Symposium on Nanotechnology Governance: Environmental Management from an International Perspective

Environmental Law Institute Summary of Participant Discussions

On May 19, 2006, ELI and the Vanderbilt Center for Environmental Management Studies sponsored a Symposium on "Nanotechnology Governance: Environmental Management from an International Perspective." The Symposium brought together over 40 key stakeholders including corporate, government, and nonprofit leaders, as well as law firm partners and academics.

Speakers during the morning session provided background information on nanotechnology, including its myriad applications and potential risks; discussed the status of efforts to develop nanotechnology environmental, health, and safety governance structures in the U.S., Europe, and Asia; and addressed the potential role and influence of nanotechnology in developing countries.

During the afternoon session, participants engaged in breakout sessions to discuss the benefits and costs from a corporate environmental management perspective of international coordination or harmonization of environmental, health, and safety governance structures for nanotechnologies. Participants also discussed whether there are principles that should be applied to any efforts to coordinate development of governance structures and what steps could be taken toward harmonization. The following outline sets out the specific questions posed to the participants and discusses the key points made during the breakout sessions and in the subsequent plenary session.

I. Threshold Issues

Several groups discussed two threshold issues:

Definition and Scope of Nanotechnology: Several breakout groups discussed what it means to develop governance structures for "nanotechnology," as nanotechnology encompasses diverse products and processes. Some participants referred to the distinctions that emerged in the context of the debate over genetically modified organisms between products versus processes and queried whether nanotechnology should be treated as a process.

Several participants pointed to the approach taken by the International Risk Governance Council, which divides nanotech development into "Frame 1" and "Frame 2." The former frame refers to nanotechnology applications that include reactive or passive nanostructures with steady behavior; whereas the latter includes more complex and/or evolving-active nanostructures and nanosystems, some of which could use fundamental molecular elements or biostructures as their building blocks. Separating nanotechnologies into these categories could be helpful, as they represent varied risk/benefit portfolios, according to some participants.

Definition of Harmonization: Several groups noted that "harmonization" could take many forms. For example, one group concluded that harmonization could mean "the same across the board," "some sort of minimum" standards, "not conflicting" standards, or some combination or variation of these approaches. Similarly, some participants pointed out that harmonization can be achieved without uniformity or that "there can be more than a single set of rules," with an effort to work toward international harmonization.

II. "What are the corporate environmental management benefits and costs of international coordination or harmonization of environmental, health, and safety governance structures for nanotechnologies?"

Participants identified both benefits and costs of harmonization of environmental, health, and safety governance structures for nanotechnologies.

A. Benefits

Efficiency: According to numerous participants, there are efficiency gains that can be realized from harmonized approaches to governance. Corporations can sell internationally, move products and people internationally, and reduce the costs of testing. Participants recognized that nanotech has the potential to be a global technology and also to spread pollutants globally. According to these participants, harmonization prevents "reinvention of the wheel" for both companies and governments with respect to governance structures.

Standards: Harmonization can bring "laggards" up to the standards of leaders and avoid the "race to the bottom," whereby countries in theory could compete for nano-industries by establishing low environmental, health, and safety standards that are less costly for firms to achieve than higher standards.

B. Costs

Trial and Error: A theme that emerged in the breakout sessions is that rigid forms of harmonization could limit the ability to learn though trial and error. Because so much is unknown at this juncture about the environmental, health, and safety risks associated with nanotech, the setting of uniform or consistent standards may not allow for experimentation that would identify the most promising governance approaches. For example, at this stage stakeholders use analogies to chemicals and biotechnology but nanotech is unique and does not fit easily into either category. In any event, numerous participants recognized that mistakes will be made, given the breadth of unknown factors and, therefore, it is necessary to design a system that is resilient, will allow for an iterative approach, and will not result in loss of public confidence if problems emerge.

Local Needs: Harmonized approaches may not be designed in a manner that reflects local needs, according to some breakout groups. It is likely, however, according

to at least one group, that an approach could be identified that could be adapted over time to local needs and still achieve the benefits of harmonization.

