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Harmonization of Environmental, Health, and Safety Governance Approaches for Nanotechnology: An Overview of Key Themes

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I. Introduction

On May 19, 2006, the Environmental Law Institute (ELI) cosponsored a Symposium entitled "Nanotechnology Governance: Environmental Management From an International Perspective" (ELI Symposium). The ELI Symposium brought together over 40 key stakeholders, including corporate, government, and nonprofit leaders as well as law firm partners and academics.[1] The ELI Symposium focused on the development of environmental, health, and safety (EHS) governance structures—including traditional regulation, voluntary programs, industry standards, disclosure, and other approaches—from an international perspective.

Nanotechnology or nanotech is the science and technology of controlling matter at the nanoscale.[2] The National Science Foundation estimates that nanotechnology may surpass the impact of the Industrial Revolution and could be a $1 trillion market by 2015.[3] Nanotechnologies will be employed in many industries ranging from health care to electronics to transportation.[4] Hundreds of products that use nanomaterials are already available today.[5]

Nanomaterials offer the potential for many environmental benefits including remediation technologies, monitoring, and green production.[6] Little is known, however, about the potential human health and environmental impacts of nanotechnologies. Although the research addressing the health risks of exposure to nanomaterials is just beginning, a recent article in *Science* described some of the initial work conducted, noting that the studies suggest that nanomaterials "are not inherently benign and that they affect biological behaviors at the cellular, subcellular, and protein levels."[7] In addition, the article notes that "some nanoparticles readily travel throughout the body, deposit in target organs, penetrate cell membranes, lodge in mitochondria, and may trigger injurious responses."[8]

The development of nanotechnologies is still at an early stage. Citing Dr. Mihail Roco of the U.S. National Nanotechnology Institute, the *Science* article explains:

> The current era is that of passive nanostructures, materials designed to perform one task. The second phase will introduce active nanostructures for multitasking, for example, actuators, drug delivery devices, and sensors. The third generation is expected to emerge around 2010 and feature nanosystems with thousands of interacting components. . . . A few years after that, the first integrated nanosystems, functioning much like a mammalian cell with hierarchical systems within systems, are expected to evolve.[9]

In addition to providing background information on nanotechnology, including its myriad applications and potential risks, speakers during the morning session of the ELI Symposium discussed the status of efforts to develop nanotechnology EHS governance structures in Asia, Europe, and the United States and also addressed the potential role and influence of nanotechnology in developing countries.[10]

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 EHS governance

Environmental Law Institute (ELI) Senior Attorney and Director of ELI's Nanotechnology Initiative (http://www2.eli.org/research/nanotech.htm). The author would like to thank the Starr Foundation for its generous support of ELI's Symposium on "Nanotechnology Governance: Environmental Management from an International Perspective." The Symposium was cosponsored by the Vanderbilt Center for Environmental Management Studies (VCEMS). In addition, the author would like to thank the participants in the Symposium for their thoughtful dialogue. The views outlined in this Article should not be attributed to the Starr Foundation, VCEMS, or to any particular participant in the Symposium.

1. A list of participants and their affiliations is available on the Internet at http://www2.eli.org/pdf/research/nanotech/participantlist5-06.pdf.
2. Lynn L. Bergeson & Bethami Auerbach, *Reading the Small Print*, Envtl. F., Mar./Apr. 2004, at 30, 31.
3. Mihail C. Roco & William S. Bainbridge Eds., National Science Foundation, Societal Implications of Nanoscience and Nanotechnology 3 (2001), *available at* http://www.wtec.org/loyola/nano/societalimpact/nanosi.pdf.
4. Nanotechnology Workgroup, Science Policy Council, U.S. Envtl. Protection Agency, Nanotechnology White Paper—External Review Draft 1, 3 (2005), *available at* http://es.epa.gov/ncer/nano/publications/whitepaper12022005.pdf.
5. Project on Emerging Nanotechnologies, Woodrow Wilson Center for International Scholars, *A Nanotechnology Consumer Products Inventory*, http://www.nanotechproject.org/index.php?id=44 (last visited Nov. 1, 2006).
6. Ernie Hood, *Nanotechnology: Looking as We Leap*, 112 Envtl. Health Persp. A741, A741 (2004); Bergeson & Auerbach, *supra* note 2, at 32.
7. Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 Science 622, 622 (Feb. 3, 2006).
8. *Id.*
9. *Id.*
10. Several of these presentations are available on the Internet at http://www2.eli.org/research/events/nanotech5.19.06.htm.

