8-2008

ELR
NEWS & ANALYSIS

38 ELR 10507

ARTICLES

A Framework Convention for Nanotechnology?

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Editors' Summary: Profs. Kenneth Abbott, Gary Marchant, and Douglas Sylvester argue that regulation of nanotechnology should be flexible and adaptive; innovative; international; and official. In order to meet these requirements, the authors call for negotiation of an international framework convention on nanotechnology as soon as possible. In response, Lynn Bergeson appreciates the inherent logic and appeal of their proposal, but questions whether the timing is right for the necessary parties to undertake the concerted effort needed to create such a convention. Similarly, David Rejeski applauds the idea, but wonders whether competitive pressures and government inaction leave any room for negotiation of such a convention or whether dramatic developments will be necessary to prompt action. On the other hand, Brent Blackwelder believes that the risks posed by nanotechnology are so great that there is no time to negotiate a convention and that a moratorium on nanotechnology should precede any other regulatory efforts.

I. Introduction

As an international policy issue, nanotechnology poses extraordinary regulatory challenges. Nanotechnology comprises a diverse set of technologies and products. As a major funding priority for governments and industry groups, it is expected to evolve rapidly and present largely unknown risks and benefits. While some have called for robust oversight, regulators still possess far less data than typically required as a predicate for regulatory action. This situation poses a dilemma: while regulatory inaction could undercut public confidence, premature or inappropriate regulation could impede the development of socially beneficial applications.

Four principles should guide the regulatory response to nanotechnology. First, regulation must be *flexible* and *adaptive*. Nanotechnology will evolve dramatically over the next decade, producing applications and risks that are currently unforeseeable.[1] A regulatory system must be capable of equally rapid change.

Second, regulation must be *innovative*. There is simply insufficient data to support traditional regulatory controls such as exposure or emission standards or restrictions on specific products. Rather, nontraditional approaches such as information gathering and disclosure, product stewardship, and practice guidelines will be essential.[2] Because such measures require the involvement of researchers and industry, these groups must be full and willing partners.

Third, regulation must be *international*.[3] All industrialized nations are actively pursuing nanotechnology. An internationally harmonized approach would limit the kinds of disparities in national regulation that produced such intense controversies over genetically modified foods.[4] Harmonization would also benefit private investors, multinational enterprises, and developing countries, which often lack the resources and expertise to develop their own regulations.[5] The initial responses of many governments to nanotechnology are comparable,[6] so harmonization should be possible.

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1. Ortwin Renn & Mihail C. Roco, *Nanotechnology and the Need for Risk Governance*, 8 J. Nanoparticle Res. 153, 156-62 (2006).
2. Diana M. Bowman & Graeme A. Hodge, *Nanotechnology: Mapping the Wild Regulatory Frontier*, 38 Futures 1060, 1068-69 (2006).
3. For a more extensive argument on the pros and cons of an international approach, see Gary E. Marchant & Douglas J. Sylvester, *Transnational Models for Regulation of Nanotechnology*, 34 J.L. Med. & Ethics 714, 716 (2006); Kenneth W. Abbott et al., International Regulatory Regimes for Nanotechnology (draft manuscript), *available at* http://papers.ssrn.com/abstract=907353.
4. Renn & Roco, *supra* note 1, at 183.
5. *See* United Nations Educational, Scientific, and Cultural Organization, The Ethics and Politics of Nanotechnology (2006) (SHS-2006/WS/10 (Rev. 2 Eng.)), *available at* http://unesdoc.unesco.org/images/0014/001459/145951e.pdf.
6. *See* Pat Phibbs, *Countries Converging on Ways to Address Nanoengineered Products, EU Official Says*, Chem. Reg. Rep. (BNA) 590 (June 12, 2006).

Fourth, regulation must ultimately be *official*. Several informal governmental and nongovernmental forums have been established for coordination of nanotechnology policy.[7] These are valuable at this point in nanotechnology's development but will be insufficient to provide public confidence and a capability for rapid regulatory response. We will almost certainly face unanticipated incidents, risks, and problems with nanotechnology that will require some official response. At least in the medium term, an appropriate regulatory process must be in place. It is critical that this process be in place *before* problems occur; there will not be sufficient time to create it thereafter. In addition, an official process will provide assurances of safety and regulatory capacity increasing public confidence in this new technology.[8]

One regulatory tool that satisfies these four requirements is an international framework convention (FC) for nanotechnology. This Article introduces the FC concept, describes several examples that provide relevant analogues for nanotechnology, and suggests how an FC on nanotechnology might be structured.

II. The FC as a Governance Tool

The FC is not a distinct legal category,[9] but merely a way of structuring treaties or other international agreements to accomplish particular political and technical objectives. Legal instruments other than treaties can also provide a "framework"; an example is the European Union's (EU's) Water Framework Directive (WFD).[10] Framework instruments are characterized by broad multilateral participation and modest institutionalization, but contain limited substantive commitments. The expectation is that the Parties will adopt additional substantive obligations over time, through protocols or similar instruments. The overall strategy is known as the FC-protocol approach.

By itself, the typical FC has the following features. First, it is a legally binding treaty (or other instrument), negotiated and ratified by States. Second, it aims for broad participation, bringing in as many as possible of the States concerned with an issue.[11] Third, it establishes a framework for governance on that issue.[12] For that purpose, the FC normally:

- defines the area to which the agreement applies;
- States agreed on regulatory objectives;
- enunciates general principles, e.g., precautionary action, special consideration for developing countries, to guide future regulatory actions;
- creates or identifies the institutions that will be responsible for such actions; and
- spells out procedures for taking and implementing subsequent regulatory actions.

