.[95]

The NMSP invited companies producing or handling nanomaterials to participate in either a basic program for reporting available data or an in-depth program involving development of new data.[96] Thirty-one companies participated in the basic program, submitting information on 132 nanomaterials.[97] Many claimed the status of confidential business information for some of their data, limiting its public availability.[98] Only four companies participated in the in-depth program.[99] This suggested to the EPA "that most companies are not inclined to voluntarily test their nanoscale materials."[100]

EPA stated that it received "a significant amount of data through NMSP submissions," which assisted it in developing "a considerably stronger and better informed understanding of the issues and commercial status of nanoscale materials in the United States."[101] However, some 90 percent of the nanoscale materials likely to be commercially available in the United States were not reported under the basic program.[102] The quality of the submissions was also disappointing; for example, many reports did not include exposure or hazard-related data.[103] Given these limitations, EPA has turned to more traditional approaches to data gathering.[104]

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92. TÜV SÜD, CERTIFICATION STANDARD CENARIOS® (2008), *available at* http://www.innovationsgesellschaft.ch/media/archive2/marketing_information/CENARIOS_Certification_Standard_e.pdf.

93. EPA OFFICE OF POLLUTION PREVENTION AND TOXICS, NANOSCALE MATERIALS STEWARDSHIP PROGRAM: INTERIM REPORT 7–8 (2009) [hereinafter EPA, NMSP INTERIM REPORT], *available at* http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf.

94. Environmental Protection Agency, Nanoscale Materials Stewardship Program, 73 Fed. Reg. 4861 (Jan. 28, 2008).

95. EPA, NMSP INTERIM REPORT, *supra* note 93, at 8.

96. *Id*. at 28. EPA indicated that it would issue a final report in 2010, but has not yet done so.

97. *Nanoscale Materials Stewardship Program*, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/oppt/nano/stewardship.htm (last updated Mar. 21, 2011).

98. EPA, NMSP INTERIM REPORT, *supra* note 93, at 9.

99. *Id.* at 19.

100. *Id.* at 27.

101. *Id.* at 26.

102. *Id.* at 27. Some commercially important materials were reported. Meili & Widmer, *supra* note 36, at 449.

103. EPA, NMSP INTERIM REPORT, *supra* note 93, at 27.

104. *Id.* at 28.

The most striking feature of the NMSP was the limited number of participants.[105] EPA had estimated that it would receive far more submissions.[106] A number of reasons may account for this shortfall.[107] Most importantly, many companies appear to have concluded that participation would provide few benefits, but might create potential costs—for example, by drawing the attention of regulators, activists and the media. Companies were uncertain how the EPA would use submitted data, especially under the in-depth program. The heterogeneous nature of the industry was also a challenge, as one or two trade associations could not adequately represent all relevant firms. Because the EPA lacked good information on which companies were handling nanomaterials, it could not effectively reach out to encourage participation. Some firms were unsure about the program's definition of nanotechnology, while others did not wish to identify their products as nanotechnology.

8. *E.U. Code of Conduct for Responsible Research*

The E.U. Code of Conduct for Responsible Nanosciences and Nanotechnologies Research was drafted by the European Commission. Following public consultations, it was adopted in February 2008.[108] The Code is voluntary and is based on seven general principles: meaning, sustainability, precaution, inclusiveness, excellence, innovation, and accountability.[109] The Code is directed initially at member states; it calls on governments to encourage all entities in their jurisdiction that conduct nanotechnology research to follow the principles and guidelines set forth in the Code.[110]

While the Commission indicated its intent to revise the Code every two years,[111] it has not done so as of February 2012. It concluded from stakeholder consultations that awareness of the Code is limited, and that the general nature of its principles makes it difficult to implement. To address these problems, the Commission launched the NanoCode Project, a multi-stakeholder dialogue to identify knowledge and perceptions about the Code and develop tools to

105. *See, e.g.*, Press Release, Environmental Defense Fund, EPA Nanotechnology Voluntary Program Risks Becoming a ["Black Hole"] (July 28, 2008), http://www.edf.org/news/epa-nanotechnology-voluntary-program-risks-becoming.

106. U.S. ENVTL. PROT. AGENCY, SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR), EPA ICR NO. 2250.01, OMB CONTROL NO. 2070–NEW, at 14–15, http://www.epa.gov/oppt/nano/nmsp-icr-supportingstatement.pdf (last visited May 8, 2012).

107. Many of the reasons stated here were identified by industry and government participants at the conference entitled "The Biggest Issues for the Smallest Stuff" held at Arizona State University, March 21, 2011. *The Biggest Issues for the Smallest Stuff: Regulation and Risk Management of Nanotechnology*, SANDRA DAY O'CONNOR COLL. OF LAW, ARIZ. STATE UNIV., http://lsi.law.asu.edu/nanoregulation/ (last visited Apr. 7, 2012).

108. COMM'N OF THE EUROPEAN CMTYS., COMMISSION RECOMMENDATION OF 07/02/2008 ON A CODE OF CONDUCT FOR RESPONSIBLE NANOSCIENCES AND NANOTECHNOLOGIES RESEARCH, 4 (2008), *available at* http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf.

109. *Id.* at 6–7.

110. *Id.* at 5.

111. *Id.*

expand its use.[112] The Commission has since developed a "Master Plan" for revision and implementation of the Code, as well as the "CodeMeter," a tool to help firms determine if they are complying with its principles.[113]

9. *Responsible NanoCode*

The Responsible NanoCode is a voluntary, principles-based code of conduct for firms and other entities engaged in nanotechnology. It was developed by four founding partners in the United Kingdom—the Royal Society, Insight Investment, the Nanotechnology Industries Association, and the Nanotechnology Knowledge Transfer Network (a project of the U.K. Department of Trade and Industry), with input from a range of stakeholders, and launched in 2008.[114] Although initially introduced in the United Kingdom, the goal of the founders was to develop a code, "which has relevance internationally."[115] The Code aims "to establish a consensus of what constitutes good practice in businesses across the nanotechnology value chain (that is, from research and development to manufacturing, distribution and retailing) so that businesses can align their processes with emerging good practice and form the foundation for the development of indicators of compliance."[116]

The Responsible NanoCode does not include specific, auditable standards of performance, but rather identifies seven "high level"[117] principles—with "Examples of Good Practice" under each[118]—which participating firms are to implement on a "comply or explain" basis.[119] The principles cover: (1) board accountability; (2) stakeholder involvement; (3) worker health & safety; (4) EHS risks; (5) social, environmental, health and ethical implications; (6) engaging with partners; and (7) transparency and disclosure.[120] The latter two principles are intended to assure the public that nanotechnology is being developed and used responsibly.[121]

The sponsors make clear that

> the Code is not envisaged as, in any way, supplanting, displacing or otherwise subverting the evolving regulatory processes. The Code is designed to provide guidance on best practice for organizations during the transitional period in which the appropriate national and international regulatory frame-

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112. *NanoCode Newsletter*, NANOCODE 2 (May 2011), http://www.nanocode.eu/files/nanocode-newsletter-1.pdf.

113. *MasterPlan and CodeMeter for Implementation of EC Code of Conduct on N&N Research*, NANOCODE, http://www.nanocode.eu/content/view/245/117/ (last visited Apr. 1, 2012).