III. "What principles should be applied to any efforts to harmonize or coordinate environmental, health and safety governance structures for nanotechnologies?"

The breakout session participants identified numerous principles that should inform any efforts to move forward on harmonization of governance approaches.

Prioritization: Several of the groups discussed whether a guiding principle should be prioritization based not only on potential risks but also the potential benefits of nanotechnology applications. For example, one group discussed a "triage" approach whereby regulators assess which products or applications are most dangerous and which are most beneficial. For example, green nanoproducts could be given preference for regulatory review and approval. This could encourage people to invest in building those nanotechnologies that provide the most benefits. In addition, such an approach may increase public trust, as high benefits often lead the public to conclude that the risks that are taken are acceptable. This concept, which has been written about by Professor Paul Slovic in his work on risk perception, may be worth exploring, according to some participants. Another group recognized the problem of how to prioritize, but noted that the idea of a whole new framework for nanotech governance was "overwhelming." This group also noted the opportunity that could be "squandered" if a method of prioritization is not developed.

Public Involvement and Information Dissemination: Several groups identified the need to engage the public, but noted that it is not entirely clear how this should be accomplished. For example, some participants discussed whether information "just should be presented" even though recipients may not be scientifically well educated in some cases. Another group stated that stakeholder involvement is "incredibly important" and that it is not just education, but "involvement" that should be fostered to the maximum extent possible. Discussions or dialogues also were viewed as important as a way to understand stakeholder preconceptions. Other participants cited legitimacy and public acceptance as "most important" principles. Participants noted the challenge of designing a system that maintains legitimacy and public acceptance in light of the likelihood that mistakes will be made.

Several participants emphasized the importance of not "over-promising" and being "prudent" in communications with the public. For example, governments and companies should not assure the public that there are no risks associated with nanotechnologies if they do not know that this is accurate. A participant pointed to the recent disclosure failures of drug companies as a learning opportunity. Similarly, risk communication with the public must be "demystified" so as to avoid "irrational fears taking over," according to one breakout group. By communicating correctly public trust can be generated. Some participants said that labeling is a way to provide information about products to the public, but the type of information to convey and its scientific meaning are issues that would need to be addressed.

Another group said that “transparency is key” because it “achieves accountability,” as once information is publicly available, companies may feel obligated to demonstrate that they are in compliance. In addition, transparency helps foster public involvement.

Proprietary Information: Although the importance of transparency was emphasized, participants also recognized the need for exceptions for trade secrets and other proprietary interests. Some participants suggested that there should be a basic agreement about “what is not part of transparency.” The reasons that certain information is withheld should be provided to the public. Protection of proprietary information was viewed as particularly important, because information once public can be shared all around the world via the Internet.

Developing Countries: Several groups noted that a baseline level of protection is necessary worldwide and that problems should not be transferred to poor countries because it is cheap to manufacture in such countries. A participant also queried what it means to harmonize in the developing world and that the issue has many implications. Another group noted that it is important to “maximize the public good” and ensure “equity” or “access” for developing countries. This should be an “overlay” to any international governance measures, according to one breakout group.

Innovation: A breakout group identified encouragement of innovation as a key principle and the need not to “over-regulate.” Another group noted the need to preserve the ability to innovate and be “technologically dynamic.” According to one group, flexibility is needed and the importance of performance standards, as opposed to prescriptive or command/control standards, should be considered.

Liability/Insurance System: Several groups identified the important role of a liability system in the governance structures that are developed. The groups indicated that a preventive regulatory system is needed but also “an after-the-fact liability system.” It is not clear, however, what the balance should be between the two systems. Similarly, another group suggested that a liability scheme has to be used in some fashion but may not be appropriate as part of an international harmonization effort. Rather, this may be an area where it is advisable "to leave room for local standards.” Liability was viewed, however, as “an important part of the picture at the local level.” It was also suggested that addressing liability for a new technology, such as nanotech, at the front-end through insurance may reduce costs and encourage best practices. Some queried whether such an approach would work better with big companies, as opposed to small start-ups. In response, it was suggested that financial assurances could be required of small companies to level the playing field with larger companies that are more likely to have financial resources after-the-fact if there are problems. The financial assurance requirements under the Resource Conservation and Recovery Act and the Oil Pollution Act were cited as possible models.