Finally, the FC contains limited substantive obligations.[13] While there are exceptions, those that are included are typically couched in general terms, e.g., that Parties will take appropriate measures within their domestic legal and political systems to promote the objectives of the agreement.[14] However, FCs frequently impose specific and sometimes quite elaborate obligations in matters including research, information exchange, reporting, and similar matters.

By itself, then, the FC is an odd instrument: it is broad, multilateral, legally binding, and establishes institutions and procedures, but it contains few actual commitments. Clearly such an agreement can have little effect on behavior in the short term. However, the FC-protocol approach is well-suited for dynamic fields, such as environmental protection, which depend upon emerging science and technology and have clear transnational effects. Nanotechnology falls squarely within this category.

Most importantly, the FC-protocol approach allows States to address issues in the face of scientific or technical uncertainty.[15] In extreme cases, States and other actors may be unsure whether a problem even exists; this was once the case for anthropogenic climate change—which was addressed by the United Nations Framework Convention on Climate Change (UNFCCC or the Convention)[16] and its Kyoto Protocol,[17] discussed below—and may still be the case for the safety risks of genetically modified organisms. States may also be uncertain how to react to scientific innovations such as stem cell research or cloning. Initially, at least, they may simply be unable to decide whether such activities are in their interest or in accord with their values.[18]

In less extreme cases, States and other actors may be uncertain about the nature of a problem, the severity of a risk, or the point in time at which a risk is likely to appear. In addition, government actors are frequently uncertain of the appropriate strategies for responding to a scientific or technical risk. They may be unsure whether they have identified all feasible approaches, and each approach's effectiveness,

7. These initiatives include the International Dialogue on Responsible Research and Development of Nanotechnology, Meridian Institute, *Projects*, http://www.merid.org/showproject.php?ProjectID=9233.2 (last visited June 3, 2008); The International Risk Governance Council, *Nanotechnology*, http://www.irgc.org/-Nanotechnology-.html (last visited June 3, 2008); The International Council on Nanotechnology, http://icon.rice.edu/ (last visited June 3, 2008). Initiatives are also being undertaken by various national and international standard-setting bodies such as the International Organization for Standardization (ISO). ISO, *ISO Technical Committee 229*, http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983 (last visited June 3, 2008).

8. Jane Macoubrie, Informed Public Perceptions of Nanotechnology and Trust in Government 13 (Woodrow Wilson Int'l Ctr. for Scholars Project on Emerging Nanotechnologies 2005).

9. Daniel Bodansky, *The Framework Convention/Protocol Approach* (Framework Convention on Tobacco Control Technical Briefing Series, Paper No. 1, WHO/NCD/TFI/99.1, 1999).

10. European Parliament & Council Directive 2000/60/EC [Water Framework Directive], 2000 O.J. (L 327), *available at* http://www.wfduk.org/about_wfd.

11. Kenneth W. Abbott & Duncan Snidal, *Pathways to International Cooperation*, *in* The Impact of International Law on International Cooperation: Theoretical Perspectives (Eyal Benvenisti & Moshe Hirsch eds., 2004). Kenneth Abbott and Duncan Snidal compare the FC approach with two other prototypical strategies for incremental international cooperation: the "soft law" approach, initiated with an agreement that has broad multilateral participation and significant substantive content but is not legally binding; and the "plurilateral" approach, initiated with an agreement that is legally binding and has significant substantive content but has limited participation. In each case the strategy aims to strengthen the weak element over time.

12. Bodansky, *supra* note 9, at 15.

13. Abbott & Snidal, *supra* note 11.

14. Bodansky, *supra* note 9, at 21-22.

15. Abbott & Snidal, *supra* note 11, at 62-63.

16. United Nations Framework Convention on Climate Change, May 9, 1992, 1771 U.N.T.S. 107 [hereinafter UNFCCC].

17. Kyoto Protocol to the United Nations Framework Convention on Climate Change, Dec. 10, 1997, 37 I.L.M. 22 [hereinafter Kyoto Protocol].

18. Abbott & Snidal, *supra* note 11, at 65.

cost, and distribution of benefits and burdens across countries and social groups. All these forms of uncertainty are likely to exist at some point with respect to some aspects of nanotechnology. Where such uncertainty exists, States will obviously be unwilling or unable to accept concrete substantive commitments; as greater certainty is achieved, however, the FC facilitates rapid incremental action.

The FC-protocol approach also allows States to work toward international solutions that might otherwise implicate traditional notions of sovereignty and national pride. Numerous areas of traditional domestic concern, e.g., labor and the environment, have been increasingly globalized, raising the need for international solutions. Nationalistic approaches to such problems are often greater impediments to an effective response than scientific uncertainty. Yet States may be unwilling to cede national control for fear of alienating public opinion or empowering domestic opponents. In these circumstances, the FC-protocol approach allows for incremental responses that do not quickly overturn settled expectations and sentiments.

Even by itself, an FC allows States to accomplish several things. Politically, it lets them:

- acknowledge that a problem may exist, legitimating it as an international concern[19];
- draw the attention of relevant experts, interest groups, and the public to the problem;
- commit themselves to take, or at least consider, more substantive action if the problem proves to be sufficiently serious; and
- demonstrate that they are taking the issue seriously.