114. *Background to the Responsible NanoCode*, RESPONSIBLE NANOCODE, http://www.responsiblenanocode.org/index.html (last visited Apr. 7, 2012).

115. *Terms of Reference*, RESPONSIBLE NANOCODE, http://www.responsiblenanocode.org/pages/terms-reference/index.html (last visited Apr. 1, 2012) [hereinafter *Terms of Reference*].

116. *Id.*

117. RESPONSIBLE NANOCODE, INFORMATION ON THE RESPONSIBLE NANO CODE INITIATIVE 6 (2008), *available at* http://www.responsiblenanocode.org/documents/InformationonTheResponsibleNanoCode.pdf.

118. *Id.* at 9.

119. *Terms of Reference*, *supra* note 115.

120. RESPONSIBLE NANOCODE, *supra* note 117, at 10–14.

121. *See id.* at 4.

> works are being evaluated and, if necessary, developed, to complement any existing regulation.[122]

Indeed, one Example of Good Practice involves contributing "constructively to the development of appropriate regulations and standards in all markets."[123]

The Responsible NanoCode has languished somewhat because of limited resources and the lack of a central organization. To avoid conflicts of interest, the project does not accept financial contributions from entities involved in commercial nanotechnology.[124] With the recent recession, however, public and nonprofit funding have declined, slowing implementation of the Code.[125]

10. *ICON GoodNanoGuide*

The GoodNanoGuide is "an Internet-based collaboration platform specially designed to enhance the ability of experts to exchange ideas on how best to handle nanomaterials in an occupational setting."[126] It operates as an interactive information-sharing forum, in a wiki format, containing recommended work practices, guidelines, and other information on worker safety and health protection in nanotechnology workplaces. The goal is "to create a central repository for good practices for handling nanomaterials safely that can be used and contributed to by people from all over the world."[127] The GoodNanoGuide was created by the International Council on Nanotechnology (ICON), an international multi-stakeholder organization, and other partners. Begun in late 2008,[128] the GoodNanoGuide remains in a beta version.

The content in the GoodNanoGuide can be freely accessed, but only "providers"—experts who have become members of the site—can post information.[129] Information is organized into three domains based on level of expertise.[130] The GoodNanoGuide has received significant interest, measured by visitors to its website.[131] According to its Director, the strengths of the GoodNanoGuide are "the extraordinary level of collaboration among stakeholder groups," "the high level of industrial engagement at both intellectual and financial levels," and "high-impact projects on predictive modeling and

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122. *Id.*

123. *Id.* at 12.

124. *Id.* at 7.

125. FIORINO, *supra* note 22, at 34; Presentation by Steffi Friedrichs, Director, Nanotechnology Industries Association, to conference on The Biggest Issues for the Smallest Stuff: Risk Management and Regulation of Nanotechnology, Arizona State University (Mar. 21, 2011).

126. *Fact Sheet*, GOODNANOGUIDE (May 3, 2010), http://goodnanoguide.org/ (follow "Good NanoGuide Fact Sheet" hyperlink).

127. Kristen M. Kulinowski & Matthew P. Jaffe, *The GoodNanoGuide: A Novel Approach for Developing Good Practices for Handling Engineered Nanomaterials in an Occupational Setting*, 6 NANOTECHNOLOGY L. & BUS. 37, 40 (2009).

128. *Id.* at 37.

129. *Id.* at 40.

130. GOODNANOGUIDE, http://goodnanoguide.org/tiki-index.php?page=HomePage (last visited Apr. 1, 2012).

131. Kristen Kulinowski, Dir. of GoodNanoGuide, Presentation on the GoodNanoGuide at Arizona State University (Mar. 22, 2001) (presentation at Slide 9) (copy on file with authors).

design for environmental sustainability."[132] The Guide's weaknesses include its "reliance on industry funds [which] reduces credibility for some stakeholders" and challenges to the "sustainability of the model in a down economy."[133]

11. *NanoSafety Consortium for Carbon*

The NanoSafety Consortium for Carbon (NCC) is a U.S.-based association of carbon nanomaterial producers created to cooperate with federal regulatory agencies on risk management and regulatory matters relating to products such as carbon nanotubes.[134] The Consortium was created in March 2010 with 12 original company members.[135] The impetus for its creation was an EPA policy that required 90-day inhalation studies for each new carbon nanotube product and other nanomaterial products pursuant to section 5 of TSCA, a requirement with a potentially substantial impact.[136]

NCC is working with EPA to develop a mutually agreeable test program for a representative set of carbon nanomaterials, to reduce testing costs while still providing EPA sufficient data to make informed decisions.[137] In April 2011, the NCC submitted a proposed testing agreement to EPA.[138] NCC has also identified other ways to provide data and coordinate responses to regulatory initiatives.[139] The NCC states that it is committed to transparency and independence, using the best sources of scientific information and publishing all results, favorable or not, in the open literature.[140]

Membership in NCC is open "to any business entity actively involved in the manufacturing, distribution, or use of nanoscale carbon."[141] It is therefore an industry-only initiative, although NCC intends to interact with government agencies, scientific organizations and CSOs. Although it is too early to evaluate its success, the narrow and practical focus of NCC, combined with potentially significant benefits for its members, suggest that it has strong potential to achieve its limited but meaningful goals.

12. *Summary*

These are not the only soft law oversight mechanisms for nanotechnology currently in effect. Countries including the United Kingdom and Australia have implemented voluntary national reporting schemes similar to EPA's

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132. *See id.*

133. *See id.*

134. *Nanoscale Carbon EHS Issues,* NANOSAFETY CONSORTIUM FOR CARBON, http://www.nanosafetyconsortium.com/ (last visited Apr. 2, 2012).

135. *Id.*

136. John C. Monica, Jr., *An Industry-Driven Approach to EHS Issues: "The NanoSafety Consortium for Cancer*," 7 NANOTECHNOLOGY L. & BUS. 254, 258–60 (2010).

137. *Id.* at 261.

138. Letter from John C. Monica, Jr., Legal Counsel, NanoSafety Consortium for Carbon, to James Alwood, U.S. Envtl. Prot. Agency, Terms of Proposed Testing Consent Agreement (Apr. 2011), *available at* http://www.nanolawreport.com/AlwoodLetterandProposal20110406.pdf.

139. Monica, *supra* note 136, at 261–62.

140. *Id.* at 260–61.

141. *Id.* at 260.

NMSP. The Swiss government has developed a Precautionary Matrix to promote safe development of nanotechnology.[142] Some individual firms, such as the chemical manufacturer BASF, have developed voluntary codes of conduct for their own nanotechnology activities.[143]

Additional soft law mechanisms have also been suggested. Marchant and his coauthors have proposed a government-run, voluntary certification scheme for nanotechnology products that have been appropriately safety tested.[144] Howard and Murashov have proposed a partnership involving industry, government, workers, and academics to generate risk data and risk-control approaches for occupational exposures to nanotechnology.[145] Dana has proposed specific forms of liability protection and relief for companies that voluntarily test their nanotechnology products.[146] Abbott and his coauthors have proposed an international framework convention as a hybrid of hard and soft law mechanisms for coordinating nanotechnology governance.[147] Bowman and Ludlow have proposed the creation of a voluntary global searchable registry of nanotechnology data,[148] while Rollins has offered a similar suggestion for a Nanobiotechnology Information Board that would manage a public information database on nanotechnology safety and risks.[149] And Daniel Fiorino has called for the establishment of a Nano Policy Forum involving all key stakeholders to discuss and coordinate nanotechnology oversight programs and tools.[150]

II. A TYPOLOGY OF NANOTECHNOLOGY SOFT LAW: THE GOVERNANCE TRIANGLE

Abbott and Snidal have developed a heuristic device called the *Governance Triangle*, which systematically presents diverse regulatory institutions in terms of one of their most significant features: the roles played by public and private actors of different types in creating and governing them.[151] The gov-

142. *Precautionary Matrix for Synthetic Nanomaterials*, SWISS FED. OFFICE OF PUBLIC HEALTH, http://www.bag.admin.ch/themen/chemikalien/00228/00510/05626/index.html?lang=en (last visited Apr. 1, 2012).

