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A Framework Convention for Nanotechnology?

by Kenneth W. Abbott, Gary E. Marchant, and Douglas J. Sylvester

Editors' Summary: With nanotechnology now a major funding priority for governments and industry around the world, devising the manner and timing of regulation presents a challenge. Too much regulation too soon could hinder development of beneficial technologies, while too little regulation too late may allow dangerous technologies to enter the market. Kenneth Abbott, Gary Marchant, and Douglas Sylvester argue that any solution to this regulatory dilemma must have four basic characteristics: the solution must be flexible, innovative, international, and official. In this Article, they advocate a framework convention on nanotechnology as a regulatory tool meeting these four requirements. The authors use a series of case studies to reveal framework convention best practices, and conclude with a summary of how a nanotechnology framework convention might be structured.

I. Introduction

As an international policy issue, nanotechnology presents a unique set of attributes and poses an extraordinary set of regulatory challenges. Nanotechnology comprises a diverse set of technologies and products. Given that nanotechnology is a major funding priority for governments and industry groups around the world, it is expected to evolve and advance rapidly, presenting risks and benefits that are still largely unknown. While some politicians, social scientists, and activists call for robust regulatory oversight, regulators struggle with levels of information well below what they typically require as a prerequisite for regulatory action. This situation poses a dilemma: while the lack of regulation has the potential to undercut public confidence in this nascent technology, premature and inappropriate regulation could impede the development of socially beneficial products and applications.

Four principles should guide the regulatory response to nanotechnology. First, regulation needs to be *flexible and adaptive*. Nanotechnology will evolve dramatically and quickly over the next decade or two; many of the applications and risks that will eventually appear are unforeseeable

at this time.¹ A prudent and effective regulatory system will therefore need to be capable of revising the rules quickly and frequently to align with a rapidly emerging technology.

Second, any regulatory response needs to be *innovative*. There is simply not sufficient data, at least at this time, to impose traditional regulatory controls such as exposure or emission standards, or restrictions on specific products or activities. Rather, a mix of nontraditional approaches including information gathering and disclosure, product stewardship, and work practice guidelines will be essential.² Because these types of measures require the cooperation of scientific and technological researchers and of industry, these groups must be full and willing partners in any regulatory response.

Third, the regulatory response should be *international*.³ Nanotechnology is being actively pursued by all industrialized nations. Rather than allowing these governments to proceed with disparate national regulations, which are likely to lead to future controversies and trade disputes like those seen with genetically modified foods, an internationally harmonized approach would be preferable.⁴ The initial responses of many national governments to nanotechnology

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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); Renn & Roco, *supra* note 1, at 183.

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*, J.L. MED. & ETHICS (forthcoming 2006) (preliminary draft available at <http://papers.ssrn.com/abstract=907161>); 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.

are comparable,⁵ so a formally harmonized approach should be possible. Many of the private firms investing in nanotechnology are multinational enterprises that operate in many nations; these firms might benefit the most from harmonized regulation. Developing nations would also benefit from an internationally coordinated regulatory response, which would help them overcome the lack of resources and expertise needed to adopt their own national regulations.⁶

Fourth, the regulatory response needs to be *official*. In recent years, a number of informal governmental and nongovernmental forums have been established for dialogue and coordination of nanotechnology policy.⁷ These informal mechanisms are valuable, but are insufficient to provide the public confidence and the capability for rapid regulatory response that are needed for this technology to succeed. In the years ahead, there will almost certainly be unanticipated incidents or developments related to nanotechnology that will present new risks or problems requiring an official response, whether it be informational or regulatory. There should be a governmental process in place capable of making official pronouncements about the precise risks of particular nanotechnology applications or products and for taking regulatory action when appropriate. It is critical that such a process be in place before problems occur; there will not be sufficient time to create the necessary institutions, procedures, and rules after problems arise. In addition, an official process is needed to provide assurances of safety and regulatory capacity so that the public can have confidence in this new technology, which will not occur with informal or purely voluntary controls.⁸

One regulatory tool that meets these four requirements is an international framework convention for nanotechnology. This Article describes the concept of the framework convention, briefly discusses several examples of framework conventions and related agreements that may provide relevant analogues or lessons for nanotechnology, and concludes with a summary on how a framework convention on nanotechnology might be structured.

II. The Framework Convention (FC) as a Governance Tool

The FC does not constitute a distinct legal category.⁹ Rather, the term refers to a way of structuring treaties or international agreements to accomplish particular political and technical objectives. International legal instruments other than treaties can also be structured in framework form; an example is the European Union (EU) Water Framework Directive (WFD).¹⁰ Framework agreements and instruments are characterized by broad multilateral participation and a significant level of institutionalization, but contain otherwise limited substantive commitments. The expectation is that additional substantive obligations will be added in the future through protocols or similar instruments. The FC, its protocols, and other supplementary instruments are then capable of constituting a single unified system. 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 international agreement or other legal instrument, negotiated and ratified by states like any treaty. Second, it aims for broad multilateral participation, bringing in as many as possible of the states concerned with or affecting an issue area.¹¹ Third, it establishes an overall framework for governance in the issue area.¹² For that purpose, the agreement normally:

- defines the issue area to which the agreement applies;
- states the regulatory objectives to be pursued in that area;
- enunciates certain general principles, e.g., precautionary action, consideration of the special needs of developing countries, protection of an open trading system, to guide future regulatory actions;
- creates or identifies the institutions that will be responsible for such actions, setting forth their composition and authority; and
- spells out the procedures to be followed in deciding on and implementing subsequent regulatory actions.

Finally, an FC contains limited substantive obligations. The prototypical FC might include few, if any, substantive commitments; any commitments that are included are typically couched in very general form, e.g., that all parties will take appropriate measures within their domestic legal and

5. See Pat Phibbs, *Countries Converging on Ways to Address Nano-engineered Products*, *EU Official Says*, Chem. Reg. Rep. (BNA), at 590 (June 12, 2006).

6. See UNITED NATIONS EDUCATIONAL, SCIENTIFIC, AND CULTURAL ORGANIZATION, *THE ETHICS AND POLITICS OF NANOTECHNOLOGY 13* (2006), available at <http://unesdoc.unesco.org/images/0014/001459/145951e.pdf>.

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 Sept. 21, 2006)), the International Risk Governance Council project on nanotechnology (IRGC, *Nanotechnology*, <http://www.irgc.org/irgc/projects/nanotechnology> (last visited Sept. 21, 2006)), the International Council on Nanotechnology (ICON, <http://icon.rice.edu/> (last visited Sept. 21, 2006)), as well as initiatives by various national and international standard-setting bodies such as the International Organization for Standardization (ISO, *TC 229*, <http://www.iso.ch/iso/en/stdsdevelopment/tc/tclist/TechnicalCommitteeDetailPage.TechnicalCommitteeDetail?COMMID=5932> (last visited Sept. 21, 2006)).

