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Securing the Promise of Nanotechnology

Is U.S. Environmental Law Up To the Job?

A Dialogue

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A Dialogue

Prepared by the

Environmental Law Institute
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EXECUTIVE SUMMARY

This report summarizes a May 25-26, 2005 Dialogue convened by the Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies and the Environmental Law Institute entitled "Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up To the Job?" The Dialogue brought together noted scientists, lawyers, and policymakers for purposes of examining how U.S. laws and regulations, as well as additional means of governance such as voluntary programs and industry standards, can be used effectively to address the environmental, health, and safety (EHS) implications of nanotechnologies. The forty invited participants included a diverse range of organizations, such as nanotechnology firms, environmental groups, research institutions, law firms and federal government agencies.

Determining whether environmental laws are "up to the job" is of paramount importance. Nanotechnology, the science and technology of controlling matter at the nanoscale, could significantly impact many industries – from computer science to pharmaceuticals. Many applications of nanotechnology have yet to become commercially available, but already hundreds of nanoproducts, or products that contain materials that are one nanometer (a billionth of a meter) to 100 nanometers in size, are in the marketplace. These nanoproducts range from paints to cell phones to digital cameras.

Little is known, however, about the risks associated with the manufacture, use, and disposal of nanoproducts and nanomaterials. Knowledge of the chemical properties of a substance when in bulk may not help predict how that substance will behave at the nanoscale. Recent studies indicate, however, that some nanomaterials can penetrate individual cells, deposit in organ systems, and trigger inflammatory responses.

This report highlights the information and ideas shared by Dialogue participants in presentations, question and answer sessions, and breakout groups. This paper does not attempt to outline all of the Dialogue discussions, but rather to summarize key points and ideas. Overall, the Dialogue highlighted the pressing need for scientific research, legal analyses, policy work, and ongoing stakeholder dialogue on how to develop a governance structure that will ensure that environmental, health, and safety risks posed by nanotechnologies are appropriately addressed. It is hoped that this Dialogue will serve as a starting point for additional discussions and research

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I. Background

The Woodrow Wilson International Center for Scholars (WWICS) Project on Emerging Nanotechnologies and the Environmental Law Institute (ELI) convened a two day Dialogue on May 25 and 26, 2005 entitled "Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up To the Job?" The Dialogue was designed to tap the expertise of noted scientists, lawyers, and policymakers for purposes of examining how U.S. laws and regulations, as well as additional means of governance such as voluntary programs and industry standards, can be used effectively to address the environmental, health, and safety (EHS) implications of nanotechnologies.

Forty invited participants attended the Dialogue, an intentionally small group to facilitate discussion. Participants included a diverse range of organizations and disciplines, such as nanotechnology firms, environmental groups, research institutions, law firms and federal government agencies. Several of the participants were asked to make presentations on specific topics. The Dialogue agenda is attached as Appendix A. Also attached as Appendix B are the powerpoint presentations of some, but not all, of the participants who formally addressed the Dialogue. Prior to the Dialogue, ELI circulated an Issue Paper, based in part on interviews with several Dialogue participants, that outlines key questions related to the legal framework for regulating nanotechnology in the U.S. This document is attached as Appendix C.

This report highlights the information and ideas shared by Dialogue participants in presentations, question and answer sessions, and breakout groups. The breakout groups were asked to address two principal issues in their sessions: the adequacy of the legal framework and governance alternatives. This paper does not attempt to outline all of the Dialogue discussions, but rather to summarize key points and ideas. The material outlined here should not be attributed to any particular participant. Although it is notable that there was little, if any, overt disagreement about many of the issues raised, the objective was not to reach consensus but rather to foster an open dialogue about various aspects of a nanotechnology governance structure.

By way of background, and as set out more fully in the paper prepared prior to the Dialogue (Appendix C) nanotechnology is the science and technology of controlling matter at the nanoscale.[1] Nanomaterials have

[1] Lynn L. Bergeson & Bethami Auerbach, *Reading the Small Print*, ENVTL. F., Mar./Apr. 2004 at 31.

at least one dimension of 100 nanometers or less.[2] A nanometer is a billionth of a meter -- approximately 1/100,000 the width of a human hair.[3] Manipulating material at the nanoscale can change the electronic, magnetic, mechanical, and other properties of a substance;[4] the smallest change in the structure of the nanoparticle can significantly impact the functional properties that are exhibited.[5] This emerging technology could significantly impact many industries – from computer science to pharmaceuticals.

Although there are many applications of nanotechnology that have yet to become commercially available, there are 80 products[6] that use nanomaterials already found in the marketplace today, including paints, glare-reducing coasting for eyeglasses and autos, sunscreens, sporting goods, cosmetics, stain-resistant clothing, and organic light emitting diodes used in laptop computers, cell phones, and digital cameras.[7] A recent survey found there are already 1645 nanotech companies operating in the United States,[8] but that number will likely increase substantially. About one half of these companies are small businesses. Lux Research, Inc. predicts that by 2014, products that incorporate nanotechnology will constitute 15% of global manufacturing output and will total $2.6 trillion.[9]

From an environmental perspective, nanomaterials offer both opportunities and challenges. The potential environmental benefits of nanotechnology include remediation, monitoring, and green production. But the greatest promise that nanotechnologies hold for the environment may be in the manner they could fundamentally change the way goods are manufactured. Traditional manufacturing requires large amounts of raw materials generating waste and hazardous byproducts in the process. Nanotechnologies allow for building from the bottom up using only those molecules that are needed for the product, thereby eliminating waste at the source.[10]

Even as nanotech products find their way to store shelves, little is known about the risks associated with their manufacture, use, and disposal. There are only minimal data at this juncture on the effects of exposure to nanomaterials on human health and the environment. Furthermore, the methods and protocols needed

[2] Ernie Hood, *Nanotechnology: Looking as We Leap*, 112 ENVTL. HEALTH PERSP. A741, A741 (2004).
[3] Bergeson, *supra* note 1 at 31.
[4] Hood, *supra* note 2 at A741 (*citing* Kristen Kulinowski, Executive Director for Education and Policy at Rice University Center for Biological and Environmental Nanotechnology).
[5] Richard A. Denison, Environmental Defense, *A Proposal to Increase Federal Funding of Nanotechnology Risk Research to at least $100 Million Annually* (Apr. 2005) at 4, http://www.environmentaldefense.org/documents/4442_100milquestionl.pdf
[6] U.S. Envtl. Prot. Agency, *Nanotechnology White Paper External Review Draft* (Dec. 2, 2005) at 3, http://www.epa.gov/osa/pdfs/EPA_nanotechnology_white_paper_external_review_draft_12-02-2005.pdf (last visited Jan. 25, 2006) (*citing* EmTech Research); The Associated Press, *Report Examines Safety of Nanotechnology* (Jan. 11, 2006), http://www.nytimes.com/aponline/science/AP-Nano-Safety.html?_r=1 (last visited Jan. 25, 2006) (*citing* Small Times Magazine).
[7] *See* Hood, *supra* note 2 at A741; Bergeson, *supra* note 1 at 30; Applications/Products, National Nanotechnology Initiative, *at* http://www.nano.gov/html/facts/appsprod.html (last visited May 19, 2005); Jane Macoubrie (Woodrow Wilson Center for International Scholars & Pew Charitable Trusts), Informed Public Perceptions of Nanotechnology and Trust in Government at 1, 2005, *at* http://www.wilsoncenter.org/news/docs/macoubriereport1.pdf.
[8] Small Times Magazine, March 2005.
[9] Lux Research, Inc., *Revenue from Nanotechnology-Enabled Products to Equal IT and Telecom by 2014, Exceed Biotech by 10 Times* (Oct. 25, 2004), http://www.luxresearchinc.com/press/RELEASE_SizingReport.pdf.
[10] Bergeson, *supra* note 1 at 34; Hood, *supra* note 2 at A745.

to detect, measure, and characterize nanomaterials are in many cases only in the process of being developed.[11] The sheer variety of applications, properties expressed, routes of exposure, and means of disposal makes it particularly challenging to identify, predict, and manage any risks posed by nanotechnologies. Knowledge of the chemical properties of a substance when in bulk may not help predict how that substance will behave at the nanoscale. For example, aluminum is inert when it takes the form of a soda can, but is highly explosive in nanoform.[12]

The research addressing the health risks of exposure to nanomaterials is just beginning. Recent studies indicate some nanomaterials can penetrate individual cells, deposit in organ systems, and trigger inflammatory responses. For example, studies indicate that inhaled nanoparticles accumulate in nasal passages, lungs, and brains of rats. Studies also indicate inflammation and damage in the brains of large mouth bass as a result of exposure to aqueous fullerenes.[13]

[11] Denison, *supra* note 5 at 4.
[12] *Id*.
[13] Hood, *supra* note 2 at A745.