143. *This Is How We Implement Our Code of Conduct*, BASF, http://www.basf.com/group/corporate/en/sustainability/dialogue/in-dialogue-with-politics/nanotechnology/implementation (last visited Apr. 12, 2012).

144. Marchant et al., *New Soft Law, supra* note 2, at 136–52.

145. John Howard & Vladimir Murashov, *National Nanotechnology Partnership to Protect Workers*, 11 J. NANOPARTICLE RES. 1673, 1678–79 (2009).

146. David A. Dana, *When Less Liability May Mean More Precaution: The Case of Nanotechnology*, 28 UCLA J. ENVTL. L. & POL'Y 153, 160 (2010).

147. Kenneth W. Abbott et al., *A Framework Convention for Nanotechnology?*, 38 ENVTL. L. REP. 10507, 10509 (2008).

148. Diana M. Bowman & Karinne Ludlow, *Filling the Information Void: Using Public Registries as a Tool in Nanotechnologies Regulation*, 6 BIOETHICAL INQUIRY 25, 32–35 (2009).

149. Kevin Rollins, *Nanobiotechnology Regulation: A Proposal for Self-Regulation with Limited Oversight,* 6 NANOTECHNOLOGY L. & BUS. 221, 228–29 (2009).

150. FIORINO, *supra* note 22, at 42–43.

151. Kenneth W. Abbott & Duncan Snidal, *The Governance Triangle: Regulatory Standards Institutions and the Shadow of the State*, *in* THE POLITICS OF GLOBAL REGULATION 44, 49–53

ernance triangle in Figure 1 shows the eleven soft law mechanisms for nanotechnology discussed above. Table 1 identifies the abbreviations used in Figure 1.

Figure 1. The Nanotechnology Governance Triangle

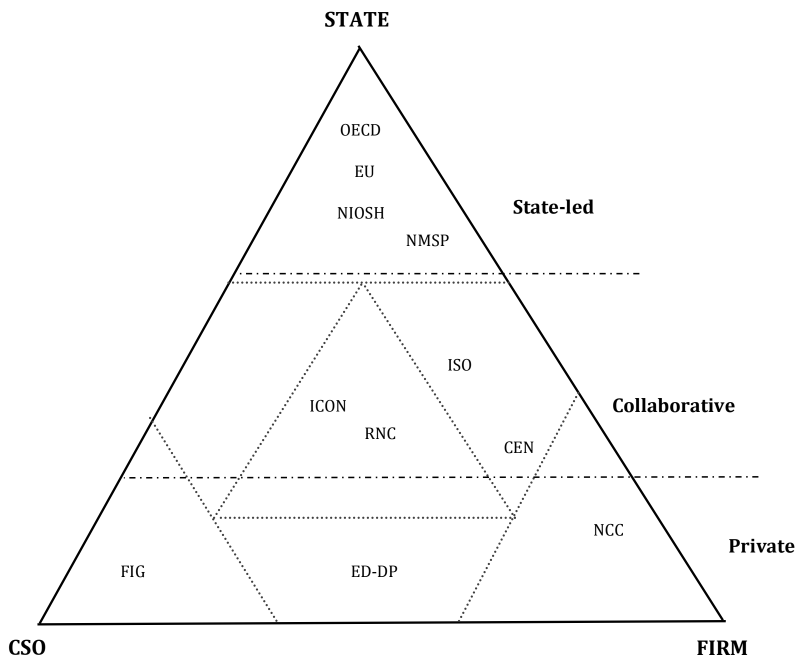

Table 1. Abbreviations of Soft Law Mechanisms for Nanotechnology

CEN	CENARIOS certification program
ED-DP	ED-DuPont NanoRisk Framework
EU	EU Code of Conduct
FIG	Foresight Institute Guidelines
ICON	ICON Good Nano Guide
ISO	ISO Standards
NCC	NanoSafety Consortium for Carbon
NIOSH	NIOSH Guidelines and Recommendations
NMSP	EPA Nanoscale Materials Stewardship Program
OECD	OECD Working Party
RNC	Responsible NanoCode

(Walter Mattli & Ngaire Woods eds., 2009) [hereinafter Abbott & Snidal, *Governance Triangle*]; Kenneth W. Abbott & Duncan Snidal, *International Regulation Without International Government: Improving IO Performance Through Orchestration*, 5 REV. INT'L ORGS. 315, 318–23 (2010) [hereinafter Abbott & Snidal, *International Regulation*]; Abbott & Snidal, *Transnational New Governance*, *supra* note 28, at 512–19; Abbott, *Transnational Regime Complex*, *supra* note 28, at 2.

The triangle is defined by three actor groups: the state, firms, and CSOs (the three vertices of the triangle). All three groups are defined broadly, so that together they encompass virtually all participants in regulatory governance. The surface of the triangle therefore represents the potential space for regulatory action. All three categories include both individual and collective actors. The state category includes individual governments or agencies (for example, the EPA) as well as groups of states or international bodies (for example, the European Union); the firm category includes individual companies (for example, DuPont, BASF) as well as industry associations (for example, the NCC); and the CSO category includes individual CSOs (for example, Foresight Institute, ED) as well as CSO coalitions.

Regulatory mechanisms are located on the triangle in accordance with the roles played by members of the three actor groups in their creation, governance and operations. We place each organization by estimating each actor group's share in its creation and governance. The greater the role played by actors from a particular group, the closer we place the mechanism to the vertex representing that group.[152] As the triangle is intended merely as a heuristic device, however, locations should not be interpreted as precise.[153]

For clarity, we divide the triangle into seven zones. Organizations in the three vertex zones involve one or more actors of a single type; those in the three zones along the sides of the triangle involve actors of two different types; and those in the central zone involve actors of all three types.[154] In addition, dashed horizontal lines divide the triangle into three tiers. In the "state-led" tier, governmental institutions are dominant; in the "private" tier, firms and CSOs are dominant; and in the "collaborative" tier, governmental bodies share governance with firms or CSOs.

For example, we place the E.U. Code of Conduct in the upper vertex zone because it is promulgated and administered by a public institution, the European Commission. We place the EPA's former NMSP somewhat lower in that zone and to the right, because the program relied almost entirely on eliciting information from private firms. We place the Nanosafety Consortium for Carbon, a coalition of firms engaged in nanotube research and manufacturing, in the Firm vertex zone. We place the Foresight Institute, a "think tank and pub-

152. In other words, the distance between each vertex and the opposite side of the triangle is a continuum, reflecting the degree of involvement by actors from that group. *See supra* Figure 1.