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. Directive 2000/60/EC (Dec. 22, 2000).

11. Kenneth W. Abbott & Duncan Snidal, *Pathways to International Cooperation*, in *THE IMPACT OF INTERNATIONAL LAW ON INTERNATIONAL COOPERATION: THEORETICAL PERSPECTIVES 50* (Eyal Benvenisti & Moshe Hirsch eds., 2004). Abbott and 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.

political systems to promote the objectives of the agreement.¹³ However, there is one important exception: FCs frequently impose specific, sometimes quite elaborate, obligations pertaining to research, information exchange, reporting, and similar matters, as discussed further below. Some FCs do include a significant number of substantive commitments; these can be considered a hybrid form.

By itself, then, the FC appears to be an odd assemblage of features. It is broad, multilateral, and legally binding, and it establishes institutions and procedures, but it contains little in the way of actual substantive commitments. Clearly such an agreement can have little effect on behavior in the short term. However, the unified FC-protocol approach is particularly well-designed for fields such as environmental protection, which turn on questions of emerging science and technology, and which have clear cross-border 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.¹⁴ In extreme cases, the relevant actors may be unsure whether a particular problem even exists. This may have been the case at one point for anthropogenic climate change—addressed by the Framework Convention on Climate Change¹⁵ and its Kyoto Protocol,¹⁶ discussed further below—and may still be the case for the safety of genetically modified organisms. States and individuals may also be uncertain how to react to novel scientific or technical 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 whether they accord with their values.¹⁷

In less extreme cases, actors may be uncertain as to the nature or extent of a problem, the potential severity of a risk, or the point in time at which a problem or risk is likely to appear or become significant. In addition, actors are frequently uncertain as to the appropriate strategies for mitigating or otherwise responding to a scientific or technical risk. They may be unsure whether they have identified all feasible approaches, and whether those they have identified will prove effective, how costly they will be, and how their benefits and burdens will be distributed across countries and social groups. All of the forms of uncertainty identified here are likely to exist at some point in time with respect to some or many aspects of nanotechnology. Where such uncertainty exists, states will obviously be unwilling or unable to agree on concrete substantive commitments.

Finally, the FC-protocol approach provides an opportunity for states to seek international solutions that otherwise implicate historical notions of domestic control, sovereignty, and nationalistic pride. Numerous areas of traditional domestic concern (labor, the environment, and to a lesser extent, trade) have been progressively globalized, increasing the need and desire for international solutions to the cross-border effects such concerns inevitably raise. En-

trenched nationalistic approaches to such problems (often in the guise of protectionism, national pride, or cultural legacy) are often greater impediments to unified approaches than the scientific uncertainty discussed above. In such cases, nations may be domestically unwilling to alter traditional approaches to these problems for fear of alienating public opinion at home or empowering domestic opponents. In these cases, the FC-protocol approach allows for incremental responses that do not quickly overturn settled expectations and nationalistic sentiments.

The FC-protocol approach allows states to respond to such situations at two points in time: the uncertain present, when the FC is adopted, and the hopefully more certain future, when additional commitments may be added through protocols and other supplementary instruments. Even at the time of adoption, the FC allows states to accomplish several things. In political terms, it lets them:

- recognize that a problem may exist, legitimating it as an issue for international concern¹⁸;
- draw the attention of relevant experts, interest groups and the general public to the problem;
- commit themselves to take or at least consider more substantive action if the problem turns out to be sufficiently serious; and
- demonstrate to advocates for action that they are taking the issue seriously.

More concretely, the FC allows states to put in place requirements for research, education, information sharing and dissemination; procedures for reporting of national activities and national regulatory responses, and possibly for peer reviews of such reports; and similar matters. These information procedures may involve the participation of experts from industry, academic institutions and research institutes, nongovernmental organizations (NGOs) and other groups, as well as governments. In these cases, the aim is to involve the entire epistemic community knowledgeable about the issue.¹⁹ Information procedures may also be made transparent to interest groups and the general public, and may be structured to encourage comments and other forms of public input.

For the future, the FC establishes institutions and procedures through which subsequent regulatory actions can be taken more speedily and at a lower cost than through standard processes of treaty negotiation or amendment. Supplementary actions like these can take several forms. Most common is the protocol, a term that simply refers to an international agreement that supplements or expands on a more fundamental parent instrument.²⁰ Other low-cost instruments and procedures are also possible. For example, the Vienna Convention for the Protection of the Ozone Layer²¹ contained few substantive commitments, but the parties added numerous legally binding obligations over time through technical annexes and agreed declarations as well as through the Montreal Protocol and amendments thereto. A protocol or other supplementary instrument may address

13. *Id.* at 21-22.

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

15. United Nations Framework Convention on Climate Change, May 9, 1992, S. Treaty Doc. No. 38, 102d Cong., 2d Sess. 1 (1992), 31 I.L.M. 849 [hereinafter UNFCCC].

16. Kyoto Protocol to the Framework Convention on Climate Change, 37 I.L.M. 22 (1998) [hereinafter Kyoto Protocol].

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

18. BODANSKY, *supra* note 9, at 20.

19. See Peter M. Haas, *Knowledge, Power, and International Policy Coordination*, 46 INT'L ORG. (SPECIAL ISSUE) No. 1 (1992).

20. BODANSKY, *supra* note 9, at 33.

21. Convention for Protection of the Ozone Layer, adopted Mar. 22, 1985, 1513 U.N.T.S. 323.

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 put in place activities and procedures designed to reduce scientific and technical uncertainty about a problem, and then to act incrementally to address that problem or particular aspects of it, as their knowledge and understanding grow. Politically, the substantive weakness of the original FC helps to attract the broadest possible participation, even if the commitment of some participants is weak or even insincere; as the process unfolds, the aim typically is to enmesh the participants in a process of social learning that will lead them to accept stronger commitments commensurate with the evolving understanding of the problem. Yet, FCs may also impose differentiated obligations. This may be provided in the text of the convention and its protocols, e.g., by setting less restrictive requirements, targets, or deadlines for developing countries, or more broadly, by allowing states to select which protocols they are willing to adhere to. Considerations like these reflect the art of institutional design: negotiators can deploy a wide variety of arrangements to optimize multilateral 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—and the interest groups and citizens that shape their preferences—can use to determine where their interests lie.²² The process 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.²³ The FC initiates processes of dialogue, persuasion, and learning that address normative concerns as well as factual, cause-and-effect questions. Indeed, even scientific and technical explanations must be interpreted and socially accepted to serve as the basis for political action. The FC-protocol process may also build trust and a sense of community, as states and other actors coalesce around common goals and values. Some even argue that it is a mistake to move directly to an agreement containing significant substantive commitments without going through such a community-building process, even if it were feasible to do so, as such commitments will often be superficial or insincere.²⁴

The FC-protocol approach can be blended with other strategies for building international cooperation.²⁵ For example, a similar approach might be built around soft law instruments that lack legally binding character. The parties might begin with a framework document and add additional commitments through supplementary instruments, none of which are legally binding. At some point, if the entire corpus of commitments has received sufficient acceptance, it can be rolled into a legally binding treaty. Alternatively, an international organization or group of states might begin the

process with soft law declarations setting certain normative parameters, followed by an FC-protocol process rather than a full-fledged treaty. As discussed below, this was the approach originally intended for the international regulation of tobacco.²⁶ All such approaches share the incremental, information-based quality of the pure FC-protocol approach.