II. Context

The Dialogue discussions helped define the framework within which any environmental, health, and safety governance structure for nanotechnology will be developed. Many participants emphasized the numerous and often unique regulatory challenges presented by nanotechnologies. The challenges cited most frequently included the rapid rate of nanotechnology development, the limited EHS-related data, the lack of nanotechnology-specific laws and regulations, and the influence of public perception. These are discussed below:

A. Pace of Development: Participants concurred that rapid development and deployment of nanotechnologies create substantial pressure to develop an appropriate governance structure in a timely manner. Some participants emphasized the large number of nanoproducts that have already entered commerce. Thus, workers and consumers are already being exposed to nanoproducts, and nanomaterials are already being emitted and discharged into the environment. Furthermore, nanoproduct disposal has started and is expected to grow markedly. Participants generally thought that the pressure to ensure that nanotechnologies are rolled out in a protective manner will increase, if the number of products and volumes of production grow as quickly as predicted. Some cited recent reports indicating that in 2005, the U.S. government invested $1.6 billion and U.S.-based corporations invested $1.7 billion in nanotechnology.

B. Data Issues: Numerous participants pointed out in a variety of ways the dearth of data on the environmental, health, and safety impacts of nanotechnologies. A participant emphasized that the "science is way behind," while others ventured to estimate that the science necessary for understanding EHS issues would not be available for ten to fifteen years. Participants also pointed out that nano-analytical methods for monitoring, cleanup and other activities are not yet readily available. Furthermore, according to some participants, little is known about nanomaterials in the workplace, as compared to other materials used in the workplace. Several pointed out that the lack of common nomenclature only increases the challenge.

Some participants noted that the limited data now available indicate that some nanomaterials present health or environmental hazards at least to some degree, and that such toxicity may occur through novel mechanisms that are hard to predict based on the behavior of conventional materials. Some also pointed out that the inherent characteristics of nanomaterials – their small size and proportionally greater surface area – tend to make nanomaterials more reactive, and thus potentially biologically active, than other materials.

One presenter provided the following information about the biological and environmental implications of nanotechnology, based on studies to date:

- Nanomaterials can access intracellular space in living organisms, which means they can be used in drug delivery devices or as diagnostic agents; however, it also means that nanomaterials can disrupt the function of cells and could prove to be toxic;

- Nanoparticles are active in biological environments; they can be highly reactive and promote free radicals, which in some cases may cause cell damage;
- Biological implications/hazard studies conducted to date indicate the following:
  - Single walled nanotubes instilled in lungs of rats and mice have some harmful effects, such as the agglomeration of tubes into clumps that can physically block the airways of rodents and also produce inflammatory effects;
  - Large mouth bass exposed to clusters of carbon fullerene molecules show evidence of oxidative damage to their brains;
  - Quantum dots are cytotoxic under certain circumstances;
  - Fullerenes are found in water-soluble forms – not as individual molecules, but as clusters or nanosized aggregates. Specifically, under certain circumstances individual buckeyballs can cluster together and on their surface there is a water-soluble form of the buckeyball, which is less toxic than dioxin but more toxic than paraquat. In this form, they did not act similar to their organic counterpart. Instead, they were more similar chemically to pesticides and substances that have high electrical activity.
    - It may be possible, however, to affect the cytotoxicity of these buckeyball clusters by adding small chemical groups to their surfaces, thereby tuning their toxicity to the point where a fully hydroxylated species results. Thus, there may be a strategy for environmental protection, provided it is possible to retain the desired features.

C. Lack of Nanotechnology-Specific Laws and Regulations: Participants emphasized the challenge presented by the absence of a nanotechnology-specific regulatory structure and, therefore, the need to evaluate and potentially adapt current regulatory vehicles and develop new voluntary approaches. The challenge is compounded, according to some participants, by the multitude of current and potential applications, which are spread throughout a wide range of industries. Similarly, nanotechnologies are under the jurisdiction of numerous federal and state agencies including the United States Environmental Protection Agency (EPA), state departments of environment, the Consumer Product Safety Commission, the Food and Drug Administration, the Department of Defense and others. Despite these challenges, several participants emphasized that it may be difficult to correct problems *post hoc* and, thus, the need to identify and address concerns as early as possible is paramount. A related theme throughout the Dialogue was that even if existing statutory authorities are adequate in theory to regulate effectively nanotechnologies; in practice, numerous barriers may exist to using those authorities. Specific examples are discussed below.

D. Importance of Public Perception: Several participants recognized the importance of public perception and the potential controversy that could surround nanotechnologies, thereby impeding their development and deployment. The public perception challenge is particularly notable, according to these participants, because of the rapid introduction of nanoproducts into the market and the limited data on their environmental, health, and safety effects.

III. Issues

Through presentations, breakout group discussions, and question and answer sessions, participants discussed a wide array of issues. Some of their observations are outlined in this section. Specific proposals about how to move forward in developing a governance structure and recommendations to policy makers or stakeholders are discussed in Section VI.

A. Overview of Regulatory Issues: The principal, although not only, question discussed by participants was whether U.S. laws and regulations are adequate for purposes of addressing the environmental, health, and safety implications of nanotechnologies. Multiple participants struck similar overarching themes with respect to the design or implementation of any regulatory structure. These include:

New Legislation Is Unlikely in the Near to Medium Term: Virtually all participants who addressed the topic agreed that the likelihood that new legislation would be enacted to regulate nanotechnologies in the near to medium term was remote and, therefore, the current focus should be on how to use existing laws effectively.

An Integrated Regulatory Approach is Needed: Participants recognized that nanomaterials present multimedia challenges, as they will be emitted into the air, discharged into the water, and disposed of on land. Although recognizing that the Toxic Substances Control Act (TSCA) is in many ways the most apt vehicle for regulating nanotechnologies, many participants emphasized that TSCA alone would not necessarily provide the optimal level of protection or address comprehensively the challenges presented by nanotechnologies. Instead, a multi-statute approach that relies on the principal environmental statutes being used in a coordinated manner may be preferable. Participants recognized, however, the challenges inherent in implementing such an approach, including the "stovepipe" nature of EPA's programs. For example, a participant explained that because state-implemented water, waste, and air programs are not generally aware of TSCA-related controls and cannot refine the controls or assure their implementation, use of a product-based program may make it difficult to ensure that any restrictions imposed ripple through to state programs. According to some participants, unless and until there is improved coordination among federal regulatory programs, nanotechnology controls may not be fully successful.

In a similar vein, a participant noted that nanotechnologies present cross-media trade-offs. For example, nanotechnologies present an environmental opportunity (e.g., as environmental sensors) but also can be viewed as creating environmental problems. The manner is which such trade-offs will be resolved is unclear, as a framework and process are lacking for resolving such inter-program disputes, according to one participant.

The Lack of Data Presents Challenges: As noted above, virtually all participants recognized the challenge of assessing and developing a regulatory approach, given the lack of available data on human

health and eco-toxicology. Some participants, however, emphasized the need to move forward in developing a regulatory approach despite current data gaps. Most participants recognized the inadequacy of federal funding for environmental, health, and safety research. Questions about the appropriate allocation between the public and private sectors for data development and funding were also noted.

Existing Volume-Based Limitations May Not Be Appropriate: Several participants noted that a number of existing regulatory programs contain volume-based exemptions. Some participants pointed out that these exemptions may not be appropriate in light of the physical/chemical properties of nanomaterials -- specifically, their greater relative surface area and hence reactivity.