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for nanotechnologies. Participants also discussed whether principles could be identified to develop governance structures and steps that could be taken toward harmonization. This Article provides an overview of the key themes that emerged during the breakout sessions and in the subsequent plenary session with respect to these questions. The views described in this Article should not be attributed to any particular participants, but instead represent the author's effort to capture key themes that emerged from the discussions.

A. The Corporate Environmental Management Benefits and Costs of International Coordination or Harmonization of EHS Governance Structures for Nanotechnologies

Participants identified both benefits and costs of harmonization of EHS governance structures for nanotechnologies. Participants emphasized *efficiency* as a key benefit. 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 participants, harmonization prevents "reinvention of the wheel" for both companies and governments with respect to governance structures. Participants also identified the *establishment of standards* as a principal benefit of harmonization. Specifically, harmonization can bring "laggards" up to the standards of leaders and avoid the "race-to-the-bottom," whereby countries in theory could compete for nanoindustries by establishing low EHS standards that are less costly for firms to achieve than higher standards.

Participants also identified costs associated with harmonization. Several participants emphasized that rigid forms of harmonization could limit the ability to learn through *trial and error*. Because so much is unknown at this juncture about the EHS 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. In addition, harmonized approaches may not be designed in a manner that reflects *local needs*, according to some breakout groups. It is likely, however, according to some ELI Symposium participants, that an approach could be identified that could be adapted over time to local needs and still achieve the benefits of harmonization.

B. Principles That Should Be Applied to Any Efforts to Harmonize or Coordinate EHS Governance Structures for Nanotechnologies

Participants identified numerous principles that should inform any efforts to move forward on harmonization of governance approaches. Several of the participants discussed whether *prioritization* should be a guiding principle, based not only on potential risks but also on the potential benefits of nanotechnology applications. Some participants 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. Some participants emphasized the challenges presented by any effort to prioritize, but also recognized the opportunity that could be "squandered" if a method of prioritization is not developed.

Participants also identified *public involvement and information dissemination* as key principles. For example, participants recognized the need to engage the public, but several noted that it is not entirely clear how this should be accomplished. For example, some participants discussed whether information should be presented, even though recipients may not be scientifically well educated in some cases. Participants 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. Similarly, discussions or dialogues were viewed as a way to understand stakeholder preconceptions and possibly provide information that could address related concerns.

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 "overpromising" 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 some participants. Similarly, by communicating correctly, participants said public trust can be generated. Some participants cited labeling as 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.

Transparency with respect to EHS information and data also was viewed as key because it "achieves accountability." Furthermore, once information is publicly available, companies may feel obligated to demonstrate that they are in compliance. In addition, transparency helps foster public involvement. Although participants emphasized the importance of transparency, they 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 for withholding certain information should be provided to the public. *Protection of proprietary information* was viewed as particularly important.

Several participants recognized the importance of retaining some degree of *sovereignty* to address local issues and

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for political and cultural reasons. Some examples of issues for which sovereignty may be important are liability approaches and risk management, which are referenced below.

Equity was another principle cited by several participants. They 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. Similarly, participants noted that it is important to "maximize the public good" and ensure "equity" or "access" for developing countries. This principle should be an "overlay" to any international governance measures, according to some participants.

Encouragement of *innovation* also was identified as a key principle and the corresponding need to avoid overregulation was emphasized, citing the importance of being "technologically dynamic." According to some participants, flexibility is needed, and the importance of performance standards, as opposed to prescriptive or command/control standards, should be considered.

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, according to participants, what the balance should be between the two systems. Similarly, some 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 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, through insurance at the front-end 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[11] and the Oil Pollution Act[12] were cited as possible models.