III. Case Studies

There are many international agreements that may provide useful lessons when considering a potential FC for nanotechnology; these and other agreements are the focus of a larger research project in which the authors are currently engaged. We summarize here a few examples of FCs and other agreements that share some of the characteristics of FCs.

*A. United Nations Framework Convention on Climate Change (UNFCCC)*²⁷

The UNFCCC was adopted in 1992 as part of the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro. The Convention was negotiated over 18 months by an intergovernmental negotiating committee, established by the United Nations (U.N.) General Assembly in December 1990 with a mandate to negotiate a convention in time for signature at the June 1992 UNCED meeting.²⁸ Initially, there was disagreement over whether the agreement should be a substantive treaty reducing greenhouse gas (GHG) emissions or an FC that put in place a process for future action, but the negotiators eventually agreed on the FC approach.²⁹ The UNFCCC was signed by 154 nations at UNCED, and entered into force in 1994.

The Convention did not include binding obligations to reduce GHGs, but it did include an “action framework” that set an ultimate goal of stabilizing GHGs “at a level that would prevent dangerous anthropogenic interference with the climate system.”³⁰ More specifically, major industrialized nations agreed to a “nonbinding aim” to pursue voluntary measures to reduce their GHG levels to 1990 baseline levels by the year 2000.³¹ This provision is illustrative of two variations on the standard FC model discussed previously: blending the legally binding FC approach with soft law, and establishing differentiated obligations for nations in different circumstances.

Although the UNFCCC included no binding substantive commitments, it did put in place a highly significant ongoing institution, the Conference of the Parties (COP). The COP was to meet annually, and could consider enacting more stringent and binding measures for controlling global warming.³² Although the COP is composed of representatives of the states parties, its structure included an important innovation, allowing non-state entities and NGOs to partici-

22. Abbott & Snidal, *supra* note 11, highlight the rational perspective; BODANSKY, *supra* note 9, at 17-18 refers to this as producing “cognitive consensus.”

23. 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, at 17-18 refers to this as building normative consensus.

24. Brunnee & Toope, *supra* note 23, at 30-31.

25. See Abbott & Snidal, *supra* note 11, at 79-84.

26. Allyn L. Taylor, *An International Regulatory Strategy for Global Tobacco Control*, 21 YALE J. INT'L L. 257 (1996).

27. UNFCCC, *supra* note 15.

28. Daniel Bodansky, *The United Nations Framework Convention on Climate Change: A Commentary*, 18 YALE J. INT'L L. 451, 453 (1993).

29. *Id.* at 493-94.

30. UNFCCC, art. 2.

31. *Id.* art. 4(2)(b).

32. *Id.* art. 7(2).

pate in the COP process as observers.³³ In December 1997, negotiations with the COP resulted in agreement on the Kyoto Protocol, which did impose mandatory GHG emission cuts for industrialized countries by 2008 to 2102.³⁴ Currently, the COP is serving as the forum for negotiations on a second round of commitments to come into force following the time for compliance with the initial Kyoto Protocol targets.

The UNFCCC also had several other important provisions. The preamble to the Convention established a number of key agreed-upon principles that have continued to be influential for ongoing discussions. Examples include the principle of “differentiated responsibilities and respective capabilities” of the states parties³⁵ and recognition of “the legitimate priority needs of developing countries for the achievement of sustained economic growth and the eradication of poverty.”³⁶ The UNFCCC also includes 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.³⁷ These inventories provided rich databases of information for future assessment and policy development on global warming.³⁸ The Convention also included provisions for education, public awareness and training,³⁹ joint implementation of policies or measures,⁴⁰ and technology transfer.⁴¹

The UNFCCC also established a Subsidiary Body for Scientific and Technological Advice.⁴² The functions of this group were to assess the state of scientific knowledge on global warming, to evaluate new technologies having the potential to reduce GHG emissions, and to review the effects of measures taken to implement the Convention.⁴³ The Convention also authorizes the Subsidiary Body to draw upon “existing competent international bodies,”⁴⁴ a clear reference to the Intergovernmental Panel on Climate Change (IPCC), 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. The periodic assessments issued by the IPCC on the global warming problem and its potential effects and mitigation efforts have been highly influential, and the IPCC is often regarded as an effective model for scientific input into other international governance initiatives.⁴⁵ Both the Subsidiary Body and the IPCC are intergovernmental organizations. At least in the case of the IPCC, this official status is thought to have enhanced its influence and authority to both the public and governments:

33. *Id.* art. 7(6).

34. Kyoto Protocol, *supra* note 16.

35. UNFCCC, pmb. ¶ 6.

36. *Id.* pmb. ¶ 21.

37. *Id.* art. 4(1).

38. Bodansky, *supra* note 28, at 509.

39. UNFCCC, arts. 4(1)(i), 6.

40. *Id.* art. 4(2)(a).

41. *Id.* art. 4(3), (5).

42. *Id.* art. 9.

43. *Id.* art. 9(2).

44. *Id.*

45. Dagmar Lohan, *Assessing the Mechanisms for the Input of Scientific Information Into the UNFCCC*, 17 *COLO. J. INT'L ENVTL. L. & POL'Y* 249, 265-79 (2006); Mark Schrope, *Consensus Science, or Consensus Politics?*, 412 *NATURE* 112, 114 (2001).

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.⁴⁶

While the UNFCCC has not been an overwhelming substantive success in addressing the problem of global warming, largely due to the difficult political and economic challenges of the issue and the sharply differing perspectives and interests of the participating nations, the Convention has been successful in providing an institutional and procedural structure for official international discussions and negotiations. A key factor in the success of this structure is its flexibility, rooted in the FC-protocol approach, for negotiating new requirements in response to changing scientific information and political and technological trends. As Daniel Bodansky wrote shortly after the UNFCCC was negotiated, “[w]hile immediate emissions stabilization would be desirable, establishing a dynamic international process is more important for the long-term.”⁴⁷

B. Framework Convention on Tobacco Control (FCTC)

The World Health Organization (WHO) FCTC⁴⁸ is not a typical FC. However, its development clearly suggests the role this legal instrument can play in international regulation. Thus, we briefly review its history here.