A Facility-Based Focus May Have Advantages: Some participants addressed the potential value in egulating nanotechnologies at least in part at the facility level, rather than at the product level. TSCA was used as an example of a product-based approach while the Clean Air and Clean Water Acts take a facility-based approach that relies in large part on monitoring and reporting discharges and emissions.

Lifecycle Analysis Should Be a Component of the Governance Structure: Several participants emphasized the need to develop a governance structure that takes into account a full life cycle perspective that starts, for example, with basic research and development in universities and companies, includes proof of concept, manufacturing along the supply chain, and product use, and ends with disposal. According to these participants, using a lifecycle framework can help to assess how various statutory tools could apply at each stage in the lifecycle of nanotechnologies, as well as increasing the odds that an adequate regulatory system is applied.

Incentives Should Be Maintained and Provided: Several participants noted that although it is critical to address EHS concerns in the near term, this should be done in a manner that reduces uncertainty and creates incentives, rather than disincentives, for the development of nanotechnologies.

The Governance Structure Should Be Sensitive to Company Size: Some participants emphasized that in designing a governance structure it may be important to account for small and medium-sized nanotechnology companies and the special compliance challenges that such companies face, as compared to larger companies.

B. Specific Statutes: Participants discussed the major statutes that EPA implements, in order to assess their value as tools for regulating nanotechnologies.

1. Toxic Substances Control Act: The first panel discussion and considerable question and answer and breakout session time were devoted to an examination of whether TSCA would serve well as a means for regulating nanotechnologies. Participants' opinions varied as to whether TSCA could work effectively. Some believed that it would work if there was "the will" to use it, particularly if bolstered by economic drivers and

environmental concerns. In addition, some recognized that TSCA previously has been adapted to regulate risks associated with new technologies.

Several participants emphasized, however, the weak infrastructure and tools in place to ensure that TSCA-imposed controls are implemented. Furthermore, some participants voiced concern about the lean EPA TSCA program budget and warned against expecting too much. Participants also noted that TSCA is a data-driven statute and that the cost of collecting the data needed to use TSCA effectively represents a serious challenge. Other participants emphasized the lengthy duration of most TSCA rulemakings. The limitations with respect to using specific TSCA authorities were discussed:

Prohibitions and Limits on Chemicals: Section 6 provides EPA with authority to prohibit or limit the manufacture, import, processing, distribution in commerce, use, or disposal of a chemical if there is a "reasonable basis to conclude the chemical represents or will represent an unreasonable risk of injury to health or the environment." Participants identified several limitations on using this authority to regulate nanotechnologies including:

- To determine "unreasonable risk," EPA must consider risks and benefits, determine the availability of substitutes, assess the economic consequences of regulation of the chemical, and identify the least burdensome regulatory measure that provides adequate protection. These determinations must be made based on "substantial evidence" through a rulemaking process.
  - According to one participant, these determinations are difficult to make and judicial interpretation of Section 6 places a considerable burden on EPA with respect to making these showings.
  - For example, a participant explained that identifying and quantifying risks and benefits is particularly difficult because of the early stages of commercial development of nanotechnologies and the absence of a track record of performance.

New Chemicals/Pre-Manufacture Notice: Section 5 authorizes EPA to review activities associated with the manufacture, processing, use, distribution in commerce, and disposal of any new chemical substance before it enters commerce and requires Premanufacture Notice (PMN) reporting. Some exemptions to PMN requirements are self-executing and others require EPA approval. Participants highlighted several issues with respect to the use of this authority to regulate nanotechnologies:

- Whether particular nanomaterials should be considered "new chemicals" that require PMN is ambiguous, according to several participants. For example, certain nanomaterials could be considered listed on the TSCA Inventory and, therefore, existing chemicals, because they fall within a broader category of Inventory chemicals, such as carbon. Some participants strongly disagreed with that view and took the position that nanoparticles made up of substances already listed on the TSCA Inventory are developed precisely because of their novel properties,

which could differ significantly from those of the conventional materials. Therefore, such nanoparticles should be considered new chemicals, unless their chemical and physical properties are demonstrably identical to the conventional substance.

- Participants noted that the hazard-estimation models EPA often uses in PMN reviews (because of the lack of actual hazard data) are not designed for nanoscale materials and, therefore, questions are raised with respect to how EPA will review PMNs for nanomaterials. Although EPA could modify or override its models, it would still need to input physical-chemical data for nanomaterials in order to obtain useful output from most of the models, according to one participant.

- The basis for EPA's review and approval of a PMN for a new nanoscale substance was also described as unclear, particularly because the statute does not require test data to be routinely submitted. At least one participant stated that hazard and exposure data sufficient to characterize the risks should be included in PMN reviews, including toxicity, environmental fate and transport, physical/chemical, and use/exposure data. Participants also raised questions about the burden that should be placed on the submitter of a PMN with respect to a showing of "no unreasonable risk" of a nanoscale material.

  - Several participants recognized that certain exemptions to the PMN requirements, particularly those based on volume, might not be appropriate for nanomaterials, including the low volume, low release/low exposure substances, and polymer exemptions. Concerns about the appropriateness of some of the exemptions led at least one participant to state that nanomaterials should not be eligible for exemptions until a sufficient scientific basis is established to allow EPA to determine whether the scientific rationales underlying the current exemptions and thresholds are applicable to nanomaterials.

Significant New Use Rule (SNUR): Section 5 authorizes EPA to develop SNURs. This authority allows EPA to evaluate new uses to assess whether additional data are required (e.g., when certain production-volume thresholds are reached) or limitations on production, use, distribution, or disposal should be imposed. Once a SNUR is in place a Significant New Use Notice must be submitted by entities that intend to manufacture SNUR-designated chemicals in a manner that is restricted by the SNUR. Participants noted several drawbacks to using this authority to regulate nanotechnologies:

- What constitutes a "new use" is open to interpretation, according to some participants. For example, a nanoscale material could be a "new use" of an existing chemical or a "new chemical," given that nanoscale materials may or may not reflect the hazard and exposure characteristics of a chemical already listed on the Inventory.

- In addition to concerns about how to define what constitutes a new use, a participant pointed out that when Section 5 is used as a regulatory tool, the rulemaking process requires Office of Management and Budget approval, involves considerable time and resources, and has uncertain results.

New Data Development: Section 4(a) authorizes EPA to require manufacturers and or processors of chemical substances to develop new data on health and environmental effects that are needed to assess potential risk from chemicals. EPA must make certain statutory findings to utilize this authority. One participant noted impediments to using this TSCA authority for nanotechnologies including:

- Promulgation of a Section 4 test rule can take many years;
- The data needed to make the showing required in some cases that the chemical may present an unreasonable risk of injury may not be available in the nanotechnology context;
- In some cases a showing is required based on production volume, a metric that may not be useful or relevant for purposes of applying Section 4 to nanomaterials;
- Section 4 test authority cannot be used if a volume exemption applies, potentially excluding many manufacturers of nanoscale materials; and
- EPA decisions under Section 4 are often litigated, further delaying implementation of any requirements imposed by EPA.

Exporter Notice Requirements: A participant explained that Section 12(b) requires exporters to notify EPA in writing if they export, or intend to export, chemical substances or mixtures that are subject to certain TSCA rules or orders. EPA then notifies foreign governments of hazards that may be associated with a chemical substance or mixture, absent requirements in the importing country. This participant identified a number of limitations with respect to using this authority. For example, for a TSCA Section 12(b) export notification to apply, there must be a final Section 4 rule or a rule proposed or final under Section 5, 6, or 7. This requirement limits the use of Section 12(b) authority, because these underlying rules are not in place for nanomaterials.

2. Clean Water Act (CWA) and Clean Air Act (CAA): A few participants addressed the potential role of the Clean Water and Clean Air Acts in regulating nanotechnologies. One participant suggested that EPA could issue guidance under these laws to require permitting authorities to tighten up controls for nanomaterials. Another participant observed that, unlike TSCA, the Clean Water and Clean Air Acts have strong implementation infrastructures. In addition, as noted above and discussed below in more detail, a participant suggested that facility-based laws such as the Clean Water and Clean Air Act may be effective for regulating nanotechnologies, particularly if an information disclosure approach is used.