153. The organizations in Figure 1 involve complex governance arrangements that may differ as between particular activities and may change over time.

154. *Contra* FIORINO, *supra* note 22, at 14–15. Fiorino defines "voluntary initiatives" for nanotechnology as involving only "collective efforts," thereby excluding oversight efforts by a single firm or other organization. In contrast, as suggested by the seven zones of the triangle, we consider oversight efforts by individual organizations (for example, the EPA and Foresight Institute) to be relevant. Empirically, Fiorino argues that most voluntary initiatives fall in three categories: government-sponsored programs designed to attract business participation; collective business efforts; and business-CSO collaborations. While we include these categories in Zones 1, 2 and 6 respectively, we also identify initiatives that fall into other Zones.

lic interest organization focused on transformative future technologies,"[155] in the CSO vertex zone.

Turning to collaborative arrangements, we place the ED-DuPont NanoRisk Framework, developed through collaboration between a business firm and an environmental CSO, in the zone that spans the lower side of the triangle. We place the ICON GoodNanoGuide in the central tripartite zone. ICON is a multi-stakeholder body, managed by a university, which involves in its deliberations government, the nanotechnology industry and nongovernmental organizations.[156] We place the Responsible NanoCode in the same zone.[157]

While the location of a particular mechanism reflects its individual structure, the triangle as a whole provides a snapshot of the roles played by government, business and civil society—individually and in combination—in nanotechnology oversight. Three points are initially apparent from Figure 1. First, in the state-led tier, regulatory agencies in both the United States and the European Union have turned to voluntary measures (of different kinds) to deal with the uncertainties and other challenges of nanotechnology governance. Second, in the private-led tier, both business and civil society, singly and in collaboration, have introduced soft law mechanisms for nanotechnology. And third, in the Collaborative tier, several public-private partnerships—all involving business, but not all involving civil society—have engaged in nanotechnology oversight. Considering the private-private ED-DuPont Framework along with the public-private mechanisms in the Collaborative tier, nearly half of the mechanisms on the triangle are collaborative.

III. BENEFITS AND COSTS OF SOFT LAW

In this Part, we outline some characteristic advantages and disadvantages of soft law oversight. Existing nanotechnology mechanisms reflect many of these benefits and costs. We address first, mechanisms adopted by public agencies, and then those adopted by private actors or public-private collaborations.

A. Public Mechanisms

1. *Advantages*

Soft law mechanisms can serve as stop gap measures when formal regulatory processes are too slow to address emerging technological risks. In the early stages of development of a new technology, data gaps, and uncertainties often preclude formal regulation. A regulatory agency can use a soft law mechanism to gather technical information from firms and researchers to help

155. *About the Foresight Institute*, FORESIGHT INST., http://www.foresight.org/about/index.html (last visited Apr. 1, 2012).

156. *About ICON*, INT'L COUNCIL ON NANOTECHNOLOGY, http://icon.rice.edu/about.cfm (last visited Apr. 1, 2012).

157. *See* RESPONSIBLE NANOCODE, http://www.responsiblenanocode.org (last visited Apr. 1, 2012) (providing background information about the collaborative arrangement among the four founding partners of the Responsible NanoCode).

the agency determine whether regulation is needed and what form it should take. That was the explicit goal of the EPA's NMSP.[158] Information-gathering mechanisms can also seek broader forms of information, such as public perceptions of a technology or public and industry reactions to potential policy approaches.

An agency can use soft law more substantively to encourage firms and researchers to address potential risks, and to do so in desired ways. For example, a major goal of the E.U. Code of Conduct is to promote precautionary and sustainable research practices.[159] Soft law mechanisms based on principles, guidelines and consultation can be more nuanced than regulatory application of the precautionary principle, which is often viewed—in the United States, at least—as unduly limiting innovation and economic development.[160]

An agency can likewise use substantive soft law as the basis of its own response, when information on risks is not as fully developed or as certain as necessary for the adoption of binding regulations, or when a particular risk is emerging more rapidly than the agency can develop formal regulations. For example, an agency might use soft law to reduce the scale of exposure to emerging health or safety risks, to the benefit of those handling the technology as well as the public.[161] NIOSH presents an interesting variation. Because NIOSH itself lacks authority for regulation, it uses soft law guidelines to enhance workplace safety before other agencies have taken regulatory action.

To be sure, not every soft law mechanism can be adopted quickly. For example, the EPA's modest NMSP took years to develop. Nor does soft law have the blanket coverage of regulations that bind all firms in an industry; instead, public soft law mechanisms generally require voluntary opt in by regulated entities, as in the case of the NMSP[162] and E.U. Code,[163] or simply rely on voluntary compliance, as in the case of NIOSH.[164] Nonetheless, by managing risks for entities that participate and setting informal standards of care for those that do not, soft law can at least partially fill the oversight gap,

A second, related advantage of soft law is flexibility. Flexibility over time is particularly important in the early stages of an emerging technology, when information on risks and trajectories changes rapidly. Soft law allows an agency to update its response as new information emerges, without the delays of the formal regulatory process. This helps agencies to rectify errors, as when regulatory norms prove more costly to implement than originally foreseen, or to adjust the stringency of norms in response to new understandings. While

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158. EPA, NMSP INTERIM REPORT, *supra* note 93, at 3.

159. COMM'N OF THE EUROPEAN CMTYS., *supra* note 108, at 6.

160. Gary E. Marchant, *From General Policy to Legal Rule: The Aspirations and Limitations of the Precautionary Principle,* 111 ENVTL. HEALTH PERSP. 1799, 1802 (2003).

161. Diana M. Bowman & Graeme A. Hodge, *Counting on Codes in Examination of Transnational Codes as a Regulatory Governance Mechanism for Nanotechnologies*, 3 REG. & GOVERNANCE 145, 147–48 (2009).

162. *See supra* notes 93–107 and accompanying text.

163. *See supra* notes 108–13 and accompanying text.

164. *See supra* notes 54–57 and accompanying text.

most nanotechnology mechanisms are still very recent, NIOSH has already updated its guidelines,[165] and the European Union is now preparing to do so.[166]

Flexibility across regulatory targets is also important. Formal regulations tend to be relatively uniform in their application, but soft law allows agencies to more easily fine-tune norms to the circumstances of particular groups—for example, small and large firms, or firms operating at different stages of the product life cycle—increasing regulatory efficiency. EPA's negotiations with NCC, for example, contemplate agreement on testing norms designed specifically for producers of carbon nanomaterials. Both types of flexibility are continuing advantages, making soft law valuable as an ongoing tool of regulation, not simply as a temporary step.

The flexibility of soft law across targets can help make regulation "responsive" to the conduct of particular firms or industry groups.[167] Rather than regulating all firms, even those already taking precautionary measures, an agency can allow responsible firms to operate under a soft law regime, or even self-regulation so long as they continue to act responsibly, while focusing hard regulation, inspections and sanctions on less responsible actors. The former EPA Performance Track illustrates this approach.[168] The flexibility of soft law allows the agency to modulate its actions rapidly, in either direction, in response to the behavior of particular firms. Responsive regulation can reduce the demands on regulators and the social cost of regulation, encourage responsible behavior, and move beyond the adversary nature of mandatory regulation. At its best, it engages firms as partners in furthering public goals.