More concretely, the FC allows States to provide for research, information sharing and dissemination, reporting of national activities relevant to the problem, national regulatory responses, and similar matters. Such information procedures may involve participation by experts from industry, universities, research institutes, and nongovernmental organizations (NGOs) and other groups, as well as governments. The aim is to involve the entire epistemic community knowledgeable about the issue.[20]

Looking forward, the FC establishes institutions and procedures through which subsequent regulatory actions can be taken more rapidly and at a lower cost than standard treaty processes. Supplementary actions can take several forms. As noted above, the most common is the protocol, simply an international agreement that supplements a more fundamental parent instrument.[21] Other low-cost procedures are also possible. For example, under the Vienna Convention for the Protection of the Ozone Layer,[22] States added numerous obligations over time through technical annexes and agreed declarations as well as through the Montreal Protocol and its amendments.[23] A supplementary instrument may address a particular activity, product, or other aspect of a problem, or it may revise the entire agreement.

In sum, the FC-protocol approach allows States to acknowledge a potential problem, initiate activities and procedures designed to reduce scientific and technical uncertainty, and then act incrementally to address the problem as their knowledge and understanding grow. Politically, the substantive weakness of the original FC helps to attract broad participation. As the process unfolds, the aim is to enmesh participants in a process of social learning that will lead them to accept stronger commitments commensurate with their evolving understanding. Yet FCs may also impose differentiated obligations, perhaps by setting less restrictive requirements for developing countries, or more broadly by allowing States to select protocols to follow. Such considerations reflect the art of institutional design: negotiators can deploy a wide variety of arrangements to optimize participation, flexibility, and effective substantive commitments.

This dynamic process can be understood in purely rational terms. The process produces scientific and technical information that States, including their interest groups and citizens, can use to determine their regulatory interests.[24] It may also mobilize domestic interest groups and NGOs to support or oppose particular regulatory actions so that informed and democratic national decisions can be made. But advocates of the FC-protocol approach frequently urge a more normative understanding.[25] The FC initiates processes of dialogue, persuasion, and learning that address normative concerns as well as factual questions. Indeed, even scientific explanations must be socially accepted if they are to serve as the basis for political action. The FC-protocol process also helps build trust and community as States and other actors coalesce around common goals. Some even argue that it is a mistake to move directly to a deep substantive agreement without such a community-building process, as many States' commitments may be superficial or insincere.[26]

The FC-protocol approach can be blended with other strategies for building international cooperation.[27] For example, a similar approach might be built around soft law instruments that are not legally binding. The Parties might begin with a soft framework document and add additional nonbinding commitments over time; at some point, if the entire corpus of commitments has received sufficient acceptance, it can be formalized into a binding treaty. Alternatively, an international organization or group of States might begin with soft law declarations setting normative parameters, followed by an FC-protocol process rather than a full-fledged treaty.[28] All these approaches share the incremental, information-based quality of the pure FC-protocol approach.

19. Bodansky, *supra* note 9, at 20.

20. For a discussion of epistemic communities, see Peter M. Haas, *Knowledge, Power, and International Policy Coordination*, 46 Int'l Org. (Special Issue) 1 (1992).

21. Bodansky, *supra* note 9, at 33.

22. Convention for the Protection of the Ozone Layer, Mar. 22, 1985, 1513 U.N.T.S. 324.

23. Montreal Protocol on Substances That Deplete the Ozone Layer, Sept. 16, 1987, 1522 U.N.T.S. 3.

24. Abbott & Snidal, *supra* note 11, highlights the rational perspective. Bodansky, *supra* note 9, refers to this as producing "cognitive consensus."

25. *E.g.*, Jutta Brunnee & Stephen J. Toope, *Environmental Security and Freshwater Resources: Ecosystem Regime Building*, 91 Am. J. Int'l L. 26, 26 (1997). Bodansky, *supra* note 9, refers to this as building "normative consensus."

26. Brunee & Toope, *supra* note 25, at 30-31.

27. *See* Abbott & Snidal, *supra* note 11.

28. The approach to tobacco reflected this process. *See* Allyn L. Taylor, *An International Regulatory Strategy for Global Tobacco Control*, 21 Yale J. Int'l L. 257 (1996).

III. Case Studies

Many international agreements provide useful lessons for an FC for nanotechnology; we are currently engaged in a larger research project on these agreements. We summarize here a few examples.

A. UNFCCC

The UNFCCC[29] was opened for signature in 1992 at the United Nations Conference on Environment and Development (UNCED). The Convention was negotiated over 18 months, because of a United Nations (U.N.) General Assembly mandate to prepare the convention for signature at UNCED.[30] The Convention entered into force in 1994 and has been ratified by 192 States.[31]

The UNFCCC did not include binding obligations to reduce greenhouse gas (GHG) emissions, but it did include an "action framework" with the ultimate goal of stabilizing such emissions "at a level that would prevent dangerous anthropogenic interference with the climate system."[32] More specifically, industrialized (but not developing) nations accepted a "nonbinding aim" to reduce emissions, through voluntary measures, to 1990 levels by 2000.[33] This provision illustrates two variations on the standard FC model: blending the legally binding FC approach with soft law, and establishing differentiated state obligations.

Although the UNFCCC included no binding substantive commitments, it did establish an important institution, the Conference of the Parties (COP). The COP was to meet annually and was authorized to adopt more stringent and binding measures.[34] Although the COP is composed of representatives of the States Parties, it incorporated an important innovation: it allowed NGOs and other non-State entities to participate as observers.[35] In December 1997, negotiations within the COP produced the Kyoto Protocol, which did impose mandatory emissions reductions for industrialized countries by 2008-2012.[36] Currently, the COP serves as the forum for negotiations on a second round of commitments designed to succeed the Kyoto Protocol.