Nevertheless, numerous points were made about the limitations inherent is using the Acts to regulate nanotechnologies, such as neither Act requires that any special attention be paid to nanotechnologies. As opined by a participant, the Clean Air and Clean Water Acts, at least as currently interpreted, are "not destined" to play a large part in the regulation of nanotechnology, particularly in the near term, because to apply the statutes to nanotechnologies EPA would be required to make data-intensive, and probably controversial decisions.

Furthermore, participants noted that the Acts rely heavily on monitoring, unlike TSCA. This raises important questions with respect to nanotechnologies, according to a participant, because new protocols will be needed for nanomaterials. It was also pointed out that even after protocols are developed, extensive monitoring may not be affordable.

A participant commented on the principal authorities that could be used to regulate nanotechnologies:

> ***National Ambient Air Quality Standards/Fine Particulates***: Nanoparticles released into the air would be regulated under the fine particle standards of the Clean Air Act. According to this participant, however, nanoparticles are likely to be only a small fraction of the total inventory of particles emitted into the air and all particles are regulated alike under the statute. Although, in theory, EPA could regulate nanoparticles specifically, in order to do so, EPA would be required to show under the statute that nanoparticles are emitted from numerous or diverse mobile or stationary sources. It is unlikely, in this participant's view, that nanoparticles would meet this requirement.
>
> ***Hazardous Air Pollutants***: Nanomaterials are not currently listed as hazardous air pollutants (HAPs), but EPA could add them to the list after making a discretionary decision that considers emissions, ambient concentrations, bioaccumulation, or deposition and finding that one of these factors is known to cause or may be reasonably anticipated to cause adverse health or environmental effects. Because ambient concentrations are a factor in making the decision to add a pollutant to list, the conditions for listing nanoparticles may not be present if releases are "kept down," according to the participant. In addition, this participant noted that the "truly meaningful" HAPs control requirements apply only to sources that emit certain volumes of pollutants. This test is not an appropriate metric for nano-releases; however, in order to lower the volumetric threshold, EPA would be required to make certain discretionary findings with respect to, for example, potency and potential for bioaccumulation.

Toxic Water Pollutants: According to a participant, one of the strongest options would be to list certain nanomaterials as toxic water pollutants to enable EPA to impose tight technological controls. This would require EPA to make determinations as to toxicity, persistence, degradability, and additional factors. Such determinations may be difficult to make, due to the limited data available and the time and resources required.

3. Resource Conservation and Recovery Act (RCRA): Two participants made presentations on RCRA, the law that provides EPA the authority to regulate the generation, transportation, treatment, storage, and disposal of hazardous waste, and how it may apply to nanomaterials. They offered the following observations:

RCRA Jurisdiction: RCRA requirements only apply to nanomaterial if it meets the definition of a "solid waste" or a "hazardous waste."

- *Solid Waste*: According to a participant, the definition of solid waste is very complex, subject to court challenges, and is being revised. Furthermore, several exemptions exist, including for materials discharged under a Clean Water Act permit. Therefore, if a nanomanufacturing facility is regulated under the Clean Water Act, wastewater discharges that contain nanomaterials may not be covered under RCRA. In addition, recycling/reuse exemptions under RCRA could apply in the nanotech context. According to a participant, it is likely that many nanoscale materials may be useable in a specific context and then once used, or if not manufactured up to specifications, could be reused in a different fashion. It will need to be determined, however, precisely how the RCRA reuse exemptions would apply to nanoscale materials.

- *Hazardous Waste*: For a solid waste that includes nanomaterials to constitute a hazardous waste, it must be either a "listed" or "characteristic" hazardous waste.

  - *Characteristic Waste*: Under RCRA, a waste is deemed to exhibit a characteristic, and thus to qualify as a hazardous waste, if it meets one of four criteria specifically defined by the regulations: toxicity, corrosivity, reactivity, and ignitability. Some aspects of these tests may be germane to nanomaterials, according to a participant, because the tests look at physical characteristics and are not necessarily influenced by the size of the waste particles. More specifically, another participant explained that ignitability should not be an issue with nanomaterials because in order to have a low flash point a vapor is usually needed and vapors are comprised of smaller particulates than nanomaterials. With respect to reactivity and corrosivity, this participant noted that some nanomaterials may qualify but most would not. Finally, if a toxic metal is built into the structure then a nanomaterial will likely be considered to meet the toxicity requirement, according to this participant. It was noted by one participant, however, that the toxicity characteristic may be more problematic to apply to nanomaterials, because of built-in assumptions that may

not apply easily to nanomaterials, such as assumptions about the manner is which waste is disposed.

- *Listed Waste*: A solid waste can also become hazardous if EPA expressly includes that waste on a list of hazardous wastes. To date, EPA has designated several hundred waste streams as "listed" hazardous wastes, some relatively broad (e.g., spent solvents) and some much narrower (e.g., wastes from a very specific manufacturing process). Because EPA has not yet listed nanoscale materials as hazardous wastes, this approach may lead to the classification of some nanoscale wastes as hazardous even if they lack any of the dangers that caused EPA to list the original wastes in its non-nanoscale form. EPA hazardous waste listings, however, may still apply to other wastes generated during the manufacturing of nanoscale materials. For example, a manufacturer may use a specific solvent to manufacture carbon nanotubes, and that spent solvent containing nanotubes may constitute listed F006 hazardous waste upon disposal. Furthermore, if such a listed hazardous waste is mixed with a nonhazardous waste, the entire mixture is presumed to be the listed, hazardous waste. Finally, under the "contained in" principle, if hazardous waste is mixed with a medium such as soil, the soil is deemed to be hazardous waste.

  - *Hypothetical*: To emphasize the challenge presented by nanomaterials for purposes of RCRA regulation, a participant provided the example of a toxin-containing buckyball that is used for drug or pest control purposes. The participant queried whether a buckyball with a listed chemical inside would be considered a hazardous waste. The participant explained, for example, that EPA could decide it constitutes a tiny container of a toxic chemical or in the alternative that it is not a container because of quantum reactions between the shell and material inside. The hypothetical buckyball could also be considered a delivery device. Furthermore, if there is less than one inch of material in a container, the container is considered empty and not covered by RCRA, provided all normal means are used to empty the container. It is unclear how this principle would apply with respect to buckyballs or other nanomaterials.

- *Applicability*: RCRA applies to generators, transporters, and to operators of treatment, storage and disposal facilities. Issues with respect to generators in the nanowaste context include the suitability of applying existing small quantity generator and satellite accumulation exemptions to nanomaterial production, according to a participant.

- *Exemptions*: A participant raised several additional issues related to how RCRA exemptions may apply in the nanotechnology context including, for example, exemptions for household hazardous wastes, co-products and by-products, and waste from oil/gas exploration and production.

Substantive Requirements: Once a nanoscale material is deemed hazardous, it must meet RCRA treatment standards for disposal, including land disposal treatment standards. It will be necessary to determine the treatment standards that should be used for disposing of nanoscale compounds and whether current regulations make sense as applied to nanoscale materials, according to a participant. Furthermore, this participant emphasized that state standards may vary from federal standards in states where the program has been delegated. To complicate matters, nanomaterials themselves may be used by facilities to treat hazardous wastes.

Additional RCRA Authorities: It was observed that there are additional authorities in the statute, such as the authority in Section 7003, that allow EPA to take action when a solid or hazardous waste contributes to an imminent and substantial endangerment to health or the environment. EPA's omnibus authority to impose permit conditions that are determined necessary to protect human health and the environment could also apply to the regulation of nanomaterials. Another participant noted that while there is broad statutory authority to regulate materials as hazardous under RCRA, if it can be proven that they pose a risk, it takes a long time to promulgate a RCRA rule even in simpler types of situations.