Reducing the adverse health effects of tobacco use has been on the agenda of the WHO since at least 1970.⁴⁹ In that year, the World Health Assembly adopted the first in a long series of resolutions calling attention to the risks of tobacco use and urging national controls.⁵⁰ In addition, with the support of the Assembly, the WHO Secretariat initiated a long-term program of research, education, and publicity: the Tobacco-Free Initiative. Finally, in 1995, the World Health Assembly began to consider a more rule-based approach. It requested the Director-General to report to the next Assembly on the feasibility of developing either a soft law instrument (guidelines or a declaration) or an international convention on tobacco control.⁵¹

In support of the Director-General's work on this task, Ruth Roemer and Allyn Taylor developed a comprehensive legal strategy.⁵² After reviewing the authority of the WHO to adopt legal instruments and the advantages and disadvan-

46. Bodansky, *supra* note 28, at 465 n.83.

47. *Id.* at 558.

48. WHO Framework Convention for Tobacco Control, WHA 56.1, May 21, 2003 [hereinafter FCTC].

49. See World Health Assembly Resolution, *Health Consequences of Smoking*, WHA 23.32 (May 19, 1970).

50. The WHO resolutions are available at http://www.who.int/tobacco/framework/wha_eb/wha_resolutions/en/index.html (last visited Sept. 21, 2006).

51. WHA 48.11, May 12, 1995.

52. ALLYN L. TAYLOR & RUTH ROEMER, *INTERNATIONAL STRATEGY FOR TOBACCO CONTROL*, WHO/PSA/96.6 (1996).

tages of various soft law instruments and treaty forms, they recommended a dual approach: obtaining a nonlegally binding U.N. General Assembly resolution that would encourage national and international action against tobacco, and subsequently or concurrently beginning negotiations on an FC under WHO auspices. Roemer and Taylor argued that there are two principal advantages of an FC: it has greater political acceptability to states than other legally binding forms of agreement, and it creates an institutionalized forum for negotiations on substantive protocols, thereby increasing the chances for achieving consensus. Its main drawbacks, they suggested, are delay and a possible diminution of political pressure for action after the FC stage. They concluded that the FC-protocol approach was particularly well-suited to the area of tobacco control, "because this model can be a continuous and dynamic process of law-making."⁵³

In his report, the Director-General adopted Roemer's and Taylor's strategy and reasoning in their entirety.⁵⁴ Like their paper, the Director-General's report clearly viewed 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 The WHO Executive Board and Health Assembly both approved the FC-protocol approach as proposed, urging the Director-General to make a part of this approach "a strategy to encourage Member States to move progressively toward the adoption of comprehensive tobacco control policies. . . ."⁵⁶

Negotiations began in 1999, first through a Working Group, then in 2000 through an Intergovernmental Negotiating Body. The Negotiating Body completed its work in 2003. The FCTC was adopted by the Assembly in May of that year and opened for signature. It entered into force on February 27, 2005, and currently has 137 parties.

While the plans for the Convention clearly anticipated a long-term incremental approach, the negotiations actually produced a more complete agreement than its proponents had expected. In many ways, the FCTC follows the standard FC model. It sets a broad objective for the issue area (to protect present and future generations from the devastating consequences of tobacco use and exposure)⁵⁷; spells out principles to guide action, e.g., importance of financial and technical assistance to developing countries and participation of civil society⁵⁸; 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.⁵⁹ It includes fairly typical commitments on research, surveillance, and the exchange of information, reporting, and scientific cooperation.⁶⁰ And it establishes a framework for fu-

ture action, creating a COP and Secretariat,⁶¹ and spelling out procedures for adopting amendments, technical annexes, and protocols.⁶²

Yet the FCTC also includes numerous specific commitments. In particular, it obligates states to take a wide range of measures to reduce demand for tobacco products. While not complete in every respect, these provisions include detailed obligations to protect citizens from secondhand smoke, require producers to disclose the contents of tobacco products, require health warnings on packaging, and ban tobacco advertising subject to national constitutional principles. The Convention also requires a more limited set of measures to reduce supply, especially by controlling illicit trade.

One risk of expanding the content of an FC in this way is that fewer states will ratify the agreement; after all, increasing its political acceptability by limiting its substantive commitments was the rationale for pursuing an FC in the first place. Yet this seems not to have occurred with the FCTC, which was ratified by 137 states in about three years. A second risk, however, is that states will not implement the agreement effectively. On this, the jury is still out with respect to the FCTC.

The first meeting of the COPs to the FCTC, held in February 2006, created working groups to develop two protocols. The first concerns cross-border advertising and promotion, an area earmarked for future development in the Convention itself. The second is illicit trade, which is already treated in some detail in the FCTC, but involves complex transborder enforcement issues. In addition, the conference decided to develop nonbinding guidelines to assist countries in developing regulations under the FCTC and in creating smoke-free sites.

C. General Agreement on Tariffs and Trade (GATT)⁶³

GATT is, admittedly, the least likely of the agreements discussed so far to be considered an FC. Birthed in 1947, GATT was formulated and adopted at a time when the concept of an FC had not yet been developed. Moreover, since GATT was conceived as a preliminary document antecedent to the creation of a robust new institution to govern international trade,⁶⁴ it was not intended to have any future, much less to act as the foundation of a new order for international trade. Despite these limitations, or perhaps because of them, GATT's ability to act as a framework for negotiations, and its early focus on aspirational goals rather than detailed substantive rules, has been 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 Allied victors of World War II turned their attention to reforming

53. *Id.* at 17.

54. 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. An International Framework Convention for Tobacco Control, EB 97.R8 (Jan. 23, 1996); International Framework Convention for Tobacco Control, WHA 49.17 (May 25, 1996).

57. FCTC art. 3.

58. *Id.* art. 4.

59. *Id.* art. 5.

60. *Id.* arts. 20-22.

61. *Id.* arts. 23-24.

62. *Id.* arts. 28-29, 33.

63. For a deeper discussion of the history of the GATT, see generally KENNETH DAM, THE GATT: LAW AND INTERNATIONAL TRADE ORGANIZATION (1970).

64. 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 others. See CLAIR WILCOX, A CHARTER FOR WORLD TRADE (1949). The ITO never came into existence because the U.S. Congress never ratified it.

the system of international trade.⁶⁵ Chief among the problems needing reform was the centuries-old tradition of “preferential trade.”⁶⁶ As the name implies, in the old international trading regime, nations frequently offered preferred trading terms to some countries while offering less beneficial ones to others. The most obvious example was the British Commonwealth trading group—in which Commonwealth members enjoyed advantageous trading relationships while discriminating against all others.⁶⁷ As one can easily imagine, the ability to discriminate among trading partners was considered an essential sovereign prerogative and not one likely to be easily dismissed. In addition to preferential trading, sovereign-centric rather than system-focused decisionmaking had resulted in very high tariffs across the board. The drafters of GATT⁶⁸ sought to replace this regime with an open, nondiscriminatory, free trade system.