The UNFCCC included other important provisions. Its Preamble established a number of key principles that continue to be influential, such as the principles of "differentiated responsibilities and respective capabilities" of States[37] and "the legitimate priority needs of developing countries for sustained economic growth and the eradication of poverty."[38] The Convention also established information and reporting requirements, including an obligation for each Party to develop, periodically update, and publish national inventories of GHG emissions and removals by sinks.[39] These inventories provide rich databases of information for future policy development.[40] The UNFCCC also included provisions for education, public awareness and training,[41] joint implementation of policies or measures,[42] and technology transfer.[43]

The UNFCCC established a Subsidiary Body for Scientific and Technological Advice (Subsidiary Body).[44] Its functions were to assess scientific knowledge on global warming, evaluate new technologies having the potential to reduce GHG emissions, and review the effects of measures taken under the Convention.[45] The Convention authorized the Subsidiary Body to draw upon "existing competent international bodies,"[46] a clear reference to the Intergovernmental Panel on Climate Change (IPCC). The IPCC was established by the World Meteorological Organization and the United Nations Environment Programme in 1998 to provide authoritative scientific reviews of climate change and its effects.[47] The periodic assessments issued by the IPCC have been highly influential, and it is often regarded as a model for scientific input into international governance.[48] Both the Subsidiary Body and the IPCC are intergovernmental organizations. At least for the IPCC, its official status is thought to have enhanced its authority with the public and governments.[49]

While the UNFCCC has not been an overwhelming substantive success, it has provided an institutional and procedural structure for international discussions and negotiations. A key factor in the success of this structure has been its flexibility in responding to rapidly changing scientific information and political sentiments.

B. Framework Convention on Tobacco Control

The Framework Convention on Tobacco Control (FCTC), sponsored by the World Health Organization (WHO), is not a typical FC. Its development nevertheless suggests the role that framework instruments can play in international regula-

29. UNFCCC, *supra* note 16.
30. Daniel Bodansky, *The United Nations Framework Convention on Climate Change: A Commentary*, 18 Yale J. Int'l L. 451, 453 (1993).
31. For the status of ratifications, see UNFCC, *Status of Ratification*, http://unfccc.int/essential_background/convention/status_of_ratification/items/2631.php (last visited June 3, 2008).
32. UNFCCC, *supra* note 16, art. 2.
33. *Id.* art. 4(2)(b).
34. *Id.* art. 7(2).
35. *Id.* art. 7(6).
36. Kyoto Protocol, *supra* note 17.
37. UNFCCC, *supra* note 16, pmbl. ¶ 6.
38. *Id.* pmbl. ¶ 21.
39. *Id.* art. 4(1).
40. Bodansky, *supra* note 30, at 509.
41. UNFCCC, *supra* note 16, arts. 4(1)(i), 6.
42. *Id.* art. 4(2)(a).
43. *Id.* art. 4(3), (5).
44. *Id*. art. 9.
45. *Id.* art. 9(2).
46. *Id.*
47. IPCC, *Homepage*, http://www.ipcc.ch/about/index.htm (last visited June 3, 2008).
48. Dagmar Lohan, *Assessing the Mechanisms for the Input of Scientific Information Into the UNFCCC*, 17 Colo. J. Int'l Envtl. L. & Pol'y 249 (2006); Mark Schrope, *Consensus Science, or Consensus Politics?*, 412 Nature 112 (2001).
49. According to Bodansky, *supra* note 30, at 465 n.83:

> While some officials no doubt wished simply to slow down the climate change issue, which they felt was hurtling out of control, others correctly felt that the intergovernmental nature of the IPCC would ultimately increase the pressure for strong policy responses, both by giving the IPCC's conclusions greater public prestige, and by giving governments a greater sense of ownership and stake in the results. Ultimately this view was vindicated. Because even skeptical countries such as the United States and Saudi Arabia participated fully in the IPCC (even holding leadership positions), the IPCC's report was much harder for governments to ignore or question than earlier scientific assessments.

tion. Reducing the adverse health effects of tobacco use has been on the WHO agenda since at least 1970.[50] In 1995, the World Health Assembly began to consider a rule-based approach, requesting the Director-General to determine the feasibility of developing either a soft law instrument (guidelines or a declaration) or a treaty on tobacco control.[51]

To assist the Director-General, Allyn Taylor and Ruth Roemer developed a comprehensive legal strategy.[52] They recommended a dual approach: obtaining a nonbinding U.N. General Assembly resolution encouraging national and international action against tobacco, and subsequently or concurrently beginning negotiations on an FC. Taylor and Roemer identified two principal advantages of an FC: it is more politically acceptable to States than other legally binding agreements, and it creates an institutionalized forum for negotiations on substantive protocols, increasing the likelihood of achieving consensus. As its main drawbacks, they identified delay and a possible diminution of pressure for substantive action. They concluded that the FC-protocol approach was well-suited to tobacco control, "because this model can be a continuous and dynamic process of law-making."[53]