***Sovereignty*:** Several participants recognized the importance of retaining some degree of sovereignty to address local issues and for political and cultural reasons.

Risk Management: Several breakout groups discussed principles of risk management. It was noted that presumptions will be built into whatever approach to risk management is taken. For example, a preference for a risk-based versus a precautionary approach will influence how much initial information disclosure is required. A group identified risk management as the key challenge in the development of harmonized governance approaches, noting that differing views and ideas about risk, particularly in light of the very limited information available, will be difficult to address. For example, the Registration, Evaluation and Authorization of Chemicals (REACH) approach is likely to differ substantially from any approach the U.S. would take to regulation of nanotech. Concern was expressed that technologies could be frozen with a premature application of precautionary principles. Another group questioned whether risk management should be left to individual countries and not be included in harmonization efforts, as opposed to risk assessment, for example, which may better lend itself to harmonization. A group noted that risk management is an important issue in which additional time should be invested.

Lifecycle Approach: A lifecycle-oriented or holistic approach should be used in developing governance approaches, according to at least one group.

Use of New Versus Existing Tools and Approaches: Several participants discussed whether the institutions and risk assessment methods that are needed to address environmental, health, and safety concerns with respect to nanotech are already in place. A participant proposed that the similarities are greater than the differences between nanotech and other technologies. According to this participant, it is "not a question of starting at ground zero." Similarly, a participant said that existing laws should be used to regulate nanotech and that it is better to interpret current laws than to try to develop a consensus on new legislation. Another participant queried whether nano is different from or any worse than familiar chemicals such as hexane. In response, a participant reasoned that nanotech is not necessarily worse – it is just a question of familiarity. There is a great deal known about hexane but not as much is known about nanotech. As a result, there is a need to design a regulatory system differently. For example, according to this participant, current approaches often consider small amounts of chemicals "not so bad."

A participant emphasized, however, that it is naive to say that nano is "just a little different," and that a prudent person "won't buy it." It was also noted that nanotech, because of its differences from other technologies, really challenges preconceptions about how to regulate. For example, application of the European Union End-of-Life Directive to nanotech, "wouldn't get very far." Thus, the "rethinking of current governance structures is needed as the nano-revolution continues."

On a similar note, another participant noted that there are two philosophies: the first holds that nanotech is evolutionary, the second that it is revolutionary and represents a paradigm shift. Other participants suggested that perhaps current industrial applications could be viewed as evolutionary, while self-assembly because it represents "doing things completely differently" is more revolutionary. In the same vein, a participant cited the

International Risk Governance Council's Frame 1 and Frame 2, discussed above, and noted that existing governance structures may work for today's passive structures and there is no need to "reinvent the wheel," but current approaches probably may not work later when the challenges will be "completely unfamiliar."

Time Frame: Several participants pointed to the concern, in a variety of ways, that in developing governance approaches, it is important to consider whether there is the "luxury of time." The danger pointed out by some participants is that if there is a catastrophic environmental, health and safety problem with respect to nanotechnologies, it may lead people to regulate "quickly and poorly," as has been the case historically with some environmental issues. This concern should be accounted for as governments and private actors seek to develop governance structures, according to these participants.

Early Action: A breakout group noted that the US, Europe, and Japan are at the same level of regulation today, but cultural differences may result in divergence in the future. If harmonization is achieved early, it may be easier to accomplish because governments and people "become invested in a certain way of doing things." Thus, if there is an interest in harmonization, countries should develop approaches that at least can be transferred easily to a harmonized approach, if not harmonized initially, according to some participants. Furthermore, often efforts to harmonize do not necessarily result in a merit-based selection of approaches, as a result of political forces and preferences for the *status quo*. Because there are limited investments in nanotech governance structures to date, early action takes away the pressure to adopt the approach that most countries already have in place.