Yet GATT did not attempt to answer all questions about how best to achieve these transformative goals. Instead, it reflected little more than a theory: nations should rescind their traditional sovereign right to differentiate among trading partners and instead offer identical terms to all. This idea was enshrined in the concept of “most favored nation” (MFN)—all signatories of GATT would treat all other signatories as their MFNs. This “parity of obligation” became, albeit with numerous exceptions and derogations, the driving principle behind the international trade regime.⁶⁹

Once in force, GATT still did not immediately seek to answer all of the issues that would inevitably arise in a global trading system, nor did it create robust institutions to adopt regulations or resolve disputes. Instead, GATT served as a forum where the contracting parties could debate and negotiate the nature and substance of the trading system. Over the next 50 years, GATT was where Members of the international community came together to discuss tariff reductions,⁷⁰ problems of the developing world,⁷¹ and other issues of trading policy.

GATT sponsored many sets of global negotiations, or rounds, as they are termed, producing not only reductions in tariffs but also an expanding body of rules, codes, and side

agreements on troublesome issues such as government procurement, antidumping procedures and subsidies.⁷² In spite of the MFN obligation, however, many of these agreements resulted in a la carte obligations, much as in an FC under which states can choose which protocols to accept. This eventually came to be seen as a significant problem; to many, the uniform approach envisioned by GATT had become balkanized. Calls began anew for a more robust international institution to govern trade,⁷³ one able to enforce uniform rules and resolve disputes between Member States.

Beginning in 1986, members of GATT took part in the final round of its existence, the Uruguay Round. These negotiations culminated in 1994 with the creation of the World Trade Organization (WTO). The WTO, unlike GATT, was a formal organization with robust dispute resolution authority, and it was charged with administering an even larger and more complex body of rules applicable to all members.⁷⁴ After 1994, the ideal of GATT as a pseudo-FC no longer existed. Yet it can be argued that the rapid transformation of the global trading system, from preferential systems to today’s global market within one-half a century, was made possible by the minimalist framework of the original GATT.

GATT was not an FC, but it worked as one. GATT was a legally binding international agreement, accepted by its state parties. Given its aim, to create a unified trading system based on MFN and open borders, GATT sought broad participation, so that it could provide a forum for all countries, developing and developed alike. GATT provided a formal solution to long-standing, cross-border problems—trade barriers and discriminatory measures—but it did not attempt to enunciate all the necessary rules in advance. Instead, the original GATT and its numerous rounds acted as forum and framework for negotiations on the substantive regulation of global trade.

As we have discussed elsewhere,⁷⁵ a chief obstacle to the future success of nanotechnology is the danger of disparate nationalistic approaches. The promoters of GATT faced a similar dilemma—an area of clear cross-border concern that fell within the jealous domain of sovereign prerogative. The FC character of GATT—its focus on broad principles and inclusion—may be a model for those who see an international solution as the best one for nanotechnology’s future success.

D. European Union Water Framework Directive

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, integrated policies could be developed for different bodies of water, for example, surface water and groundwater; uses, like drinking, recreation, and fishing;

65. See generally DAM, *supra* note 63 at 10-16; see also WILLIAM A. BROWN, *THE UNITED STATES AND THE RESTORATION OF WORLD TRADE* (1950).

66. 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* 31 (Till Geiger & Dennis Kennedy eds., 1996).

67. See JAMES N. MILLER, *ORIGINS OF THE GATT: BRITISH RESISTANCE TO AMERICAN MULTILATERALISM* (2000), available at <http://www.levy.org/pubs/wp/318.pdf>. We are also purposefully sidestepping the existence of preferential trading systems, such as the North American Free Trade Agreement and the EU, which are legal under GATT and the WTO. See generally Jagdish Bhagwati & Arvind Panagariya, *The Theory of Preferential Trade Agreements: Historical Evolution and Current Trends*, 86 AM. ECON. REV. 82 (1996).

68. There is little question that the United States was the driving force behind GATT. See DAM, *supra* note 63.

69. See generally ROBERT E. HUDEC, *DEVELOPING COUNTRIES IN THE GATT LEGAL SYSTEM* (1987).

70. The Kennedy Round, which lasted from 1963 to 1967, was focused mainly on reducing tariffs between developed nations. 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%”).

71. 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 nonreciprocity provisions for developing countries. See Sungjoon Cho, *The WTO’s Gemeinschaft*, 56 ALA. L. REV. 483, 498-99 (2004).

72. See Demaret, *supra* note 70, at 127-28.

73. See John H. Jackson, *What’s Needed for the GATT After the Uruguay Round*, 86 AM. SOC’Y INT’L L. 69, 71 (1992) (referring to GATT’s balkanization).

74. See WTO, *The World Trade Organization . . . in Brief* (2005), available at http://www.wto.org/english/res_e/doload_e/inbr_e.pdf.

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

and problems, such as pollution from agriculture, and urban wastewater treatment.⁷⁶ A number of existing directives will be repealed and replaced by actions taken under the WFD, while others will be integrated into it.

Like an FC, the Directive sets a broad objective: to achieve “good water status,” as defined, for all European waters by 2015. And it creates a general, incremental framework for achieving that goal: the river basin management approach. The WFD first requires Member States to identify all European river basins. By analogy to the negotiation of protocols, it then requires Member States (with successive deadlines) to characterize each basin in terms of environmental pressures and impacts, establish a monitoring network for the basin, identify a program of measures designed to achieve the overall objective in that basin in a cost-effective way, produce a management plan, and implement the agreed measures in time to meet the 2015 deadline. The Member States and Norway have also agreed on a detailed implementation plan.

One of the most striking features of the WFD is its emphasis on public participation. This suggests that an FC, while intergovernmental in character, could—and perhaps should—likewise be structured to encourage the participation of industry, the research community, advocacy groups, and consumers. The WFD indicates in its preamble that the success of the river basin management approach depends on close cooperation among EU institutions, Member States, and local governments, with public consultation and involvement. To ensure public participation, it is necessary to conduct the planning process transparently, providing proper information and progress reports to the public.⁷⁷ Operative Article 14 of the Directive requires Member States to encourage the “active involvement” of all “interested parties” in implementation of the WFD and especially in development of river basin management plans; in addition, Member States must publish and make available for comment their work programs, drafts and other documents, leaving sufficient time for public consultations.⁷⁸

The European Commission, Member States, and Norway have developed nonbinding guidance documents to help local planners and other groups deal with a variety of technical issues. One of these documents addresses public participation, and it interprets the requirements of the Directive broadly.⁷⁹ In particular, it suggests that “active involvement” requires that “interested parties” or stakeholders (including among others professional groups, business associations, academics, environmental NGOs, and individual citizens and firms) actually have the ability to influence the planning process. Thus, stakeholders must be able to discuss issues with planners and make substantive contributions to the solutions they develop. The rationales for such involvement are to improve decisions—to ensure that they are based on shared knowledge and experience and on scientific

evidence, and that creative options are considered—and to increase their acceptability to the public. These are all issues facing the architects of governance in other complex technical areas, certainly including nanotechnology.