4. Comprehensive Environmental Response, Compensation and Liability Act (CERCLA or Superfund law): The potential use of the Superfund law to regulate nanomaterials was addressed by at least one participant. The statute provides EPA the authority to address releases or threatened releases of hazardous substances. The Superfund statute defines "hazardous substances" to include RCRA hazardous wastes, certain substances regulated under the Clean Water Act, hazardous air pollutants under the Clean Air Act, and certain chemical substances or mixtures regulated under the TSCA. Some issues and questions associated with the use of CERCLA, according to this participant, include:

Hazardous Substances: A key question is the extent to which nanomaterials constitute hazardous substances under Superfund. If nanomaterial is a pollutant (versus a hazardous substance), it can still be subject to government response authorities, but the government's ability to recover costs from responsible parties may be limited.

"Releases" of Hazardous Substances: CERCLA generally imposes liability for responses costs when there is a release of or a threatened release of a hazardous substance. CERCLA exempts federally-permitted releases from this liability regime, but it seems likely that that at least some releases of nanomaterials will not be covered by federal permits.

Divisibility: CERCLA imposes joint and several liability, unless the harms caused are divisible. In the case of nanomaterials, it may be possible to "fingerprint" chemicals, thereby allowing for the divisibility of the harm or apportionment of the response costs.

Release Reporting: CERCLA imposes release reporting requirements for releases of hazardous substances in excess of reportable quantities. Because releases of small quantities of nanomaterials

may cause significant environmental effects, the current reportable quantity framework may need revision as it applies to nanomaterials.

Environmental Remediation: Nanomaterials have potential uses for environmental remediation. For example, nanoscale iron could be used for groundwater remediation. It is precisely the dispersive use of nanomaterials into the environment, however, that is of concern to many stakeholders. For this reason, in part, it is very difficult to establish test projects at the state level.

C. Voluntary Initiatives and Standards: Participants discussed the potential use and value of public and private sector voluntary initiatives and standards.

1. Private Sector Standards: It was emphasized by various participants that there is a strong need for consensus-based standards with respect to terminology, metrology, product quality, intellectual property, and environmental health and safety. A participant explained that the following efforts are underway:

- ASTM International is developing standards through six committees. The Terminology and Nomenclature Committees are likely to be the first to act, followed by the Characterization Committee. ASTM has emerged as the leader on developing standards, but other organizations will take a role in cooperation with ASTM.

- In addition, the American National Standards Institute (ANSI) has created a Nanotech Standards Panel to coordinate U.S. activity and the International Organization for Standardization (ISO) has formed a new technical committee on nanotech (TC 229) to develop nanotechnology standards. These efforts will be harmonized as appropriate with ASTM's efforts.

2. Private Sector Voluntary Initiatives: A participant stated that, as a threshold matter, industry must acknowledge that we cannot assume that the hazards associated with a nanomaterial can be inferred from the hazards associated with its bulk counterpart.

Recommended Actions: Participants recommended that companies develop voluntary best practices, which could include, for example, steps to:

- Promote product stewardship "along the value chain;"
- Call for proactive risk identification and management;
- Advance understanding of risks;
- Influence supply chain behavior;
- Develop and demonstrate a standard of care, which could include risk identification, risk management, transparency and accountability, and feedback mechanisms -- all from a full life cycle perspective; and
- Engage a wide range of stakeholders.

Research Funding: A participant emphasized the need for companies to support federal investment in environmental health and safety research.

- Labels: Effective labels should be an important component of industry efforts, according to some participants. A breakout group explored the possibility of developing a "nanosafe" or voluntary nanosafe labeling initiative, whereby meeting certain tests would enable the use of such labels; analysis of the feasibility of such an approach would be needed.

***Current Industry Efforts*:** A participant discussed the work of an industry group, the American Chemistry Council CHEMSTAR panel, which is comprised of over 15 companies. The Panel has agreed upon several points, including support for:

- Multi-stakeholder dialogue on responsible development and regulation of nanotechnology;
- Development of a broadly accepted means to collect existing and future health and environmental toxicity, workplace, and environmental exposure data for nanomaterials;
- Development of guidelines and procedures for tiered testing and evaluation of new nanomaterials;
- Ongoing efforts to harmonize terminology, protocols for testing and regulation internationally;
- The need for increased government funding for EHS research methods development; and
- Promoting product stewardship along the value chain.

According to the same participant, as an outgrowth of the National Nanotechnology Initiative, the chemical industry Consultative Board for Advancing Nanotechnology has established an EHS workgroup on research priorities. The Board has:

- Compiled a list of research and evaluation needs in several areas, include measurement and detection of nanomaterials, worker protection and industrial hygiene, and toxicity of nanomaterials; and
- Identified as priorities the development of the following: a toxicity test strategy for particulates, aquatic toxicity test methods, exposure monitoring, and methodologies to establish safe exposure levels.

3. Public Sector Voluntary Initiatives: Participants discussed briefly the then recently announced public meeting to be held by EPA on June 23, 2005 (70 Fed. Reg. 24574). The purpose of the meeting was to obtain stakeholder views on the purpose and scope of a potential voluntary pilot program for nanoscale materials that are existing chemical substances. According to EPA in its notice, issues associated with a potential voluntary pilot program include:

- Scope and purpose of the program;

- Kinds of information relevant to the evaluation of potential risks from exposure to nanoscale materials;
- Chemical characterization and nomenclature of nanoscale materials for regulatory purposes; and
- Identification of interested stakeholders.

Additional issues relate to the feasibility and value of such a program; its scope and design; information that would be useful in the evaluation of effects on human health and the environment resulting from exposure; size, dimensions and shapes of substances that should be considered nanoscale materials; types of information that would be useful to a voluntary program; and manufacturing processes for nanoscale materials as they might relate to product identities.

EPA's Science Policy Council Nanotechnology Framework Committee is considering broader, cross-program implications of nanotechnology. The Committee is charged with developing a framework document that addresses all aspects of nanotechnology that are relevant to EPA, such as science and research needs, regulatory and policy implications, statutory authorities, and communication approaches. A final product is anticipated from the Committee in January 2006.

D. Data Development: Numerous participants emphasized the importance of developing data on nanomaterials, ranging from health and environmental toxicity data to data on workplace exposure. Several participants emphasized that the properties of materials can be different at the nanoscale. Their relatively large surface area can make materials more chemically reactive and quantum effects start to dominate behavior at the nanoscale. As a participant opined, unlike conventionally produced materials, the novel character of nanomaterials and dearth of information and experience relevant to assessing their potential risks argues for an "information–driven" approach. Another participant said that the scientific basis of toxicology and epidemiology (exposure and risk evaluation) is "way behind," inherently slow, and long-term effects are subject to a long latency period. Another participant noted that exposure assessment is needed to provide a framework for analyzing, for example, how nanoparticles will interact, their fate, transport, transformation, and bactericidal capability. In addition, according to this participant, hypotheses should be developed for nanosize materials, as some generalized understandings about nanomaterials are needed, but this may take many years.

Another participant noted that it is important not to generalize risks with respect to nanomaterials for numerous reasons:

- Variety: A wide range of nanoscale materials exist;
- Coatings: Coatings can influence toxicity and it is important to understand, for example, their fate and transport;
- Contaminants: Although manufacturers strive for pure materials, contaminants may still be present and may convey toxicity;

- Translocation: Nanoparticles do not stay where deposited and can translocate. For example, particulates below 10 nanometers in size when deposited in the nasal pharynx can move into the brain;
- Dose Response: Nanoscale materials are unique with respect to dose response. Nanomaterials require rethinking of risk assessment and how to measure workplace standards in ways that make sense.
- Food Chain Threats: There is concern about the impacts of nanomaterials on "filter feeders," microscopic organisms that form the basis of the food chain in many acquatic ecosystems. These organisms consume materials in the nano size range, and may not be able to separate engineered nanoparticulates from their food, potentially impairing their ability to survive and reproduce.