Many participants discussed principles of *risk management* and discussed their importance in the development of governance structures. 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. Some participants 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 approach is likely to differ substantially from any approach the United States would take to regulation of nanotech. Concern was expressed that technologies could be frozen with a premature application of precautionary principles. Some questioned whether risk management should be left to individual countries and excluded from any harmonization efforts, as opposed to risk assessment, for example, which may better lend itself to harmonization.

Several participants pointed to the concern, in a variety of ways, that in developing governance approaches it is important to consider *timeliness* and whether there is the "luxury of time." Some participants pointed out that if there is a catastrophic EHS problem with nanotechnologies, it may lead people to regulate "quickly and poorly." This concern should be accounted for as governments and private actors seek to develop governance structures, according to these participants. Participants also noted that although Europe, Japan, and the United States currently are at the same level of regulation, 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 was also recognized as a factor that should be considered in moving forward. It was 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.

Several participants cited the importance of *adequate funding* and noted that only minimal funds are currently allocated to development of governance frameworks relative to the rest of nanotech funding. Some participants viewed this lack of funding as an impediment to harmonization efforts.

Finally, some participants stated that a *life cycle-oriented* or holistic approach should be used in developing governance approaches. Such an approach could include, for example, research and development, manufacturing, and product use and disposal.

C. Next Steps to Address Nanotechnology Governance

As a threshold matter, several participants discussed whether *new or existing tools and approaches* should be used to develop EHS governance structures for nanotechnologies. They questioned whether the institutions and risk assessment methods that are needed to address EHS concerns are already in place. Some said that the similarities are greater than the differences between nanotech and other technologies, and that it is "not a question of starting at ground zero." Similarly, some participants said that existing laws should be used to regulate nanotech as it is better to in-

11. 42 U.S.C. §§6901-6992k, ELR STAT. RCRA §§1001-11011.

12. 33 U.S.C. §§2701-2761, ELR STAT. OPA §§1001-7001.

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terpret current laws than to try to develop a consensus on new legislation.

In contrast, some participants said 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, challenges preconceptions about how to regulate and that "rethinking of current governance structures is needed as the nano-revolution continues."

In this vein, several participants discussed whether nanotech is essentially evolutionary or revolutionary and represents a paradigm shift. Some participants suggested that current industrial applications could be viewed as evolutionary, while self-assembly, a process whereby materials assemble themselves from the bottom up, is more revolutionary because it represents "doing things completely differently." Similarly, it was noted that existing governance structures may work for today's passive structures and there is no need to "reinvent the wheel," but current approaches may not work later when the challenges will be "completely unfamiliar."

In terms of specific steps to be taken toward EHS governance of nanotechnologies, 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 many participants. 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 participants deemed the development of screening techniques important, with some noting that the "equivalent of the structure-activity relationships" is 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."

Several groups noted the importance of *disclosure* and the need to promote cross-border information sharing about nanotechnology EHS issues. This should include obtaining the benefits of what has been done inside firms, because companies have more experience and information than government and essentially have been self-regulating. Participants noted 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.

Some participants also discussed how to foster the *development of data and information* on environment, health, and safety. In discussing the need for screening techniques and information about fate and persistence in the environment, participants raised the question of how to allocate the burden of proof in terms of production of such information. Similarly, a participant asked whether government grants should require that data be gathered and presented on risk as well as health and safety of the work being performed.

Some participants discussed whether it would be possible to "jump over" national regulations and start at the international level to develop an *international framework* that would help multinationals 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. 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 United Nations Framework Convention on Climate Change 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. It was suggested that a process without substance or "teeth" could be established initially and over time the "substance" could be developed.

Several participants 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. It also may be possible to leverage a voluntary approach into legally binding standards, as is the case with the Equator Principles. It was explained that 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.

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. Some participants viewed the United Nations and similar entities as critical for disseminating government practices worldwide.

II. Conclusion

Although clearly preliminary in nature, the multistakeholder discussions outlined in this Article highlight the potential influence of harmonization, *vel non*, on EHS governance structures for nanotechnologies. The discussions represent a valuable effort to identify the costs and benefits from a corporate environmental management perspective of harmonization on an international level. The ELI Symposium dialogue also yielded numerous principles or themes that should be explored and identified some steps that could be taken in an effort to develop harmonized governance approaches.