In addition, the guidance document suggests that even higher levels of participation, while not required by the WFD, “may be considered as best practice.”⁸⁰ Thus, in certain sectors, officials might include stakeholders in some form of shared decisionmaking, such as participation in river basin organizations with responsibility for regulatory outcomes. In other cases, authorities might consider some form of “self-determination,” handing over some aspect of river basin management to stakeholders, such as to a users association. These are more extreme options, but they show the range of potential formats for public and stakeholder involvement.

E. Internet Corporation for Assigned Names and Numbers (ICANN)

The ICANN is not an FC, but it has some of the features of one. ICANN was set up with a structure similar to that of an FC, with a governing body, a small secretariat or staff, several subsidiary groups and task forces, and a limited initial substantive mission. There have been subsequently extensive debates about, and incremental changes in, ICANN’s structure and mission over time. But ICANN is different than an FC in one important element: it is a private rather than intergovernmental institution. As such, it offers some additional lessons and insights for the establishment for a potential FC for nanotechnology.

ICANN’s legal status is as an international nonprofit organization that has responsibility for assigning Internet addresses and establishing Internet domains. It was created in 1998 when the U.S. government, which had been operating the Internet domain and address system, assigned the addressing function to ICANN under a Memorandum of Agreement with the U.S. Department of Commerce. ICANN still technically operates under contract to the U.S. government, an issue of concern to other nations. ICANN applies a “self-governance model” in which Internet address and domain name polices are “developed in a manageable, bottom-up, consensus-based process involving global, multi-stakeholder representation.”⁸¹ A Board of Directors is the governing body of ICANN, which is run on a day-to-day basis by a small staff overseen by the ICANN president.

Almost from the outset, there has been considerable controversy about the role and effectiveness of ICANN,⁸² with some critics describing it as a “failed experiment.”⁸³ A key issue is that ICANN is intended to be private rather than governmental. As the first president of ICANN noted, “ICANN was supposed to keep control of the Internet’s in-

80. *Id.* at 13.

81. ICANN, STRATEGIC PLAN: JULY 2006–JUNE 2009 DRAFT 4 (Mar. 30, 2006), available at <http://www.icann.org/strategic-plan/strategic-plan-29mar06.pdf>.

82. Kathleen E. Fuller, *ICANN: The Debate Over Governing the Internet*, 2001 DUKE L. & TECH. REV. 2, *1 (2001).

83. John Palfrey, *The End of the Experiment: How ICANN’s Foray Into Global Internet Democracy Failed*, 17 HARV. J. L. & TECH. 409, 410 (2004); Michael Geist, *Public’s Role in Net Governance Threatened*, GLOBE & MAIL, June 13, 2002, at B21 (“both supporters and critics label ICANN a failure”).

76. See EUROPA, *Introduction to the New EU Water Framework Directive*, <http://ec.europa.eu/environment/water/water-framework/overview.html> (last visited Nov. 1, 2006).

77. WFD, 2000/60/EC (2005), pmbis. 14, 46.

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

79. EUROPEAN COMMISSION, GUIDANCE DOCUMENT NO. 8: PUBLIC PARTICIPATION IN RELATION TO THE WATER FRAMEWORK DIRECTIVE (2003).

frastructure *out* of the hands of government. . . .”⁸⁴ The rationale for a nongovernmental entity was that it was “thought likely to be quicker, more responsive to changing conditions, and more suitable to the development of effective global policies than a governmental organization would be.”⁸⁵ ICANN President Stuart Lynn elaborated on this original intention in his reform proposal of 2002:

ICANN was to serve as an alternative to the traditional, pre-Internet model of a multinational governmental treaty organization. The hope was that a private-sector body would be like the Internet itself: more efficient—more nimble—more able to react promptly to a rapidly changing environment and, at the same time, more open to meaningful participation by more stakeholders, developing policies through bottom-up consensus. It was also expected that such an entity could be established, and become functional, faster than a multinational governmental body.⁸⁶

As ICANN itself concedes, the results of this more “nimble” nongovernmental approach to date are “mixed.”⁸⁷ Critics argue that as an NGO, it lacks the accountability and legitimacy that is required to effectively govern the Internet.⁸⁸ For example, a bipartisan group of four congressional leaders wrote in 2002 that “we believe ICANN now lacks the legitimacy needed to guide an international consensus body.”⁸⁹ ICANN President Lynn conceded that the existing 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.”⁹⁰

ICANN does include a Governmental Advisory Committee consisting of representatives of national governments to provide advice on policy issues. However, Lynn concluded that this limited role for governments was inadequate to “effectively [integrate] . . . the views or the influence of governments.”⁹¹ Agreeing with much of its president’s assessment, the ICANN Board concluded in 2002 that “a purely private organization will not work” and recommended structural changes to provide for greater governmental input into ICANN decisionmaking.⁹² There has continued to be a

growing chorus of calls for an even greater governmental role in ICANN.⁹³

The beginning of the end of ICANN, or at least to its being put under tighter governmental control, may be found in the June 2005 report of the Working Group on Internet Governance established by the U.N. to provide recommendations on future global governance of the Internet.⁹⁴ The report concluded that “[t]here is a lack of a global mechanism for participation by Governments, especially from developing countries, in addressing multisectoral issues related to global Internet policy development.”⁹⁵ Recognizing a “vacuum within the context of existing structures,”⁹⁶ the report proposed several options for international governance models, none of which gave much recognition or role to ICANN.⁹⁷ It seems that it may be just a matter of time before ICANN morphs into, or is largely replaced by, a new government-run global Internet governance institution.

A related controversy is the scope of ICANN’s powers and actions, including its policymaking authority. There is broad agreement that because it is nongovernmental, ICANN should not decide policy issues. As ICANN’s first chairwoman stated, “ICANN does not ‘aspire to address’ any Internet governance issues; in effect, it governs the plumbing, not the people.”⁹⁸ ICANN itself states that its jurisdiction is limited to “technical coordination” and does not extend to broader policy areas such as the rules for financial transactions, online privacy, controls on Internet content, spam control, or data protection.⁹⁹ Yet, it acknowledges that “[m]any of the technical co-ordination functions it performs have public policy implications.”¹⁰⁰ ICANN’s own Committee on Evolution and Reform concluded in 2002 that “there is not any more a legitimate debate over whether ICANN has a role in policy development and implementation. It does.”¹⁰¹ For example, the decisions on whether to grant the Palestine Authority’s request that ICANN issue a new country code domain for Palestine, whether to deny the request for a new .xxx top-level domain for adult-oriented material, and how to resolve trademark disputes about domain levels all clearly invoke policy issues.¹⁰² As one commentator noted, “ICANN’s ex-

84. Esther Dyson, *Whose Domain Is It Anyway?*, WALL ST. J., June 17, 2002, at A18.

85. ICANN, WORKING PAPER ON THE POLICY-DEVELOPMENT PROCESS 1-2 (2002), available at <http://www.icann.org/committees/evol-reform/working-paper-process-07may02.htm>; see also ICANN, *Fact Sheet*, <http://www.icann.org/general/fact-sheet.html> (last visited Sept. 18, 2006) (“ICANN’s independence enables rapid response to changes within the commercial, technical and geopolitical landscape of the Internet . . .”).

