

RESPONSE

Regulation, Governance, and Nanotechnology: Is a Framework Convention for Nanotechnology the Way to Go?

by Lynn L. Bergeson

An international framework convention protocol approach for nanotechnology is an intriguing notion and one that would appear to make good sense. This Comment on Profs. Kenneth Abbott, Gary Marchant, and Douglas Sylvester's proposal, as set forth in their excellent article entitled *A Framework Convention for Nanotechnology?*,¹ is offered more to spark further thought than as a response to the question they pose. As discussed more below, given the inherent appeal of the proposal, the real question may be not whether, but when a framework convention approach should be pursued in earnest, and how best to initiate the process to ensure its success.

I. Outline of an International Framework Convention Approach for Nanotechnology

Professors Abbott, Marchant, and Sylvester's basic proposition is that an international framework convention for nanotechnology may be the "optimal instrument" to satisfy key criteria.² The authors identify at the outset of their article the "[f]our principles [that] should guide the regulatory response to nanotechnology": (1) flexible and adaptive; (2) innovative; (3) international; and (4) official.³

The authors then explain why an international framework convention for nanotechnology may be well-suited to address these four requirements. Arguments supporting a framework convention approach are that such an approach facilitates broad multilateral participation, entails limited immediate substantive commitment, and represents a legally binding agreement while deferring significant substantive obligations until future protocols and/or other instruments are developed, presumably after they are tempered by appropriate domestic and legal systems, as the authors suggest, to "promote the objectives of the agreement."⁴ The authors note an important caveat to the point about "limited substantive commitments."⁵ Framework conventions "frequently impose specific and sometimes quite elaborate obligations in matters including research, in-

formation exchange, reporting, and similar matters."⁶ Many close to nanotechnology issues will agree that these features are important to the responsible development of nanotechnology at this nascent stage of its growth.

The authors then provide specific case studies of other framework convention prototypes, or framework convention-like best practices. The case studies reviewed include the United Nations Framework Convention on Climate Change, the Framework Convention on Tobacco Control, the General Agreement on Tariffs and Trade, the European Union Water Framework Directive, and the Internet Corporation for Assigned Names and Numbers. The authors acknowledge that some of the case studies are more successful than others, but believe nevertheless that aspects of each are useful in illustrating the relative merits of an international framework convention approach.

Building upon this background, the authors conclude that an international framework convention approach would address well 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 [framework convention] 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*.⁷

II. Discussion

The authors make a solid case for an international framework convention for nanotechnology. Though not extensively discussed in the article on which this Comment is offered, another article by Professors Marchant and Sylvester provides more explicit reasons why they believe a transnational framework for nanotechnology is preferred over a national one.⁸ The authors argue that national regulatory frameworks have appeal at many levels. For example, they often better and more faithfully reflect regional, social,

Lynn L. Bergeson is Managing Director of Bergeson & Campbell, P.C., a Washington, D.C., law firm focusing on conventional and engineered nanoscale chemical, pesticide, and other specialty chemical product approval and regulation, environmental health and safety law, chemical product litigation, and associated business issues, and President of The Acta Group, L.L.C., and The Acta Group EU, Ltd., with offices in Washington, D.C., and Manchester, United Kingdom. The author gratefully acknowledges the assistance of Dr. Shaun F. Clancy, Evonik Industries, who indulged the author's request for his valuable views on this Comment.

1. Kenneth W. Abbott et al., *A Framework Convention for Nanotechnology?*, 38 ELR (ENVTL. L. & POL'Y ANN. REV.) 10507 (Aug. 2008) (a longer version of this article was originally published at 36 ELR 10931 (Dec. 2006)).

2. *Id.* at 10513.

3. *Id.* at 10507.

4. *Id.* at 10508.

5. *Id.*

6. *Id.*

7. *Id.* at 10513.

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

and/or cultural preferences, local priorities and predilections, and can function as real-time experiments to assess what works and what does not, a feature transnational frameworks can ill afford to esouse.

Transnational frameworks, on the other hand, have significant appeal for different reasons. The most obvious advantage of an international approach, in the authors' view, may be that transnational frameworks reflect the reality of our increasingly global worldview. They state that transnational vehicles, whether conventions, treaties, or other regulatory constructs, would appear also to be uniquely well-suited to address the imperatives created by environmental issues that respect no geographic boundaries. The Kyoto Protocol on Climate Change is a prime example. Moreover, the authors argue, national approaches invite disparate and often inconsistent regulatory/governance programs. The absence of harmonized regulatory/governance approaches under these circumstances, according to the authors, seems to invite adverse consequences that in turn create distortions likely to evidence themselves in trade disruptions, blunted innovation opportunities, and a myriad of issues captured in the expression "race to the bottom" where, as Professors Marchant and Sylvester note "individual countries seek economic advantages through lax employment or environmental regulation."⁹

Another crucially important upside of international constructs, according to the authors, is their ability to maximize data and information sharing and facilitate global consultation opportunities. There is near universal agreement that much research must be completed on the environment, health, and safety (EHS) implications of nanotechnology. Tackling research priorities on a global scale is both achievable, and to some extent already underway. Because public and private resources are limited, there is no better way to ensure efficiency than to pool international resources and leverage results globally. As the authors note, an international framework convention is well-suited to facilitate data development and information sharing.