E. Worker Safety: Numerous participants emphasized that workers in nanomanufacturing facilities may be currently exposed to nanomaterials. These employees are in a wide range of industries, including foods, construction, defense, energy production, remediation, and electronics. The following points were made by a participant:

- With the explosive growth that is anticipated in the commercialization of nanoproducts, there will be increases in workforce exposure; the situation is exacerbated because nanoproducts are produced in forms that are unseen and in workplaces that look very clean;
- Relatively little is known about nanomaterials compared to other materials that are encountered in the workplace; the scientific foundation that typically would give rise to appropriate workplace controls and inform policy and regulations is currently incomplete;
- Currently, most of the workforce is in research and development operations, typically at universities or in small enterprises. This will shift toward piloting and ramping-up of operations, but full-scale production is projected to take years. Implications vary for each type of workplace setting. For example, small university labs may not have a long history of industrial hygiene and environmental controls and, therefore, exposure may decrease with the ramp up, as automated procedures and streamlined processes are put in place.
- Nanotechnologies are widely used and, therefore, it is necessary to think creatively about potential exposures in industries that range from health care to defense;
- Employees will be needed in diverse work areas ranging from manufacturing to transport to waste streams -- the specific exposure and health issues will differ in each setting;
- The current workforce is on the front line and probably will have the greatest exposures, due in part to the potential for lack of appropriate controls; and
- Mass production is just beginning but there is already concern about upsets, exposure beyond immediate manufacturing sites, and large volumes of waste that will have to be handled.

Several participants noted the need to take precautionary measures because so little is known about the health impacts of nanomaterials on workers. Some specific recommendations are outlined below in the following section and include training workers in personal protective equipment and hygiene, based on an

assumption of toxicity until shown otherwise, and conducting exposure monitoring for both workers and workplaces.

F. Public Perception and Involvement: Several participants discussed issues related to public perception and public involvement in the development and regulation of nanotechnologies. With respect to public perception, several participants noted the importance of communicating the risks of and safety information about nanotechnologies. Some participants emphasized that lack of information could lead to misperceptions and unfounded fears, and ultimately opposition to nanotechnology development. An interview project conducted by the Woodrow Wilson International Center for Scholars that was presented during the Dialogue indicates that the general public knows very little about nanotechnologies.[14] A participant noted that consumer acceptance is a critical factor. For example, over 50 percent of food in the U.S contains some form of genetically modified substance, but Europe just approved the first genetically modified food. Several factors, including the way in which the countries approach regulation, influenced public acceptance of genetically modified foods, according to this participant.

Several participants emphasized the importance of involving a wide range of stakeholders in any stakeholder dialogue or process related to environmental, health, and safety issues associated with nanotechnologies. These points are discussed in more detail below.

[14] http://www.wilsoncenter.org/news/docs/macoubriereport1.pdf

IV. The Path Forward

During the course of the panel discussions and breakout sessions, participants made numerous points and raised many issues with respect to the steps that should be taken to move forward on developing a governance structure for nanotechnologies. These points addressed both long-term and interim approaches, as well as public involvement.

A. Long-Term Considerations and Approaches: In various ways, observations offered during the Dialogue suggest a multi-pronged approach to addressing environmental, health, and safety concerns that would include regulatory and voluntary programs under existing environmental statutes, corporate stewardship, tort liability, state legislation, voluntary standards, disclosure, liability insurance, and international measures. Participants offered the following observations:

1. Develop Data: Data development was viewed as a principal goal by many of the participants, particularly in the near term. The sense among these participants was that the more information on eco-toxicity and health impacts is developed, the more effective regulatory oversight and stewardship will be in the long term. For example, a participant said that effective regulation of nanotechnologies will not be accomplished until data are available, as this "is all data driven." Another participant noted that research on risk management is needed in addition to a focus on risk assessment. As noted above, several participants emphasized the importance of taking a lifecycle approach to addressing EHS concerns that would examine, for example, research and development, manufacturing, and end-of-life disposal.

During the course of the meeting, participants made numerous suggestions with respect to data and information development some of which are similar or overlapping. For example, participants addressed the need for the following:

- Procedures and guidelines for tiered testing and evaluation of new nanomaterials;
- A simple test to use for purposes of evaluation by an independent entity;
- Internationally harmonized protocols for testing;
- A testing regimen;
- Screening data;
- Solubility data;
- Monitoring data;
- Bioavailability data;
- Basic physical properties data;
- An environmental verification program;
- Long term studies (because nanomaterials may be very durable and assumptions will be based on current markets and amounts, but use of nanoproducts will grow, as has the use of cars, for example);

- A set of research priorities, which should include best dose metrics for particulates, aquatic toxicity test methods, exposure monitors, methodologies to establish safe exposure levels; and
- A publicly available database that could include best practices for occupational health, in addition to toxicology data.

2. Focus on Disclosure: Numerous participants discussed disclosure as a potential tool for addressing nanotechnology EHS concerns. For example, a participant emphasized the need for disclosure coupled with context provided for the data and information disclosed. Some participants warned, however, that it should not be assumed that all information can be made transparent, recognizing the need to respect confidential and proprietary information. Some of these impediments, however, could be addressed by identifying areas of consensus in identifying information that is needed short of requiring disclosure of trade secrets, as the two categories do not always overlap, according to a participant.

One participant suggested a disclosure approach that focuses on reporting by individual facilities. Releases from facilities that exceed certain levels could be identified and publicized in an annual report. To be removed from the list, a facility would have to reduce its release levels or make some type of showing that its releases do not pose a health threat. The participant suggested that the approach could set up an overall framework, be far less resource intensive than substantive regulation, and encourage self-regulation.

This participant further pointed out that an adaptive management approach could be used to develop controls as the data develop, and the data could be develop based on the likely controls. Such an adaptive management approach, however, could be difficult to effectuate in the current system, as it requires that judgments be made about what is "bad enough" to be regulated, which is very difficult to do, particularly with the database changing constantly, according to this participant.

Furthermore, such a disclosure program could be viewed as unfairly stigmatizing certain materials. To address some of these concerns, a participant suggested that the report would not indicate that a chemical is "bad" just that it may be of concern. Furthermore, the report could be peer reviewed prior to or post publication. In addition, some lag time between informing a plant it will be listed and the actual listing could afford the plant time to respond. Finally, it was suggested that a public comment period could also be incorporated into such a program.

3. Catalogue Information and Initiatives: One of the breakout groups recommended that an overview of all ongoing efforts on environmental, health, and safety should be conducted -- both in the public and private sectors -- so as to avoid duplication moving forward. The group also recommended compiling the basic facts about nanotechnologies, such as the number of products in the market and the number of nanotechnology procedures.

4. Review and Utilize Current Authorities: As noted, participants agreed that enactment of new nanotechnology legislation related to EHS is unlikely in the near to medium term. A participant emphasized

that many of the ideas proposed during the Dialogue and the problems identified with the use of current programs to regulate nanotechnologies could be addressed using EPA's existing statutory authority.

***Regulatory Review*:** Some participants recommended that EPA conduct a review of its regulations for purposes of determining how to revise them on a consistent basis to make them more amenable to addressing issues raised by the nano-revolution. This participant noted that using current authorities helps identify problems to repair and build support for legislative changes, if it is determined that EPA lacks the authority to regulate effectively nanotechnologies.

***Coordination Among Regulatory Bodies*:** Some participants noted the need for the federal agencies with jurisdiction over nanotechnologies, such as the EPA, the Food and Drug Administration, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission, to coordinate their efforts and work together effectively. Another participant emphasized that the states will play an important role in any governance structure for nanotechnologies because they implement air, water, and waste laws.

5. Institute Voluntary Programs: Participants addressed voluntary programs from a variety of perspectives. One breakout group discussed a possible voluntary program that would be a partnership for the responsible development of nanotechnologies. The program would be lifecycle in scope, include diverse stakeholders, and include outreach goals. Such a program might include incentives to small and medium enterprises and be coupled with a governance/regulatory portion, whereby participation in the program offers benefits but nonparticipation would result in more regulation. This breakout group said that the "time is now" for a voluntary initiative and that it should be auditable, transparent, and data driven.

6. Address the Funding Gap: Several participants recognized the significant funding gap with respect to environmental, health, and safety research. Some participants indicated that the federal government should allocate more of its nanotechnology dollars to environmental, health, and safety concerns. Some participants noted, however, the need to move forward, regardless of whether funding is available at this time.