86. Stuart Lynn, *ICANN—The Case for Reform* (Feb. 24, 2002), <http://www.icann.org/general/lynn-reform-proposal-24feb02.htm> (last visited Nov. 1, 2006).

87. ICANN, *Fact Sheet*, *supra* note 85.

88. 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., Mar. 2003, at 30.

89. Letter from Reps. W.J. “Billy” Tauzin, John D. Dingell, Fred Upton, and 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>.

90. Lynn, *supra* note 86.

91. *Id.*

92. ICANN, *Announcement: ICANN President Recommends a Roadmap for Reform* (Feb. 24, 2002), <http://www.icann.org/announcements/announcement-24feb02.htm> (last visited Aug. 18, 2006).

93. Michael Geist, *Public’s Role in Net Governance Threatened*, GLOBE & MAIL, June 13, 2002, at B21.

94. REPORT OF THE WORKING GROUP ON INTERNET GOVERNANCE (2005), available at <http://www.wgig.org/docs/WGIGREPORT.pdf>.

95. *Id.* at 6.

96. *Id.* at 10.

97. *Id.* at 13-16.

98. Letter from Esther Dyson, Chairwoman, ICANN, to Ralph Nader and James Love (June 15, 1999), available at <http://www.icann.org/correspondence/dyson-response-to-nader-15jun99.htm>.

99. ICANN, *ICANN Information*, <http://www.icann.org/general/> (last visited Sept. 18, 2006).

100. 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 Sept. 21, 2006).

101. Committee on ICANN Evolution and Reform, *ICANN: A Blueprint for Reform* (2002), <http://www.icann.org/committees/evol-reform/blueprint-20jun02.htm> (last visited Sept. 21, 2006).

102. See Wired News Report, *Palestine Wins Internet Home*, WIRED NEWS SERVICE (Mar. 23, 2000), <http://www.wired.com/news/politics/0,1283,35151,00.html> (last visited Sept. 21, 2006); Weinberg, *supra* note 88, at 216.

ercise of authority looked, walked, and quacked like public regulatory power.”¹⁰³

Many commentators have expressed concern that the role of ICANN will expand gradually (mission creep) to include policy issues such as control of Internet content or limiting access to some Internet users, which they assert is inappropriate for a private entity.¹⁰⁴ Other critics express a related concern that given its limitations in terms of accountability, ICANN is unable to effectively manage the policy issues relating to the Internet that urgently need to be addressed:

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.¹⁰⁵

Another controversy about ICANN has been its alleged lack of transparency, openness, and opportunity for public participation.¹⁰⁶ ICANN briefly experimented with direct elections of a subset of its Board of Directors, but dropped that initiative based on low voter participation and other problems.¹⁰⁷ More fundamentally, there is an inconsistency between ICANN’s purported narrow mission of technical management of the Internet and the goal of a more democratic, open, and accountable governance of the Internet.¹⁰⁸ As one scholar has commented:

ICANN’s complex hybrid structure is the root of its legitimacy problem. Rather than being chosen as the structure most able to manage the [domain name and addressing system], or to achieve the principles of openness and representation, ICANN’s structure was a compromise in the worst sense of the word. The designers attempted to blend the best parts of a corporation, a standards body, and a government entity, but they ended up with a structure that does not carry the legitimacy of authority or effectiveness of any of its component parts.¹⁰⁹

Despite the many problems and criticisms that ICANN has encountered, and its uncertain future role, there are some positive lessons from the ICANN experience. ICANN’s structure and function has evolved over the first eight years of its existence, in part in response to some of the concerns and criticisms expressed above.¹¹⁰ This flexibility and adaptivity in both its organization and mission is an important requirement for an international governance model for a rapidly evolving technology such as the Internet or nanotechnology. Moreover, ICANN has established a number of subsidiary bodies and advisory committees as part of its overall governance structure, providing a model for incor-

porating the views and contributions from different sectors of society.¹¹¹

Notwithstanding these modest positive lessons, the bottom line of the ICANN experience is that a purely private NGO lacks the legitimacy to make regulatory policy at the international level for a rapidly evolving technology such as the Internet or nanotechnology.

IV. Toward a Framework Convention 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 over upcoming decades, the flexibility provided by an FC is essential for any regulatory response. An FC for nanotechnology would put in place an institutional and procedural structure capable of responding in a prompt, internationally harmonized, and official manner to any new nanotechnology risk, crisis, or incident that emerges in the future. Moreover, an FC constitutes a commitment to incremental regulation, again a necessary approach to a technology that is expected to evolve in significant and unforeseen directions in the future. Finally, the FC-protocol approach may allow state leaders to engage internationally on nanotechnology issues and explore possible regulatory approaches that differ from historical domestic approaches. The FC-protocol approach may well be the optimal instrument to satisfy the four regulatory requirements identified at the outset of this Article—that any regulatory response be *adaptive, innovative, international, and official*.

The case studies summarized above further support the concept of an FC for nanotechnology and offer insights into the potential form and content of such a convention. For example, just as scientific uncertainties were a primary impediment to negotiation of an international agreement on climate change, uncertainty about future nanotechnology products and risks is likely to be a significant obstacle to any international nanotechnology agreement.¹¹² By putting in place a framework agreement that is largely institutional and procedural, with few initial substantive requirements or commitments, some of this reluctance based on uncertainty can be overcome. Like GATT, by starting off modestly and with agreement on some broad principles and the establishment of a negotiating forum, a nanotechnology FC can evolve into a progressively more effective, respected, and powerful agreement over time.

Equally important, FCs in areas of technical uncertainty, such as the UNFCCC, put in place procedures for developing, sharing and assessing scientific information, addressing the problem of uncertainty itself. Once the institutions are in place, there is a process for efficiently negotiating substantive requirements once the science has

103. Weinberg, *supra* note 88, at 217.

104. Center for Democracy and Technology, *Clarifying the Mission and Powers of ICANN: Analysis and Proposed Solutions*, <http://www.cdt.org/dns/icann/021030cdt.shtml> (last visited Sept. 21, 2006); Fuller, *supra* note 82, at *17; Palfrey, *supra* note 83, at 435.