The Director-General adopted this strategy in its entirety,[54] clearly viewing the FC-protocol approach as incremental: it "does not seek to resolve all the substantive issues in a single document; rather it divides the negotiation of separate issues into separate agreements."[55] While plans for the Convention anticipated a long-term incremental approach, the negotiations actually produced a much more complete agreement. In many ways, the FCTC follows the FC model. It sets a broad objective (to protect present and future generations from the devastating consequences of tobacco use and exposure)[56]; spells out basic principles, e.g., financial and technical assistance for developing countries and civil society participation[57]; and imposes general obligations, e.g., each Party shall implement comprehensive tobacco control programs, including, "in accordance with its capabilities," legislative, administrative and other measures.[58] It includes commitments on research, surveillance, and information exchange, reporting, and scientific cooperation.[59] It creates a structure for future action, establishing a COP and Secretariat[60] and detailing procedures for adopting amendments, technical annexes, and protocols.[61]

Yet the FCTC also includes specific commitments. In particular, it obligates States to take numerous measures to reduce demand for tobacco products by requiring disclosure of product ingredients, requiring health warnings on packaging, and banning tobacco advertising subject to national constitutional principles.[62] It also requires more limited measures to reduce supply, especially by controlling illicit trade.[63]

One risk of expanding the content of an FC in this way is that fewer States will ratify it; after all, increasing political acceptability by limiting substantive commitments is one of the basic rationales for an FC. Yet this seems not to have occurred with the FCTC, which has been ratified by over 150 States in just three years. A second risk, however, is that States will not effectively implement the agreement. It remains to be seen whether States will give full effect to the range of specific obligations in the FCTC.

C. General Agreement on Tariffs and Trade

The General Agreement on Tariffs and Trade (GATT) is less clearly an FC than the other agreements discussed so far.[64] Birthed in 1947, it was adopted when the FC concept had not yet been developed. In addition, since GATT was conceived as a temporary bridge to a robust new international trade organization,[65] it was not intended to have any future, much less to serve as the foundation of a new trade order. Yet GATT did provide a flexible framework for negotiations, and its early focus on aspirational goals rather than detailed rules was crucial to the development of the global trading system.

Against the backdrop of two world wars, a massive depression, and an international economy in ruins, the Western allies turned their attention to reforming the international trade system.[66] Chief among the problems needing reform was the tradition of "preferential trade": offering preferred trading terms to favored countries.[67] In addition, state-centric decisionmaking had resulted in high tariffs across the board. The drafters of GATT sought to replace this regime with an open, nondiscriminatory, free trade system.[68]

Yet GATT did not prescribe in detail how to achieve these transformative goals. Instead, it reflected little more than a theory: nations should limit their right to differentiate among trading partners and offer identical terms to all.[69]

50. *See* World Health Assembly, *Health Consequences of Smoking*, WHA23.32 (May 19, 1970), *available at* http://www.who.int/tobacco/framework/wha_eb/wha23_32/.
51. World Health Assembly, *An International Strategy for Tobacco Control*, WHA48.11 (May 12, 1995), *available at* http://www.who.int/tobacco/framework/wha_eb/wha48_11/.
52. Allyn L. Taylor & Ruth Roemer, International Strategy for Tobacco Control (1996) (WHO/PSA/96.6).
53. *Id.* at 17.
54. WHO, *The Feasibility of Developing an International Instrument for Tobacco Control: Report of the Director-General*, EB97/INF.DOC./4 (Nov. 30, 1995).
55. *Id.* ¶ 13.
56. World Health Assembly, *WHO Framework Convention on Tobacco Control*, art. 3, WHA56.1 (May 21, 2003), *available at* http://www.who.int/tobacco/framework/final_text/.
57. *Id.* art. 4
58. *Id.* art. 5.
59. *Id.* arts. 20-22.
60. *Id.* arts. 23-24.
61. *Id.* arts. 28-29, 33.
62. *Id.* arts. 6-14.
63. *Id.* arts. 15-17.
64. For a deeper discussion of the history of the GATT, see generally Kenneth Dam, The GATT: Law and International Trade Organization (1970).
65. Under the Havana Charter, drafted at the conclusion of World War II and intended to create governing institutions in international law, the Allied victors proposed creation of an International Trade Organization (ITO) as well as others. *See* Clair Wilcox, A Charter for World Trade (1949). The ITO never came into existence because the U.S. Congress never ratified it.
66. *See generally* Dam, *supra* note 64, at 10-16; William A. Brown, The United States and the Restoration of World Trade (1950).
67. *See generally* Patricia Clavin, *The Triumph of Regionalism Over Globalism: Patterns of Trade in the Interwar Period*, *in* Regional Trade Blocs, Multilateralism, and the GATT: Complementary Paths to Free Trade (Till Geiger & Dennis Kennedy eds., 1996).
68. The United States was the driving force behind GATT. *See* Dam, *supra* note 64.
69. *See generally* John H. Jackson, World Trade and the Law of GATT 575-90 (1969).

This idea was enshrined in the most favored nation (MFN) principle, which became, albeit with numerous exceptions, the cornerstone of the trade regime.[70]

Once in force, GATT served as a forum where the Parties could negotiate the substance of the trading system in an incremental fashion. Over the next 50 years, GATT was the forum in which States could come together to discuss tariff reductions,[71] developing country problems,[72] non-tariff barriers, and other issues. GATT has since been replaced by the World Trade Organization (WTO)—a formal organization with strong dispute resolution authority, charged with administering a far more complex body of rules applicable to all members.[73] The role of GATT as a pseudo-FC has run its course, yet GATT's minimalist and incremental framework made possible the rapid transformation of the global trading system from preferential associations to today's global market.

As we have discussed elsewhere,[74] a chief obstacle to the success of nanotechnology is the danger of disparate national approaches to regulation. The promoters of GATT faced a similar dilemma—an area of clear international concern that fell within the jealous domain of sovereign prerogative. GATT as an FC may thus be a model for those who see international cooperation as the strongest basis for successful global nanotechnology regulation.