A key potential downside of any international framework convention is embedded in the goal of the exercise itself. It is more likely than not that reasonable people will disagree on what ultimate goal is being pursued, and how the framework convention approach is being conceptualized and implemented to achieve the goal. For example, while many would agree that climate change is a real and serious problem, not everyone agrees the provisions of the Kyoto Protocol are the best or only way to mitigate the problems created by greenhouse gas emissions.

Reasonable people may disagree as to whether transnational regulatory/governance frameworks are good, bad, or perhaps even inevitable. One point is clear, however, and that is the internationalization of the governance of nanotechnology is already underway. Over the past few years, an unprecedented and impressive array of global nanotechnology initiatives has mushroomed. These initiatives fall loosely into several broad categories, including EHS research, nomenclature and terminology standard-setting, and regulatory/governance. No effort is made here to define each of these terms or categories with precision. The work has been undertaken by a wide range of government organizations, including the National Institute for Occupational

Safety and Health, the U.S. Environmental Protection Agency, and the United Kingdom Department for Environment, Food, and Rural Affairs, among others; international organizations, including the International Organization for Standardization (ISO), ASTM International (formerly the American Society for Testing and Materials), and the Organization for Economic Co-operation and Development (OECD); public interest/research organizations, including the Environment Defense Fund, the Meridian Institute, and the Action Group on Erosion, Technology, and Concentration, among others; and private-sector entities, including, among others, DuPont, the American Chemistry Council Nanotechnology Panel, and the Business and Industry Advisory Committee to the OECD.

The OECD, in particular, has been extremely energetic in the area of nanotechnology. Two OECD committees are relevant: the Chemicals Committee and its Working Party on Manufactured Nanomaterials (WPMN), and the Committee on Science and Technological Policy's Working Party on Nanotechnology, which focuses on creating supportive frameworks for innovation on nanotechnologies. While both committees are active, the WPMN has been particularly busy.

Last year, the WPMN initiated work on six projects, each managed by a steering group (SG). The projects are: (1) SG1, "Development of an OECD Database on EHS Research"; (2) SG2, "EHS Research Strategies on Manufactured Nanomaterials"; (3) SG3, "Safety Testing of Representative Set of Manufactured Nanomaterials"; (4) SG4, "Manufactured Nanomaterials and Test Guidelines"; (5) SG5, "Co-operation on Voluntary Schemes and Regulatory Programmes"; and (6) SG6, "Cooperation on Risk Assessment and Exposure Assessment." These projects have commanded the international cooperation of an unprecedented number of OECD participants and others, and are advancing the goals of each SG at a rapid pace. The output is expected to be historic at several levels, not the least of which is the international cooperation exhibited to complete the six projects. Much more could be written about these OECD projects. The point is these activities reflect an internationalization of effort focusing on advancing the responsible development of nanotechnology that has commanded the time, attention, and commitment of global stakeholders unlike any other transnational challenge.

Other global initiatives are underway in the standard-setting arena. The ISO Technical Committee 229 on Nanotechnologies created three working groups: (1) terminology and nomenclature; (2) measurement and characterization; and (3) health, safety, and environment. ASTM International Committee E56 on nanomaterials is also working on nanotechnology standards, and its Subcommittee E56.01 approved a standard on nanotechnology terminology—E2456-06—last December. Other global initiatives are also underway, sponsored by various private standards associations.

III. Conclusion

Against this cursory backdrop of pertinent global nanotechnology initiatives, a question that must be asked is whether the international framework convention approach outlined by the authors is the best, or only, transnational reg-

9. *Id.* at 717.

ulatory/governance tool well-suited to address the regulatory challenges posed by nanotechnology, and whether its time has come. To some extent, the numerous international governance, standard-setting, and related global initiatives that populate the nanotechnology horizon have already created a loosely structured, virtual transnational framework for nanotechnology that is serving some, if not many, of the international governance needs that nanotechnology has inspired. These include EHS research and data development and information sharing, global consultation, technical/scientific protocol development, nomenclature and terminology development, and cooperation and information exchange on voluntary and regulatory programs. These initiatives are certainly flexible and adaptive, international, and innovative. They are not all that “official” in the same way an international protocol or convention is “official,” but many of these initiatives are pursued by international regulatory agencies.

At the end of the day, the approach the authors suggest has appeal. An international framework convention is innovative, flexible, international, and official. As outlined by the authors, the approach would appear to offer more opportunity for success than other regulatory paradigms that necessarily are premised on more traditional and thus less nimble regulatory/governance paradigms.

Whether the global community is ready now to devote the considerable time, energy, and resources necessary for building an international framework convention, and how such a heroic effort would be teed up, are different matters. As an intellectual construct, the proposal makes good sense. As a practical matter, however, finding the resources to build the construct and framing it in a way that would achieve some semblance of consensus may well distract an already overtaxed nanotechnology infrastructure and perhaps even diminish the significant positive energy fueling the global initiatives described above. The political process required for engineering the development of an international framework convention would come with an almost certain divisive rancor that must also be factored into the mix. It is unclear what toll this debate would take on the development of nanotechnology, or whether its commercialization would even survive given the number of detractors it has attracted in its young life.

As with any tough choice, interested parties must decide what is worth their effort, and reasonable people will likely disagree as to whether an international framework convention is the best way to go, and even if so, whether now is the time to push for it. Given the inherent appeal of the proposal, however, while its time may not be now, it is probable its time will come.