7. Coordinate at the International Level: Several participants recommended an effort that would determine research gaps at the international level and a strategy for filling those gaps. It was also noted that there should be a place in the U.S. federal government or an international body for gathering and spotlighting data. It was emphasized that international consistency and harmonization are important with respect to protocols and regulations or a secure business climate is not provided. It was noted, however, that there is no obvious vehicle for this and any effort will need to include countries, such as China, that will be players.

8. Take Into Account Private Law Suits: A few participants talked about the important role that toxic tort liability could play in the governance structure for nanotechnologies. One participant quipped that tort liability could be calculated by taking regulatory liability and adding two zeros to account for the cost of a

toxic tort suit coupled with the loss of public credibility. This participant said companies should disclose and be transparent, as a means of reducing their potential toxic tort liabilities.

B. Interim Measures: Many participants addressed the tension between the dearth of data related to environmental, health, and safety impacts of nanotechnologies and the need to take action in the short term. The problem is intensified by the lack of funding for data development, according to some participants. This is about "managing uncertainty," according to a participant, who emphasized the need to allow for people to manage information and provide context rather than wait and do nothing for 15 years. The same participant acknowledged the likelihood of unanticipated consequences, but said the issue for industry is what conditions should be in place when the first public scare occurs and how the system can be as adaptable as possible.

To meet this challenge, the participant suggested "working by analogy." This participant explained that similar to the approach taken in the TSCA program, nanochemicals could be analogized to similar chemicals and treated similarly for purposes of regulation. This is a challenge, however, with nanomaterials because they have novel properties. Therefore, it will be necessary to look at particle size, shape, and other factors to determine the categories of concern, according this participant. Similarly, this participant noted that a chemical-by-chemical review is not feasible and that some information and data are needed that will enable general conclusions about safety and risks. The participant emphasized the value of articulating to people outside the regulatory process what is of concern and why people should care about and participate in any program that is adopted.

In a similar vein, a participant referred to the "anchor and adjust" heuristic whereby, similar to the path taken with biotechnology regulation, actions are "anchored" or tied to an approach taken in a similar context and then "adjusted" or modified to the current situation. In the biotechnology context, according to this participant, this approach was implemented in stages by first imposing a moratorium until regulations were in place. The National Academy of Sciences was then asked to develop screening or prioritization techniques. The NAS recommended the use of proxies such as familiarity with the substance in question. Thus, if the material already is found in nature it is considered of less concern. The next step in the biotech regulatory process was to interpret existing laws in a manner that allowed for some actions to be taken and for administrative, versus legislative, remedies to be exhausted to the greatest extent possible.

During the course of the Dialogue, participants made numerous recommendations for immediate or near-term steps that could be taken by government, researchers, industry, or environmental and community groups, as appropriate. These include:

- Reduce exposure to nanomaterials;
- Restrict dispersive uses until hazard, exposure, and fate data are available;
- Prioritize substances of concern;

- Identify pragmatic approaches, such as classification of substances and performance-based controls from models;
- Develop engineering controls for exposure;
- Conduct exposure monitoring – for both workers and workplaces;
- Conduct health surveillance;
- Assess and disclose lifecycle risks in advance of commercialization;
- Conduct release and environmental monitoring;
- Train workers in personal protective equipment and hygiene and assume toxicity until shown otherwise;
- Treat wastes as hazardous materials;
- Develop some type of fast screens for determining problems; and
- Engage a wide range of stakeholders including, not only environmental organizations, but community, consumer, health, and labor groups.

C. Stakeholder Involvement: The path forward on stakeholder involvement was discussed in a variety of ways by participants, but virtually all agreed on the importance of stakeholder engagement. Some supported a multi-stakeholder dialogue. A participant also mentioned a regulatory negotiation. Several emphasized the need to cast the net widely in bringing stakeholders into the process, as many key nanotechnology players are not typically at the table for federal environmental policy discussions, such as startups and non-U.S. manufacturers. Thus, according to these participants, a thorough identification of stakeholders is needed as well as encouragement of those stakeholders to participate. According to a participant, real-life scenarios drive policy and if key players are missing from the policy development discussions, it can lead to a distortion of policy. Stakeholder involvement will also provide credibility and stature to any outputs, according to some participants. Because of the importance of public perception, discussed above, it was recommended that some type of strategic plan be developed with respect to addressing public perceptions of nanotechnology.

V. Conclusion

The Dialogue yielded a plethora of ideas with respect to the issues and challenges presented in developing a governance structure for addressing environmental, health, and safety concerns in the nanotechnology context. Dialogue participants also presented myriad suggestions for possible paths forward. It is hoped that this Dialogue helped frame some of the key issues for purposes of continuing discussions on this important and timely topic.

APPENDIX A

DIALOGUE AGENDA

SECURING THE PROMISE OF NANOTECHNOLOGY: IS U.S. ENVIRONMENTAL LAW UP TO THE JOB?

A Dialogue Sponsored by the
Environmental Law Institute and the
Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies

Choate Conference Room
Carnegie Endowment for International Peace
1779 Massachusetts Avenue, NW, Washington, DC
May 25 and 26, 2005

WEDNESDAY, May 25, 2005

1:00 **Welcome and Introductions**

David Rejeski, Executive Director, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars

1:10 **Perspectives on Benefits and Risks of Nanotechnology Applications**

Larry Andrews, Ph.D., Chair, American Chemistry Council, Nanotechnology Panel

Kenneth A. Mundt, Ph.D., ENVIRON International Corporation

Kristen Kulinowski, Ph.D., Center for Biological and Environmental Nanotechnology and International Council on Nanotechnology, Rice University; and Chair of ASTM Subcommittee E56.06 Nanotechnology Risk Management and Product Stewardship

John Balbus, M.D., MPH, Environmental Defense

2:25 **Applicability of U.S. Environmental Laws to Assess, Prevent and Control Risks of Nanotechnology**

Toxic Substances Control Act

Lynn L. Bergeson, Bergeson & Campbell, P.C.

Jim Willis, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency

Karen Florini, Attorney, Environmental Defense

3:45 **Break**

4:00 **Utility of Media Programs under the Clean Air and Clean Water Acts, Alternative Multi-media Approaches, Assessment Authorities and Tools**

William F. Pedersen PLLC

Mark Greenwood, Ropes & Grey

5:00 **Role of the federal Resource Conservation and Recovery Act and State Waste Programs**

Tracy Hester, Bracewell & Patterson, LLP

Aaron Goldberg, Beveridge & Diamond, P.C.

6:15 **Review of Next Day's Agenda and Adjourn**

6:15-7:00 **Reception**

THURSDAY, May 26, 2005

8:30 **Opening Remarks**

Leslie Carothers, President, Environmental Law Institute

8:40 **Breakout Group Sessions: Adequacy of Existing Legal Framework**

Are federal environmental laws and institutions adequate or readily adaptable to deal with nanotechnology? Why or why not? What do we need to know to decide whether the existing structure will work?

10:00 **Break**

10:15 **Reports from Breakout Groups**

11:15 **Role of Voluntary Industry Initiatives and Guidelines**

Karen Florini, Attorney, Environmental Defense

Kristen Kulinowski, Ph.D., Center for Biological and Environmental Nanotechnology and International Council on Nanotechnology, Rice University; and Chair of ASTM Subcommittee E56.06 Nanotechnology Risk Management and Product Stewardship

12:00 **Luncheon – Learning Lessons from Biotech for Nanotech**

E. Donald Elliott, Wilkie, Farr & Gallagher

1:00 **Breakout Group Sessions: Governance Alternatives**

What are the governance options and how should they be evaluated? (e.g., regulation, market incentives, disclosure of information, voluntary guidelines, reliance on common law remedies for harm, contracts, hybrid approaches.)

2:00 **Reports from Breakout Groups and General Discussion**

2:45 **Summary and Next Steps**

3:00 **Adjourn**

APPENDIX B

SPEAKER PRESENTATIONS AND PAPERS

The presentations and papers given at the Dialogue are available at http://www2.eli.org/research/events/nanotech5.25.05.cfm.