Finally, soft law is particularly valuable in international contexts. International agencies generally lack strong regulatory authority over states, and very few are empowered to adopt norms directly applicable to private actors. Bodies such as the OECD and ISO therefore use soft law to promote transnational harmonization. However, legal systems, business structures, regulatory capacity and other conditions vary widely across countries, increasing the costs of uniform regulation. Consequently, transnational bodies frequently rely on the flexibility of soft law.

2. *Disadvantages*

The most serious disadvantage of public soft law is also the most obvious—soft law is soft. "The obvious weakness of voluntary initiatives is that they do not necessarily make anyone do anything."[169] To be sure, in many situations—for example, where risks are uncertain—the voluntary nature of soft law is a major advantage; in other settings, however, voluntariness can be its downfall. For example, both the NMSP and the E.U. Code—for different

165. NAT'L INST. OF OCCUPATIONAL SAFETY & HEALTH, *supra* note 55.

166. *See supra* notes 112–13 and accompanying text.

167. *See generally* IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE (1992).

168. *See supra* text accompanying note 45.

169. FIORINO, *supra* note 22, at 39.

reasons—have had limited effect because of weak participation by target actors.

Agencies can overcome this limitation if soft law is backed by positive or negative incentives.[170] In some relatively successful mechanisms, the state itself provides positive incentives. For example, the European Union's EMAS system creates potential market benefits by allowing participating firms to distinguish themselves through the use of its logo,[171] and the Performance Track did so by relaxing burdensome aspects of regulation.[172] However, none of the public nanotechnology mechanisms reviewed here provide such incentives.[173] In other cases, consumers, investors, insurers, workers, CSOs or the general public can create positive market or reputational incentives.[174] However, it is difficult for such groups to organize and act collectively, and their role is limited by the complexity and uncertainty surrounding new technologies.

The principal alternative to such incentives is "the shadow of the state," that is, the threat of hard regulation should soft law mechanisms fail[175] or—in responsive regulation—should particular firms or industries fail to implement such mechanisms.[176] To cast a strong shadow, however, the state must achieve a level of certainty that may not be possible. Even when a threat of hard regulation is feasible, moreover, it puts at risk other benefits of soft law, such as the ability to act flexibly and in nonadversarial fashion.

Because public soft law is voluntary, the target entities must trust the responsible agency. Perhaps most clearly, firms will be hesitant to fully disclose their research and manufacturing activities if trust is lacking; problems of this sort reduced the effectiveness of the NMSP. Firms may fear that disclosure could hurt them financially and politically in the future, drawing regulatory scrutiny or increasing the stringency of future hard law. An information-gathering mechanism can sow further distrust if the information submitted is not handled carefully; at the same time, however, confidentiality reduces transparency and public understanding. It is vital that the agency clearly convey the purpose and intended operation of the mechanism, the incentives that accompany it, and the ways information will be dealt with.

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170. Neil Gunningham, *The New Collaborative Environmental Governance: The Localization of Regulation*, 36 J.L. & SOC'Y 145, 161–62 (2009).

171. Abbott & Snidal, *International Regulation, supra* note 151, at 327.

172. Abbott & Snidal, *Transnational New Governance*, *supra* note 28, at 521–23.

173. CENARIOS indicates its intention to provide a "seal of approval," but it is unclear how this is to be operationalized. TÜV SÜD, *supra* note 92, part A at 16.

174. Tim Büthe, *Global Private Politics: A Research Agenda,* 12 BUS. & POL., Oct. 2010, art. 12, at 1, 1–2 [hereinafter Büthe, *Global Private Politics*]; Tim Büthe, *Private Regulation in the Global Economy: A (P)Review,* 12 BUS. & POL., Oct. 2010, art. 2, at 1, 1 [hereinafter Büthe, *Private Regulation*].

175. Abbott & Snidal, *Governance Triangle*, *supra* note 151. *See* Tanja A Börzel & Thomas Risse, *Governance Without a State: Can It Work?*, 4 REG. & GOVERNANCE 113, 116–17 (2010) (using a broader term "shadow of hierarchy). *Cf.* FIORINO *supra* note 22, at 25 ("[T]he less [voluntary initiatives] are perceived as being purely voluntary, the more likely they are to be effective.").

176. AYRES & BRAITHWAITE, *supra* note 167, at 35–40.

A third disadvantage is that soft law mechanisms may systematically favor larger firms. For example, large firms are typically better prepared than smaller competitors to generate and submit data to information-gathering programs. Many large firms have a staff (for example, an environmental management office) that maintains information on health and safety risks; if not they have the resources to gather and transmit such information. The same is true of compliance with substantive norms. In addition, large firms have the resources to negotiate with agencies about the nature of compliance, expectations for the program and incentives for participation. To benefit the industry as a whole, then, soft law programs should be designed with input from a cross-section of industry actors.

B. Private and Public-Private Mechanisms

1. *Advantages*

Many of the advantages discussed above also attach to private and public-private soft law, including business (for example, the NCC), CSO (Foresight Institute) and multi-stakeholder (for example, ED-DuPont Framework, Responsible NanoCode) mechanisms. Like public soft law, these mechanisms are easier than formal regulations to adopt, modify and individualize. As a result, they allow firms, researchers and other concerned actors to respond to new information and deal proactively with risks. Private soft law is even less adversarial than public soft law. And arrangements like the NanoRisk Framework and Responsible NanoCode provide new avenues for information sharing and learning.

Private soft law also has unique advantages. First, it allows the regulatory system as a whole to benefit from the capacities of private actors, rather than relying primarily on the capacities of public regulators.[177] Expertise is perhaps the most relevant private capacity,[178] but other capacities are also relevant. In particular, firms and research organizations have the managerial authority to implement regulatory norms and provide incentives for compliance by their employees. Engaging these capacities is essential to the success of any regulatory program. Collaborative arrangements such as the Responsible NanoCode allow actors with distinct, often complementary capacities to pool them, producing better informed and more effective regulation.

Second, as Figure 1 suggests, the coexistence of private soft law and public measures produces a variety of regulatory approaches.[179] Distinct mechanisms can be designed to address specific issues and accommodate the interests of different actors.[180] Like-minded firms or researchers may form "clubs,"

177. Abbott & Snidal, *Transnational New Governance*, *supra* note 28, at 524–26.

178. *See id.* at 549 (noting that "firm schemes have unparalleled business expertise and managerial capacity").

179. *Id.* at 526–27.

180. *Cf.* Robert O. Keohane & David Victor, *The Regime Complex for Climate Change*, 9 PERSP. ON POL. 7 (2011) (addressing public mechanisms).

so adopting more stringent standards than others of their type.[181] Ideally, public and private approaches will be synergistic, with a cumulative impact superior to that of any single measure. For these reasons, scholars increasingly call for the creation of multiple governance arrangements, public and private, to address complex problems.[182]

Third, because soft law reduces the "barriers to entry" for the creation of new mechanisms, it enables experimentation with regulatory approaches.[183] Experimentation helps particular sets of actors to develop regulatory approaches appropriate to their situations, while allowing all relevant actors to learn from their successes and failures. With effective mechanisms for information sharing and learning, experimentation can help the entire regulatory system improve over time.[184]

Finally, private soft law allows diverse societal actors to participate directly in the regulatory process.[185] Participation allows regulatory mechanisms to engage diverse private capacities, and enhances their legitimacy.[186] Many scholars also view participation as desirable in itself: "An opportunity for participation by stakeholders in decisions over matters that affect their lives is a democratic good independent of any improved outcomes that follow from it."[187] To be sure, mechanisms vary widely in terms of participation. At one end of the spectrum is the Forest Stewardship Council. Its General Assembly includes three "chambers" of public and private members—economic, social and environmental—with equal voting power; each chamber is subdivided into developed and developing country units with voting parity.[188] At the other end is the exclusive structure of an individual firm code of conduct.