D. WFD

The WFD, adopted in 2000, shares many elements with the FC-protocol approach. It was designed to create a framework for water quality across the European Community so that coherent policies could be developed for different bodies of water, including surface water and groundwater; uses, such as drinking and recreation; and problems, such as pollution from agriculture and urban water treatment.[75]

Like an FC, the WFD sets a broad objective: to achieve "good water status" for all European waters by 2015. It creates a general, incremental framework for achieving that goal: the river basin management approach. The WFD states that the success of the basin management approach depends on cooperation among community institutions, States, and local governments, and on public involvement. To ensure public participation, it calls for transparency in planning, with information and progress reports provided to the public.[76] Article 14 requires States to encourage "active involvement" by all "interested parties" in implementing the WFD and to solicit public consultation on programs.[77]

Nonbinding guidance documents have been developed to help local planners deal with various technical issues. One guidance document notably calls for broad public participation.[78] It interprets "active involvement" as requiring that "interested parties" or stakeholders (including professional groups, business associations, academics, NGOs, and individuals) influence planning. Thus, stakeholders must be able to meet with planners and make substantive contributions to their work. Such involvement is said to improve decisions by ensuring that they are based on shared knowledge and scientific evidence and that creative options are considered. Stakeholder involvement also increases public acceptance. These are all issues facing the architects of governance in other complex technical areas, including nanotechnology.

This guidance document suggests that even higher levels of public participation "may often be considered as best practice."[79] In certain sectors, therefore, officials might include stakeholders in "shared decision-making."[80] In other cases, authorities might consider "self-determination," in which aspects of basin management are delegated to stakeholders.[81] These recommendations reveal the range of potential formats for public involvement.

E. Internet Corporation for Assigned Names and Numbers

The Internet Corporation for Assigned Names and Numbers (ICANN) is not an FC, but it has some of the features of one. ICANN was established with a typical FC structure: a governing body, a small secretariat overseen by a president, several subsidiary groups and task forces, and a limited substantive mission.[82] Yet ICANN differs from an FC in one important respect: it is a private institution. As such, it offers other lessons for a potential FC for nanotechnology.

ICANN is an international nonprofit organization that has responsibility for assigning Internet addresses and establishing Internet domains.[83] It was created in 1998 when the U.S. government, which had operated the domain and address system, assigned those functions to ICANN under a memorandum of agreement with the U.S. Department of

70. *See generally* Robert E. Hudec, Developing Countries in the GATT Legal System (1987).

71. The Kennedy Rounds are generally considered major "tariff reduction" negotiations. *See* Paul Demaret, *The Metamorphoses of the GATT: From the Havana Charter to the World Trade Organization*, 34 Colum. J. Transnat'l L. 123, 127 (1995) (noting that "the Kennedy Round[] resulted in the reduction of the customs duties of the contracting parties by an average of 35%").

72. In the mid-1960s, with the lobbying of organizations including the United Nations Conference on Trade and Development, the GATT contracting Parties amended GATT to include non-reciprocity provisions for developing countries. *See* Sungjoon Cho, *The WTO's Gemeinschaft*, 56 Ala. L. Rev. 483, 498-99 (2004).

73. *See* WTO, *Homepage*, http://www.wto.org (last visited June 3, 2008).

74. *See* Marchant & Sylvester, *supra* note 3; Abbott et al., *supra* note 3.

75. Water Info. Sys. for Europe, *Introduction to the New EU Water Framework Directive*, http://ec.europa.eu/environment/water/water-framework/info/intro_en.htm (last visited June 3, 2008).

76. WFD, *supra* note 10, pmbl. ¶¶ 14, 46.

77. *Id.* art. 14. Annex VI of the directive also requires that management plans include a summary of publicly disclosed information, the results of public consultations, and how public input was used.

78. Common Implementation Strategy for the Water Framework Directive (2000/60/EC), Guidance Document No. 8: Public Participation in Relation to the Water Framework Directive (European Community 2003), *available at* http://www.Waterframeworkdirective.wdd.moa.gov.cy/docs/GuidanceDocuments/Guidancedoc8Publicparticipation.pdf.

79. *Id.* at 13.

80. *Id.*

81. *Id.*

82. Officials at ICANN have described the organization as having a limited mission. In one example, ICANN Chief Executive Officer Mike Roberts, took issue with "well-meaning people all over the world" who "mistakenly" view ICANN as a global institution, without "noticing that we're a small company with a limited mission." Scribe's Notes: ICANN Board Meeting, Yokohama, Japan (July 16, 2000), *cited in* John Palfrey, *The End of the Experiment: How ICANN's Foray Into Global Internet Democracy Failed*, 17 Harv. J.L. & Tech. 409, 450 (2004)

83. *See* ICANN, *Registrar Accreditation: History of the SRS*, http://www.icann.org/registrars/accreditation-history.htm (last visited June 3, 2008).

Commerce.[84] ICANN still technically operates under contract to the U.S. government.

From the outset there has been controversy over ICANN's role and effectiveness. A key issue has been its private status. Some argue that as an NGO, ICANN lacks the accountability and legitimacy to effectively govern a global asset like the Internet.[85] ICANN has admitted that its nongovernmental character has been a problem.[86] In 2002, the ICANN Board of Directors concluded that "a purely private organization will not work" and recommended structural changes to provide greater governmental input,[87] an approach that has still not satisfied all.[88] Indeed, it may be just a matter of time before ICANN is largely replaced by an intergovernmental institution. Ultimately, ICANN's private character has left it open to accusations that it lacks legitimacy[89] and accountability,[90] and fails to attend to public views.[91] The bottom line of the ICANN experience is that purely private NGOs are deeply problematic solutions to transnational problems.