Company Size: One breakout group noted that the success of information gathering and other efforts will vary based on whether small versus large companies are involved. There can be "a real divergence between large firms and small, localized companies that aren't plugged into any standardization process." It is necessary, however, to find a way to involve small companies in the development and implementation of governance structures. For example, best practices and other ways of reaching smaller companies and bringing them into a dialogue were cited as important.

IV. "What steps could be taken toward harmonization or coordination on an international level to address conflicting or inconsistent nanotechnology governance approaches?"

Standardization: Numerous participants expressed the view that formal protocols and standardization, as well as "good guidance" are essential. For example, participants said that some level of standardization is critical, as currently "there is not a framework to determine if a nanotechnology does or does not cause risk or even to assess whether it does or not." Data need to be gathered by standardized protocols, measures and testing techniques, according to several breakout groups. Participants also cited standards for nomenclature, basic testing, work practices, and risk assessment, with many participants recognizing that developing standardized terminology was "easy" to identify as a first step. It was noted that the International Organization for Standardization effort touches

on most of these areas. Several breakout groups deemed the development of screening techniques important, with one group noting that the "equivalent of the structure-activity relationships" are needed. Participants identified several factors as "all-important for focusing scarce resources," such as fate and persistence in the environment, including "whether something may reproduce in the environment" or "be synergistic with other compounds in the environment."

Disclosure: Several groups noted the need to promote information sharing across borders about what is known about nanotechnology environmental, health, and safety issues. This should include obtaining the benefits of what has been done inside companies, because companies have more experience and information than government has now and essentially have been self-regulating. Participants noted, for example, that it is "absolutely clear" that data sharing is critical and should be a first step. A participant pointed to the model of amnesty for airline pilots who report problems. A similar system is needed for companies to disclose what they have learned with assurances that they will not be pilloried for coming forward. According to these participants, such an approach will allow for an iterative system that will improve over time.

Development of International Governance Structures: One breakout group discussed whether it would be possible to "jump over" national regulations and start at the international level to develop a framework that would help multi-nationals to "do the same thing in all parts of the world." This approach could avoid "trade wars" based in part on disparate national approaches, but has not been done before, according to participants.

Potential Fora: Participants proposed a range of possible fora for dissemination of good governance internationally, including the International Council on Nanotechnology, the International Organization for Standardization, and the Organization for Economic Co-operation and Development, the latter of which was recognized as already conducting work on certain risks and implications of engineered nanomaterials. The international dialogue in Tokyo, Japan in June 2006 was also mentioned. Some participants viewed the United Nations and similar entities as critical for disseminating government practices worldwide.

Voluntary Versus Regulatory Approaches: Several groups grappled with the question of whether to proceed with traditional regulation versus voluntary approaches. Some proposed that rather than require regulation, promotion of best available or good practices would be preferable. A group noted that it is easier to harmonize voluntary approaches than traditional regulations, but that a voluntary approach could lead to lack of public confidence and "bad actor" problems. In addition, it may be possible to leverage a voluntary approach into legally binding standards, as is the case with the Equator Principles, according to a participant. Public and private funders of project finance in developing countries, consistent with the Equator Principles, now routinely require in contracts the performance of environmental assessments, thereby making the environmental assessments legally enforceable.

Framework Convention: Some participants recognized the advantages of a "let a thousand flowers bloom" approach at the international level but noted that, given the limited knowledge at this juncture, it may make sense to have a more coordinated structure in place. The Climate Change Convention was cited as a possible model. In addition, an entity similar to the International Panel on Climate Change could be established to provide a scientific viewpoint. Another participant suggested that a process without substance or "teeth" could be established initially and over time the "substance" could be developed.

Funding: A breakout group noted the minimal funds allocated to development of governance frameworks relative to the rest of nanotech funding. This lack of funding is an impediment to harmonization efforts, according to this group.

Burden: At least one group discussed whether government grants should require the development of information to be gathered and presented on risk, as well as health and safety of the work being done. A consensus did not emerge on this issue within the breakout group. Similarly, in discussing the need for screening techniques and information about fate and persistence in the environment, one group raised the question of how to allocate the burden of proof in terms of production of such information, but no consensus was reached.