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181. ASEEM PRAKASH & MATTHEW POTOSKI, THE VOLUNTARY ENVIRONMENTALISTS: GREEN CLUBS, ISO 14001, AND VOLUNTARY REGULATIONS 18, 36 (2006)

182. Such calls are common in the field of climate change. *See, e.g.*, Daniel Cole, *From Global to Polycentric Climate Governance*, European University Institute Working Paper, Robert Schuman Centre for Advanced Studies Global Governance Programme 2011/30, *available at* http://ssrn.com/abstract=1858852; Keohane & Victor, *supra* note 180 (describing the range of disjointed regulatory institutions and their advantages over comprehensive regimes in adaptability and flexibility); Eric W. Orts, *Climate Contracts*, 29 VA. ENVTL. L.J. 197, 199 (2011).

183. *See* Charles F. Sabel & Jonathan Zeitlin, *Learning from Difference: The New Architecture of Experimentalist Governance in the EU*, 14 EUROPEAN L.J. 271, 305–07 (2008); Charles F. Sabel & William H. Simon, *Minimalism and Experimentalism in Administrative State*, 100 GEO. L. REV. 53, 81–82 (2011).

184. Christine Overdevest & Jonathan Zeitlin, *Assembling an Experimentalist Regime: EU FLEGT and Transnational Governance Interactions in the Forest Sector*, 6 REG. & GOVERNANCE (forthcoming 2012) (manuscript at 6–7), *available at* http://www2.warwick.ac.uk/fac/soc/csgr/green/workingpapers/.

185. Abbott & Snidal, *Transnational New Governance*, *supra* note 28, at 527–28.

186. Steven Bernstein, *Legitimacy in Intergovernmental and Non-State Global Governance*, 18(1) *Review of International Political Economy* 17–51 (2011).

187. AYRES & BRAITHWAITE, *supra* note 167, at 82.

188. LARS H. GULBRANDSEN, TRANSNATIONAL ENVIRONMENTAL GOVERNANCE: THE EMERGENCE AND EFFECTS OF THE CERTIFICATION OF FORESTS AND FISHERIES 54 (2010).

2. *Disadvantages*

Again, many of the disadvantages of public soft law are also relevant here. Private soft law is even softer than public mechanisms: The shadow of the state is weaker; mechanisms must provide private benefits to induce firms to participate;[189] and incentives for compliance must be provided almost wholly by consumers, investors, CSOs and similar groups. However, the influence of those groups is often unreliable and subject to sudden change as new issues seize the headlines. Private mechanisms may also favor large organizations.

Private mechanisms differ from public regulation (hard and soft) because they are created in decentralized fashion, not through an ordered process.[190] Their creation depends primarily on the initiative of entrepreneurs within firms, industry associations, research organizations or CSOs, each with its own, possibly idiosyncratic, motivations. For nanotechnology, as for other areas, the result is a dispersed array of organizations. In Figure 1, nanotechnology mechanisms appear in six of the seven zones of the triangle. Such decentralization may lead to gaps or overlaps in terms of issues, participants and regulatory approaches. In addition, individual mechanisms within such an array may feel it necessary to engage in costly forms of competition.

Private actors have unequal capabilities to initiate and participate in soft law mechanisms. Business, in particular, typically has greater resources and more effective organization than other potential participants. Business actors' resources, expertise and managerial capacity allow them to adopt self-regulatory measures—perhaps to preempt public regulation[191]—and to ensure their inclusion in collaborative arrangements, or what Abbott and Snidal call, respectively, "go-it-alone power" and "inclusion power."[192] In Figure 1, these effects are reflected in the preponderance of mechanisms situated in the right half of the triangle. The leading role of business raises concern in many areas of private governance, including nanotechnology.[193]

Second, while multiple institutions can produce synergy, they can also increase the costs of regulation. Potential participants face increased transaction costs. They must determine which arrangements to join, and perhaps fulfill obligations under several different programs. Other costs fall on consumers, the public and other audiences that seek to understand the relevant mechanisms. Still other costs fall on society as a whole, including the adverse results of regulatory gaps and overlaps, as well as the possibility of forum

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189. *See generally* Jessica Green, *Private Standards in the Climate Regime: The Greenhouse Gas Protocol*, 12 BUS. & POL. 3 (Article 3) 1 (2010) (explaining the success of private authority over state regulation of greenhouse gas emissions)

190. Abbott & Snidal, *Transnational New Governance*, *supra* note 28, at 546–50.

191. FIORINO, *supra* note 22, at 39 (voluntary programs may provide an excuse for public authorities not to regulate). *See also* Büthe, *Global Private Politics*, *supra* note 174, at 6–8; Büthe, *Private Regulation*, *supra* note 174.

192. Abbott & Snidal, *Governance Triangle*, *supra* note 151, at 72–73.

193. *See, e.g.*, FIORINO, *supra* note 22, at 39 (several activists rejected the ED-DuPont NanoRisk Framework on this basis); Tim Büthe, *Global Private Politics*, *supra* note 174, at 6–8; Robert Falkner, *Private Environmental Governance and International Relations: Exploring the Links*, 3 GLOBAL ENVTL. POL. 72, 72 (2003).

shopping.[194] These are not yet significant problems for nanotechnology, but could become so if private mechanisms proliferate further.

Third, some mechanisms lack essential regulatory capacities. For example, self-regulatory schemes benefit from the expertise, resources and managerial capacity of business, but lack the independence of CSOs and the authority of public agencies, potentially leading to reduced transparency and reducing public legitimacy. Scholars have urged government to require civil society participation in self-regulatory arrangements,[195] but effective participation is difficult in highly technical areas. Many private mechanisms rely on external funding; as the Director of the GoodNanoGuide has noted,[196] most potential sources of funding are uncertain; some create costs or come with undesirable strings attached. In general, collaborative mechanisms such as the NanoRisk Framework and Responsible NanoCode are more likely to possess all necessary capacities.

Finally, private soft law mechanisms may create less public confidence than traditional regulation. An important secondary benefit of government regulation is assuring the public that independent regulators are managing the risks of a technology. Private soft law mechanisms can fail to provide the accountability and legitimacy needed for public assurance.[197] Opinion surveys confirm that for nanotechnology, as for other emerging technologies, voluntary private standards—at least those emanating from industry—may fail to generate public trust; additional government oversight will often be necessary.[198]

IV. ASSESSING THE DESIGN OF SOFT LAW MECHANISMS

Public and private (or public-private) soft law mechanisms share many common advantages and disadvantages, as discussed in the previous Part. Yet the design of specific mechanisms can shift the balance toward greater or lesser effectiveness. One important design choice, already discussed, is the selection of the actors to participate in governance and operations. This Part considers two additional choices: (1) the stages of the regulatory process that

194. These problems are also associated with governmental "regime complexes." *See* Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1 (2004) (detailing the incentives and consequences of state and nonstate actors shifting intellectual property rights negotiations into international fora); Kal Raustiala & David G. Victor, *The Regime Complex for Plant Genetic Resources*, 58 INT'L ORG. 277, 279 (2004).