84. *Id.*

85. *E.g.*, Jonathan Weinberg, *ICANN and the Problem of Legitimacy*, 50 Duke L.J. 187, 212-17 (2000); Simon Garfinkle, *The Net's Faltering Democracy*, 106 Tech. Rev. 30 (2003). For example, four congressional leaders wrote in 2002 that "we believe ICANN now lacks the legitimacy needed to guide an international consensus body." Letter from Reps. W.J. "Billy" Tauzin, John D. Dingell, Fred Upton & Edward J. Markey, to Hon. Donald L. Evans, Secretary of Commerce (June 20, 2002), *available at* http://lists.essential.org/pipermail/random-bits/2002-June/000899.html [hereinafter Letter from Tauzin et al.].

86. The president of ICANN conceded that its private structure "left ICANN isolated from the real-world institutions—governments—whose backing and support are essential for any effective global coordinating body to accomplish its assigned tasks." Stuart Lynn, *ICANN President's Report: The Case for Reform*, Feb. 24, 2002, http://www.icann.org/general/lynn-reform-proposal-24feb02.htm (last visited June 3, 2008).

87. ICANN, *Announcement: ICANN President Recommends a Roadmap for Reform*, Feb. 24, 2002, http://www.icann.org/announcements/announcement-24feb02.htm (last visited June 3, 2008).

88. Michael Geist, *Public's Role in Net Governance Threatened*, Globe & Mail, June 13, 2002, at B21.

89. A major criticism has been that private institutions should not be engaged in public regulatory policy. ICANN describes its jurisdiction as limited to "technical coordination," not broader policy areas such as online privacy and controls on Internet content. Yet, it acknowledges that "[m]any of the technical co-ordination functions it performs have public policy implications." ICANN, *The Internet Domain Name System and the Governmental Advisory Committee (GAC) of the Internet Corporation for Assigned Names and Numbers (ICANN)*, http://gac.icann.org/web/about/gac-outreach_English.htm (last visited June 3, 2008). In 2002, ICANN's Committee on Evolution and Reform concluded that "there is not any more a legitimate debate over whether ICANN has a role in policy development and implementation. It does." ICANN, *ICANN: A Blueprint for Reform* (2002), http://www.icann.org/committees/evol-reform/blueprint-20jun02.htm (last visited May 9, 2008); *see also* Mission Paper, Ctr. for Democracy and Tech., Clarifying the Mission and Powers of ICANN: Analysis and Proposed Solutions (Oct. 30, 2002), http://www.cdt.org/dns/icann/021030cdt.shtml (last visited June 3, 2008); Kathleen E. Fuller, *ICANN: The Debate Over Governing the Internet*, 2001 Duke L. & Tech. Rev. 2, *1; Palfrey, *supra* note 82, at 410.

90. Michael Geist has noted:

> Internet governance policies strike at the core of free speech, privacy, and a competitive marketplace. ICANN's seeming inability to address these issues in an accountable, transparent, and timely manner has alienated some of its strongest supporters, opening the door to the prospect of major changes to the global internet landscape.

Michael Geist, *More Democracy Needed in Governing Web*, Toronto Star, Apr. 3, 2006, at D3.

91. Letter from Tauzin et al., *supra* note 85; Fuller, *supra* note 89, at *21; Palfrey, *supra* note 82, at 446-57.

IV. Toward an FC for Nanotechnology

The advantages of an FC fit well with the regulatory challenges facing nanotechnology. Because the future direction of nanotechnology and its resulting products and risks are highly uncertain and likely to evolve rapidly, the flexibility of an FC is essential for any regulatory response. An FC for nanotechnology would establish an institutional and procedural structure capable of responding in a prompt, internationally harmonized, and official manner to any emerging nanotechnology risk, incident, or crisis. Moreover, an FC constitutes a commitment to incremental regulation, again a necessary approach with a technology that will evolve in significant and unforeseen directions. Finally, the FC-protocol approach allows state leaders to engage internationally on nanotechnology issues and explore regulatory strategies that may differ from traditional domestic approaches. The FC-protocol approach may well be the optimal instrument to satisfy the four requirements identified at the outset of this Article—that any regulatory response be *flexible and adaptive, innovative, international*, and *official*.

The case studies summarized above offer insights into the potential form and content of such a convention. For example, just as scientific uncertainty was a major impediment to an international agreement on climate change, uncertainty about nanotechnology products and risks is likely to be a significant obstacle to an international nanotechnology agreement.[92] Yet a framework agreement that is largely institutional and procedural, with few initial substantive requirements, can help overcome this reluctance. Like the UNFCCC and GATT, by starting modestly with agreement on broad principles and a negotiating forum, an FC for nanotechnology could evolve into a progressively more respected and powerful agreement.