105. Michael Geist, *More Democracy Needed in Governing Web*, *TORONTO STAR*, Apr. 3, 2006, at D3.

106. Tauzin, *supra* note 89; Fuller, *supra* note 82, at *21; Palfrey, *supra* note 83, at 446-57.

107. Palfrey, *supra* note 83, at 414-15; Jay P. Kesan, *Private Internet Governance*, 35 *LOYOLA U. CHI. L.J.* 87, 122-33 (2003).

108. Palfrey, *supra* note 83, at 416-17.

109. *Id.* at 425-26.

110. See Kesan, *supra* note 107, at 122.

111. *Id.* For a listing of ICANN Committees and Organizations, see <http://www.icann.org/committees/index-enhancement.html> (last visited Sept. 21, 2006). ICANN currently has four advisory committees—the (i) At-Large Advisory Committee; (ii) DNS Root Server System Advisory Committee; (iii) GAC; and (iv) Security and Stability Advisory Committee. It also has three subsidiary organizations—the (i) Address Supporting Organization; (ii) Country Code Names Supporting Organization; and (iii) Generic Names Supporting Organization, as well as a number of other committees and task forces.

112. Bodansky, *supra* note 28, at 476.

identified real risks requiring regulation. Consider the following observation about some previous international environmental agreements:

[W]hen both the [U.N. Economic Commission for Europe] 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.¹¹³

The main lesson from the ICANN experiment is that a private, nongovernmental entity lacks the legitimacy to make policy for or regulate a technology. An active, official government role is essential to provide credibility to both regulated parties and the public. Prof. Jay Kesan, in his analysis of ICANN, concluded that the minimal governmental involvement in an effective international technology governance system should 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.”¹¹⁴ A similar set of government roles are likely to be indispensable for any international regulatory system for nanotechnology.

Of course, the need for a leading government role does not exclude the possibility of a hybrid system in which private institutions play some role.¹¹⁵ In the case of nanotechnology, a number of countries, including Australia, Japan, the United Kingdom, and the United States, have independently come to the conclusion that some form of voluntary industry product stewardship program is likely to be the most effective at this early stage of nanotechnology development.¹¹⁶ Legitimizing, implementing, and supporting a uniform transnational industry product stewardship program pursuant to an FC on nanotechnology could provide much greater consistency and effectiveness than a patchwork of different national programs, especially for multinational companies. To provide the assurance and public perception of effectiveness, however, such a system should be structured and promoted as a government-industry partnership rather than as a purely self-regulatory program. The roles of national governments in such a program, operating under the FC, would be to negotiate minimum program requirements with industry, implement a company reporting system, and oversee implementation of the program by companies.

An FC on nanotechnology could also include an intergovernmental scientific advisory committee based on the IPCC model. A recent review of the literature and precedents identified the following functions for such bodies: “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.”¹¹⁷ Many of these functions could be assigned to a scientific advisory committee established under a nanotechnology FC. Such a committee could provide periodic, official assessments of the status of scientific developments in the field, what is known and not known about the risks from specific nanotechnology products and applications, and the current best practices for control of nanotechnology risks.

Key components of effective scientific advisory committees, all of which would be facilitated by an FC, are that they are both international and governmental. As one scholarly analysis of such bodies recently observed:

Global membership of the scientific advisory body in particular, as well as a government component, promote the acceptance of its results by States, an aspect itself central to the input of scientific information. Communication between the scientific advisory and decision-making bodies, taking the form of submitting requests for information, presenting reports and subsequently allowing for questions and answers, and convening joint meetings between the bodies’ Bureaux, ensures the policy-relevance of the information produced.¹¹⁸

Another important aspect of an FC for nanotechnology is that it should be as transparent to the public as possible. One of the critical flaws in the operations of ICANN was that it was perceived to have very limited transparency, which increased distrust in the organization’s substantive decisions. In contrast, the UNFCCC was one of the first international agreements to grant observer status to NGOs and other nongovernmental entities, an innovation that has helped to build its reputation and credibility with interested parties. The EU WFD goes even further, demanding not only transparency (a passive attribute involving only visibility to the public), but also consultation with members of the public at large and active involvement by stakeholders with concrete interests in the area. The WFD’s provisions and the guidance document on public participation set out clear rationales for why transparency and meaningful public participation would be important components of an FC in a potentially controversial area such as nanotechnology, as well as a range of procedures by which transparency and participation might be implemented.¹¹⁹

A number of other procedural and structural measures could be included in a nanotechnology FC. A national reporting scheme like that in the UNFCCC that requires each party to collect and publish data on its domestic actions would be very useful for charting future regulatory directions. Like the other FCs discussed above, a nanotechnology FC could also include provisions for education, training, and public awareness, and perhaps even technology transfer.

A final structural suggestion for an international FC on nanotechnology is that the agreement should provide for the innovative use of advisory committees and task forces to

113. *Id.* at 494.

114. Kesan, *supra* note 107, at 137.

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

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

117. 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).

118. *Id.* at 42.

119. For another discussion of these modalities, see Lohan, *supra* note 117, at 23-24.

further the overall effort. One of the more successful aspects of ICANN was its use of such subsidiary entities to channel the concerns of specific users and groups into the decision-making structure. A nanotechnology FC could include, for example, working groups or task forces on occupational issues, environmental issues, food applications, and nanomedicine, to name just a few. Given the key cooperative role that industry must play in the effective governance of nanotechnology, it might also be constructive to include an industry advisory committee—the converse of the way ICANN solicited governmental input through its Governmental Advisory Committee.

While the concept of an FC for nanotechnology may seem far-fetched on first impression, such an agreement has much to offer. In fact, because of the early development status of nanotechnology, with no obvious problems to date, this technology may be easier to regulate at the international level than other environmental problems. For example, international regulation of global warming represents a more controversial challenge than nanotechnology because it requires substantial costs and changes in a broad range of regulated industries, involves nations with very different interests and incentives—for example, oil-producing nations versus low-lying island nations—and requires allocating responsibility for past actions such as carbon emissions.¹²⁰

120. Bodansky, *supra* note 28, at 477.

Similarly, GATT required nations to sacrifice protected and entrenched economic activities to the global playing field of trade, creating strong domestic opposition to freer trade by affected interests. In contrast, because nanotechnology is so new, regulation would be primarily prospective and would not require changes in long-established activities or any allocation of responsibility for past actions. Moreover, while developing and developed countries may have some differences in priorities and goals with respect to nanotechnology, the differences among nations will not be as stark as in the global warming context, as all nations generally favor the goal of developing nanotechnology in a safe and beneficial manner.

V. Conclusion

An international framework convention for nanotechnology holds much promise for addressing the unique set of attributes and regulatory challenges associated with nanotechnology. By providing for an adaptive, innovative, international, and official framework for addressing nanotechnology risks as they arise, such an agreement could play an important facilitating role in the effective, safe, and equitable global development of nanotechnology. The key to the success of such an endeavor is to establish the institutional and procedural framework before problems arise. For nanotechnology, then, the time to act is now.