195. AYRES & BRAITHWAITE, *supra* note 167, at 54–60.

196. *See supra* note 133 and accompanying text.

197. Diana M. Bowman & Graeme A. Hodge, *A Big Regulatory Tool-Box for a Small Technology*, 2 NANOETHICS 193, 202 (2008) [hereinafter Bowman & Hodge, *A Big Regulatory Tool-Box*]; Bowman & Hodge, *"Governing" Nanotechnology*, *supra* note 32, at 478.

198. JANE MACOUBRIE, WOODROW WILSON CENTER, INFORMED PUBLIC PERCEPTIONS OF NANOTECHNOLOGY AND TRUST IN GOVERNMENT 14 (2005), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Nanotechnologies/Nanotech_0905.pdf. To be sure, this study also finds limited public trust in certain governmental agencies, including Congress, as regulators of nanotechnology. *Id.* at 12–13.

the organization will address and (2) the scope and depth of the organization's norms. Assessing nanotechnology mechanisms against these criteria suggests that most remain quite weak.

A. The Regulatory Process

To be successful, any oversight mechanism must take a series of challenging steps:

- First, advocates for oversight must place the issues to be addressed on the agenda of the relevant actors. This process has clearly begun with nanotechnology: governments, industry groups, scientific bodies and other concerned communities are not only assessing the benefits and costs of nanotechnology, but are also taking active steps toward oversight. Yet many of these actions remain tentative, and agenda setting continues in numerous venues. Especially for complex technical issues, moreover, the agenda-setting stage typically requires information gathering and other preliminary steps, such as developing agreed nomenclatures.
- The actors involved in an oversight mechanism must then negotiate, draft and promulgate appropriate norms.
- To be effective, however, the organization must go further. It must promote implementation of its norms within the target organizations, monitor adoption of and compliance with its norms, and even "enforce" those norms, or at least create incentives that promote compliance and deter noncompliance.[199]

Following Abbott and Snidal, we refer to these five tasks (Agenda setting, Negotiation of standards, Implementation, Monitoring and Enforcement—represented by the acronym ANIME) as the "regulatory process."[200]

The actors that participate in an oversight organization, as reflected in its location on the governance triangle, influence its ability to perform these functions in at least two ways. First, the involvement of actors with differing interests—as in collaborative mechanisms—makes it more difficult to agree on agendas and norms and to carry out implementation, monitoring and enforcement. Second, the capacities that actors bring to an organization influence its ability to carry out certain functions. For example, each stage of the process demands specific forms of expertise; implementation and monitoring also require operational capabilities. The participants in an organization also influence the credibility of its actions. For example, an organization dominated by the targets of regulation may be less credible to external audiences than one with greater independence.

All of the nanotechnology mechanisms reviewed here have engaged in *agenda setting* and related preliminary steps. The Foresight Institute was a pioneer, leading the research community, industry and other groups to deliberate on the implications of self-replicating nanosystems. The leaders of DuPont and ED placed responsible development on the agenda of industry.

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199. FIORINO, *supra* note 22, at 24–26.
200. Abbott & Snidal, *Governance Triangle*, *supra* note 151, at 62–64.

The NMSP gathered information on the risks of nanoscale materials to inform future regulation. ISO TC-229 and other standards-setting bodies have addressed preliminary issues essential to oversight, including nomenclature, specifications and measurement. The OECD is addressing similar issues in the context of international harmonization, as well as compiling information on research and country activities and sponsoring "awareness-raising" programs.[201]

A number of nanotechnology mechanisms have also adopted *norms*. It is important, however, to highlight how limited these activities have been.

- The ISO, OECD and NCC primarily focus on pre-rule making stages; the NMSP was not a norm-setting mechanism and is now terminated.
- NCC is still shaping its activities; the CENARIOS program appears to have stalled; the GoodNanoGuide remains in a beta version; and the Responsible NanoCode has not been actively promoted.
- The norms that nanotechnology mechanisms have adopted take highly diverse forms, ranging from codes of conduct (European Union) to management systems (NanoRisk Framework) to good practices (ICON, Responsible NanoCode). Some of these are more clearly prescriptive or rule-like than others, even though none is legally binding. More prescriptive mechanisms include the E.U. Code of Conduct, Responsible NanoCode, Foresight Institute Guidelines and NanoRisk Framework. Norms such as the GoodNano Guide and NIOSH guide are less prescriptive or rule-like.

Importantly, moreover, few nanotechnology mechanisms actively address the later stages of the regulatory process. Efforts to promote *implementation* are modest: NIOSH engages in outreach to employers; DuPont and ED promote adoption of the NanoRisk Framework; and the European Union has recently adopted a tool-based approach similar to the Foresight Guidelines' self-assessment procedure—although only after recognizing the limited uptake of the original code. Most other mechanisms do little or nothing to encourage or support implementation.

Even more striking, none of the nanotechnology oversight mechanisms makes any significant provision for *monitoring* or provides significant positive or negative *incentives* for compliance. To be sure, soft law can influence behavior in other ways: participating experts disseminate ISO standards; actors seeking to limit liability or insurance costs may seek out good practices; and executives may internalize normative principles. Nonetheless, the limited attention these mechanisms devote to implementation, monitoring and enforcement suggests they will have a modest regulatory impact.

B. Normative Scope and Depth

Because norm setting is the principal oversight activity of nanotechnology mechanisms, it is important to assess the norms they have adopted. One can

201. *See, e.g.*, *UNITAR/OECD/IOMC Awareness-Raising Workshop for Developing and Transition Countries on Nanotechnology/Manufactured Nanomaterials,* ORGANISATION FOR ECON. CO-OPERATION & DEV., http://www.oecd.org/document/54/0,3746,en_2649_37015404_44130614_1_1_1_1,00.html (last visited Apr. 2, 2012).

judge the ambition of normative systems by their scope (the issues and actors they address) and their depth (the degree of behavioral change they call for).

The normative scope of the nanotechnology mechanisms varies widely. The Foresight Guidelines are narrow, focused almost entirely on the problems of self-replicating systems, which do not yet exist. Other mechanisms have a moderate scope. They focus on certain products (NCC on carbon nanomaterials); settings (NIOSH and ICON on workplaces); or activities (European Union on research). Some rule-making mechanisms do, however, address a broad range of products, settings and activities. ISO addresses health, safety and environmental issues for nanotechnology products; the NanoRisk Framework addresses management of the risks of nanomaterials through the life cycle; and the Responsible NanoCode addresses practices throughout the value chain.