Equally important, FCs in areas of technical uncertainty, such as the UNFCCC, establish procedures for developing, sharing, and assessing scientific information, attacking the problem of uncertainty itself. These procedures promote the necessary research, and feed into the FC's process for efficiently negotiating substantive requirements once science has identified risks requiring regulation.[93]

The main lesson from the ICANN experiment is that a purely nongovernmental entity lacks the legitimacy to make policy for or regulate an important technology. An active governmental role is essential to provide credibility to regulated parties and the public. Jay Kesan, referring to ICANN,

92. Bodansky, *supra* note 30, at 476.

93. Consider the following observation about certain international environmental agreements:

> [W]hen both the ECE Long-Range Transboundary Air Pollution Convention (LRTAP) and the Vienna Convention for the Protection of the Ozone Layer (Vienna Ozone Convention) were adopted, some states remained unconvinced of the need for action. Nevertheless, even skeptical states acquiesced in the adoption of these conventions, since the conventions did not commit them to any specific measures. Later, when the scientific evidence became stronger, protocols could be adopted more quickly, since the framework conventions had cleared away many of the preliminary procedural and institutional issues.

Id. at 494.

concluded that governmental involvement must at least include "setting minimum baseline standards for rights and regulations, preventing the capture of private regulators through meaningful oversight, increasing the participation of firms in private regulatory initiatives, and also serving as the enforcer of last resort."[94] Similar governmental roles will be indispensable to an international regulatory system for nanotechnology.

Of course, this analysis leaves open the possibility of a hybrid system in which private institutions play some role.[95] In the case of nanotechnology, several countries, including the Australia, Japan, the United Kingdom, and the United States, have independently concluded that a voluntary industry product stewardship program is currently the most effective approach.[96] An FC for nanotechnology could legitimate, implement, and support a uniform transnational product stewardship program, providing greater consistency and effectiveness than a patchwork of national programs. Such a system could be a government-industry partnership where governments negotiate minimum requirements with industry, require company reports, and oversee the FC's implementation.

An FC for nanotechnology could also include a scientific advisory committee modeled on the UNFCCC Subsidiary Body and the IPCC. Possible functions would include "producing policy-relevant information, compiling assessments on the status and trend of the environment, identifying research priorities, outlining assumptions, uncertainties, and conflicting views, and suggesting response options for the treaty's implementation."[97] The committee could provide periodic assessments of scientific developments, the risks of specific products and applications, and best practices for risk control. Effective scientific advisory committees are international and governmental; an FC would support both characteristics.

An FC for nanotechnology should be as transparent as possible. A critical flaw in ICANN was its limited transparency, which increased distrust of its decisions. In contrast, the UNFCCC was one of the first treaties to grant observer status to NGOs, an innovation that helped build its reputation and credibility. The WFD goes further, demanding not only transparency but also consultation with the public and active involvement by stakeholders. The WFD and its guidance documents provide clear rationales for making transparency and meaningful public participation important components of an FC in a potentially controversial area like nanotechnology.[98]

Other procedural and structural features could be included in an FC for nanotechnology. A national reporting scheme like that in the UNFCCC would help chart future regulatory directions. Like the other agreements discussed here, an FC for nanotechnology could also provide for education, training, and public awareness, and perhaps technology transfer.

A final structural suggestion is that an FC for nanotechnology should provide for the innovative use of advisory committees and task forces. ICANN successfully used such entities to channel the concerns of specific groups into the decisionmaking structure. A nanotechnology agreement could include, for example, task forces on occupational issues, environmental issues, food applications, and nanomedicine. Given the key role that industry must play, an industry advisory committee would also be valuable.

While an FC for nanotechnology may at first seem premature, it has much to offer. In fact, because of the early development status of nanotechnology, it may be easier to regulate at the international level than other environmental problems. For example, international regulation of global warming is a more difficult challenge because it would require substantial changes in numerous industries, involve nations with very different interests, and require allocating responsibility for past carbon emissions.[99] Similarly, GATT required States to sacrifice entrenched economic protections, creating strong domestic opposition. In contrast, because nanotechnology is so new, regulation would be primarily prospective and would not require changes in long-established activities or allocations of responsibility for past actions. Moreover, while developing and developed countries have different priorities and goals with respect to nanotechnology, those differences are not as stark as with global warming.[100]

V. Conclusion

An international framework convention holds promise for addressing the unique regulatory challenges posed by nanotechnology. By providing an adaptive, innovative, international, and official framework for addressing nanotechnology risks as they arise, such an agreement could facilitate the effective, safe, and equitable global development of nanotechnology. The key is to establish an institutional and procedural framework before problems arise. For nanotechnology, then, the time to act is now.

94. Jay P. Kesan, *Private Internet Governance*, 35 Loy. U. Chi. L.J. 87, 137 (2003).

95. *See* Renn & Roco, *supra* note 1, at 183.

96. Karluss Thomas et al., *Research Strategies for Safety Evaluation of Nanomaterials, Part VIII: International Efforts to Develop Risk-Based Safety Evaluations for Nanomaterials*, 92 Toxicological Sci. 23 (2006); Bowman & Hodge, *supra* note 2, at 1070.

97. Dagmar Lohan, *A Framework for Assessing the Input of Scientific Information Into Global Decisionmaking*, 17 Colo. J. Int'l Envtl. L. & Pol'y 1, 19 (2006).

98. For another discussion of these modalities, see *id.* at 23-24.

99. Bodansky, *supra* note 30, at 477.

100. With respect to the differences between developed and developing countries in the climate change context, David Hunter, James Salzman & Durwood Zaelke observe:

> At times, divisions between blocs of countries over the negotiations of the climate change regime have been as intense as virtually any issues outside war and national security. The most consistent divisions have included a split between the North and South. . . . [This split exists] particularly because consumption of fossil fuels (and thus the release of greenhouse gases) is viewed as inextricably linked to economic development. Developing countries have not yet accepted any requirement . . . that will slow their economic growth.

David Hunter et al., International Environmental Law and Policy 663-64 (3d ed. 2007).