Substantive depth poses more serious problems. If norms do not establish significant constraints on behavior, they will have limited impact on the underlying problem, even if compliance appears to be high.[202] If norms allow excessive flexibility, moreover, they make it difficult for targets and observers to calculate the depth of the commitments, enable targets to interpret their commitments in self-serving ways, and make it difficult for external audiences to judge compliance.[203]

Even some relatively prescriptive nanotechnology mechanisms express their norms in terms of principles; these leave ample room for auto-interpretation and make the depth of commitments difficult to judge. For example, the E.U. Code explicitly "offers a set of general principles and guidelines."[204] Many of its principles are framed in very broad terms: "[R]esearch activities should be comprehensible to the public . . . and be conducted in the interest of the well being of individuals and society. . . .[R]esearch activities should be safe, ethical and contribute to sustainable development . . . .[R]esearchers . . . should remain accountable for . . . social, environmental and human health impacts. . . ."[205]

The Responsible NanoCode is similarly principles-based and similarly general: "Each organization shall ensure high standards of occupational health and safety[,]. . .carry out thorough risk assessments and minimize any potential public health, safety or environmental risks . . . [and] shall consider and contribute to addressing the wider social, environmental, health and ethical implications. . . ."[206]

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202. *See generally* George W. Downs et al., *Is the Good News About Compliance Good News About Cooperation?*, 50 INT'L ORG. 379, 380 (1996) (presenting problems of "managerial" school and solutions to those problems).

203. Abbott & Snidal, *supra* note 37, at 427; Abbott et al., *The Concept of Legalization*, *supra* note 37, at 414.

204. COMM'N OF THE EUROPEAN CMTYS., *supra* note 108, at 5.

205. *Id.* at 6–7.

206. *The Responsible NanoCode-Update May 2008*, RESPONSIBLE NANOCODE 2, http://www.responsiblenanocode.org/documents/TheResponsibleNanoCodeUpdateAnnoucement.pdf (last visited Apr. 11, 2012).

These principles-based mechanisms resemble the U.N. Global Compact, "the largest voluntary corporate responsibility initiative in the world."[207] The Global Compact has been widely criticized as ineffective because its commitments are framed in terms of broad, even vague principles and because it scrupulously avoids regulatory activities such as monitoring and sanctions.[208] Yet the Compact pursues alternative approaches. It assists firms to improve their implementation; emphasizes learning from other participants, such as U.N. bodies and CSOs; and sponsors opportunities for collaboration. It provides modest positive incentives by allowing firms in good standing to display its logo, and it has begun to reinforce those incentives by publicly identifying outstanding performers. The Compact also disseminates company "communications on progress" to investors, publicly identifies firms that fail to submit communications, and works with CSOs to assess company performance.[209] In contrast, mechanisms that fail to promote implementation or interactions and learning, and that do not provide monitoring or incentives, cannot be expected to achieve the same results.

Other nanotechnology mechanisms promulgate norms that are more precise. The NanoRisk Framework, for example, includes general principles such as transparency and accountability, but also incorporates established risk assessment and lifecycle assessment procedures.[210] It spells out the steps of these procedures in detail, and in practical terms that can be applied by managers. It includes a model information document that can be shared with stakeholders.[211] In addition, DuPont conducted "demonstration projects" in which they applied the framework to three nanomaterials, and has shared its documentation on those projects.[212]

Management systems like these have become central in many issue areas. Perhaps best known are the ISO 9000 (quality management) and 14000 (environmental management) series; the ISO nanotechnology standard on EHS risks is also a management standard. Because of their completeness, concreteness and practicality, management standards make important contributions. Yet critics have identified problems with this approach that are shared by the NanoRisk Framework.[213] Perhaps most significantly, management systems leave it to individual firms to determine their target levels of performance; the systems merely help them to meet those targets.[214] More broadly, critics argue,

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207. *Overview of the UN Global Compact,* UNITED NATIONS GLOBAL COMPACT, http://www.unglobalcompact.org/AboutTheGC/ (last updated Dec. 1, 2011).

208. *See id.*

209. *Differentiation Programme,* UNITED NATIONS GLOBAL COMPACT, http://www.unglobalcompact.org/COP/differentiation_programme.html (last updated Jan. 16, 2012).

210. ENVTL. DEF.-DUPONT NANO P'SHIP, NANORISK FRAMEWORK 14, 16 (June 2007), *available at* http://www.nanoriskframework.com/files/2011/11/6496_Nano-Risk-Framework.pdf.

211. *Id.* at 16.

212. *Id.* at 20.

213. *See, e.g.*, Stepan Wood, *Three Questions About Corporate Codes: Problematizations, Authorizations and the Public/Private Divide*, *in* ETHICS CODES, CORPORATIONS, AND THE CHALLENGE OF GLOBALIZATION 245, 253–54 (Wesley Cragg ed., 2005).

214. *Id.* at 249. NANO RISK FRAMEWORK, *supra* note 66, at 69 ("Decisions [on measures to control risks] should be based on pre-existing standards of health and safety. . . .").

management systems frame problems of risk, environmental harm and the like as technical issues capable of being solved by skilled managers removing them from political debate and taking more sweeping responses off the agenda.[215]

The appropriate role and design of mechanisms for the oversight of emerging technologies are significant and dynamic issues for the modern regulatory state. Nanotechnology provides an important test case. To date, however, soft law mechanisms for nanotechnology have had a mixed record. Some remain focused on preliminary technical matters; some have not developed fully; some have promulgated broad principles or practices whose depth of commitment is questionable; few actively promote effective implementation; and none engage in monitoring or provide strong incentives for adoption and compliance. Currently, then, few of these mechanisms seem well positioned to play significant, beneficial roles in ensuring the safe development of nanotechnology.

Public and private soft law is sometimes seen as a mere temporary gap filler that will and should be superseded once traditional regulation is promulgated. As numerous experts recognize, however, the speed and complexity of nanotechnology's development exceed the capability of traditional regulation.[216] As a result, traditional regulation alone will never be able to effectively govern rapidly developing technologies, and soft law oversight will be a necessary complement. Given the limitations of existing mechanisms, public authorities—as well as industry groups, research bodies and CSOs—should more actively promote the emergence of new soft law mechanisms for nanotechnology and work to strengthen existing mechanisms.[217] Doing so would not represent a retreat by such authorities from their own public missions. Rather, it would recognize that soft law and traditional regulation must operate contemporaneously, and hopefully synergistically, in the oversight of emerging technologies.

215. Wood, *supra* note 213, at 260.

216. FIORINO, *supra* note 22, at 15; Meili & Widmer, *supra* note 36, at 455–56; Bowman & Hodge, *A Big Regulatory Tool-Box*, *supra* note 197, at 194; Breggin & Carothers, *supra* note 20, at 310–11; Gregory Mandel, *Nanotechnology Governance*, 59 ALA. L. REV. 1323, 1365–66 (2008); Marchant et al., *New Soft Law*, *supra* note 2, at 6; Lee Paddock, *Keeping Pace with Nanotechnology: A Proposal for a New Approach to Environmental Accountability*, 36 ENVTL. L. REV. 10943, 10952 (2006); O. Renn & M.C. Roco, *Nanotechnology and the Need for Risk Governance*, 8 J. NANOPARTICLE RES. 153, 183–84 (2006).

217. Kenneth W. Abbott, *Engaging the Public and the Private in Global Sustainability Governance*, 5 INT'L AFF. 543, 560–64 (2012); Abbott & Snidal, *Transnational New Governance*, *supra* note 28, at 541–45, 564–77.