Additionally, if this report is being viewed electronically, each presentation can be viewed by clicking on the title listed below the presenter's name.

Perspectives on Benefits and Risks of Nanotechnology Applications

- Larry Andrews, Ph.D., Chair, American Chemistry Council, Nanotechnology Panel
  Developing Nanotechnology: Perspectives on Benefits and Risks

- Kenneth A. Mundt, Ph.D., ENVIRON International Corporation
  Nanotechnology in the Workplace: Occupational Health and Safety and the Environment

- Kristen Kulinowski, Ph.D., Center for Biological and Environmental Nanotechnology and International Council on Nanotechnology, Rice University; and Chair of ASTM Subcommittee E56.06 Nanotechnology Risk Management and Product Stewardship
  Biological and Environmental Nanotechnology: Applications and Implications

- John Balbus, M.D., MPH, Environmental Defense
  No Small Thing: Getting Nanodevelopment Right The First Time

Applicability of U.S. Environmental Laws to Assess, Prevent and Control Risks of Nanotechnology: Toxic Substances Control Act

- Lynn L. Bergeson, Bergeson & Campbell, P.C.
  Applicability of U.S. Environmental Laws to Assess, Prevent, and Control Risks of Nanotechnology: TSCA

- Jim Willis, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency
  Nanotechnology and the Toxic Substances Control Act

- Karen Florini, Attorney, Environmental Defense
  No Small Matter: Can TSCA Get Nano Right the First Time

Utility of Media Programs under the Clean Air and Clean Water Acts, Alternative Multi-media Approaches, Assessment Authorities and Tools

- William F. Pedersen PLLC
  Regulating Nanotechnology by Information Disclosure

- Mark Greenwood, Ropes & Grey
  Nanotechnology: Challenges to the Federal Regulatory System

Role of the federal Resource Conservation and Recovery Act and State Waste Programs

- Tracy Hester, Bracewell & Patterson, LLP
  RCRA and CERCLA in the New World of Nanoscale Materials

- Aaron Goldberg, Beveridge & Diamond, P.C.
  Present and Potential Future Classification of Nanomaterials as RCRA Hazardous Waste

Role of Voluntary Industry Initiatives and Guidelines

- Karen Florini, Attorney, Environmental Defense
  No Small Matter: Using Partnerships to Get Nano Right the First Time

- Kristen Kulinowski, Ph.D., Center for Biological and Environmental Nanotechnology and International Council on Nanotechnology, Rice University; and Chair of ASTM Subcommittee E56.06 Nanotechnology Risk Management and Product Stewardship
  Voluntary Standards: From Terminology to Stewardship

Learning Lessons from Biotech for Nanotech

- E. Donald Elliott, Wilkie, Farr & Gallagher
  Regulate Nano Now

APPENDIX C

ENVIRONMENTAL LAW INSTITUTE ISSUE PAPER

Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up to the Job? May 25-26, 2005 Washington, DC

I. Background

Nanotechnology is the science and technology of controlling matter at the nanoscale.[1] Nanomaterials have at least one dimension of 100 nanometers or less.[2] A nanometer is a billionth of a meter – approximately 1/100,000 the width of a human hair.[3] Manipulating material at the nanoscale can change the electronic, magnetic, mechanical and other properties of a substance;[4] the smallest change in the structure of the nanoparticle can significantly impact the functional properties that are exhibited.[5] This emerging technology could significantly impact many industries – from computer science to pharmaceuticals.

Size (nm)	Examples	Terminology
$\geq 10^4$	**Bulk materials**	**Macro**
10^3 - 10^4	**Living cells**	**Micro**
1- 1000	**Proteins, DNA**	**Nano**

Although there are many applications of nanotechnology that have yet to become commercially available, there are 80 products[6] that use nanomaterials already found in the marketplace today, including paints, glare-reducing coasting for eyeglasses and autos, sunscreens, sporting goods, cosmetics, stain-resistant clothing, and organic light emitting diodes used in laptop computers, cell phones, and digital cameras.[7] A recent survey found that there are already 1645 nanotech companies operating in the United States,[8] but that number will likely increase substantially. About one half of these companies are small

[1] Lynn L. Bergeson & Bethami Auerbach, *Reading the Small Print*, ENVTL. F., Mar./Apr. 2004 at 31.
[2] Ernie Hood, *Nanotechnology: Looking as We Leap*, 112 ENVTL. HEALTH PERSP. A741, A741 (2004).
[3] Bergeson, *supra* note 1 at 31.
[4] Hood, *supra* note 2 at A741 (*citing* Kristen Kulinowski, Executive Director for Education and Policy at Rice University Center for Biological and Environmental Nanotechnology).
[5] Richard A. Denison, Environmental Defense, *A proposal to increase federal funding of nanotechnology risk research to at least $100 million annually* (Apr. 2005) at 4, *at* http://www.environmentaldefense.org/documents/4442_100milquestionl.pdf
[6] U.S. Envtl. Prot. Agency, *Nanotechnology White Paper External Review Draft* (Dec. 2, 2005) at 3, http://www.epa.gov/osa/pdfs/EPA_nanotechnology_white_paper_external_review_draft_12-02-2005.pdf (last visited Jan. 25, 2006) (*citing* EmTech Research); The Associated Press, *Report Examines Safety of Nanotechnology* (Jan. 11, 2006), http://www.nytimes.com/aponline/science/AP-Nano-Safety.html?_r=1 (last visited Jan. 25, 2006) (*citing* Small Times Magazine).
[7] *See* Hood, *supra* note 2 at A741; Bergeson, *supra* note 1 at 30; Applications/Products, National Nanotechnology Initiative, *at* http://www.nano.gov/html/facts/appsprod.html (last visited May 19, 2005); Jane Macoubrie (Woodrow Wilson Center for International Scholars & Pew Charitable Trusts), Informed Public Perceptions of Nanotechnology and Trust in Government at 1, 2005, *at* http://www.wilsoncenter.org/news/docs/macoubriereport1.pdf.
[8] Small Times Magazine, March 2005.

businesses. Lux Research, Inc. predicts that by 2014, products that incorporate nanotechnology will constitute 15% of global manufacturing output and will total $2.6 trillion.[9]

Nanotechnology is what some term a "general purpose technology" much like the Internet, electricity, or steam power. As such, it will have broad impacts across multiple industrial sectors and products, and these impacts may be difficult to predict in advance (think about the number of ingenious ways people are using the Internet). The table below outlines some of the existing and near-term applications across different sectors.

Automotive Industry • Lightweight construction • Painting • Catalysts • Tires (fillers) • Sensors • Coatings for windshield and bodies	Chemical Industry • Fillers for paints • Composite materials • Impregnation of papers • Adhesives • Magnetic fluids	Engineering • Protective coatings for tools and machines • Lubricant-free bearings
Electronics • Displays • Data memory • Laser diodes • Fiber optics • Optical switches • Filters • Conductive, antistatic coatings	Construction • Materials • Insulation • Flame retardants • Surface coatings for wood, floors, stone, tiles, roofing, etc. • Mortar	Medicine • Drug delivery systems • Contrast medium • Rapid testing systems • Prostheses and implants • Antimicrobial agents • In-body diagnostic systems
Textiles • Surface coatings • Smart textiles	Energy • Fuel cells • Solar cells • Batteries • Capacitors	Cosmetics • Sun screens • Lipsticks • Skin creams • Tooth paste
Food and Drinks • Packaging • Sensors for storage life • Additives • Clarifiers (for juices)	Household • Ceramic coatings for irons • Odor removers • Cleaners for glass, ceramics, metals, etc.	Sports/Outdoors • Ski wax • Tennis rackets, golf clubs • Tennis balls • Antifouling coatings for boats • Antifogging coatings for glasses/goggles

Adapted from: Industrial Application of Nanomaterials: Chances and Risks, Wolfgang Luther (ed), Dusseldorf, Germany: Future Technologies Division of the VDI Technologiezentrum (done with support from the European Commission).

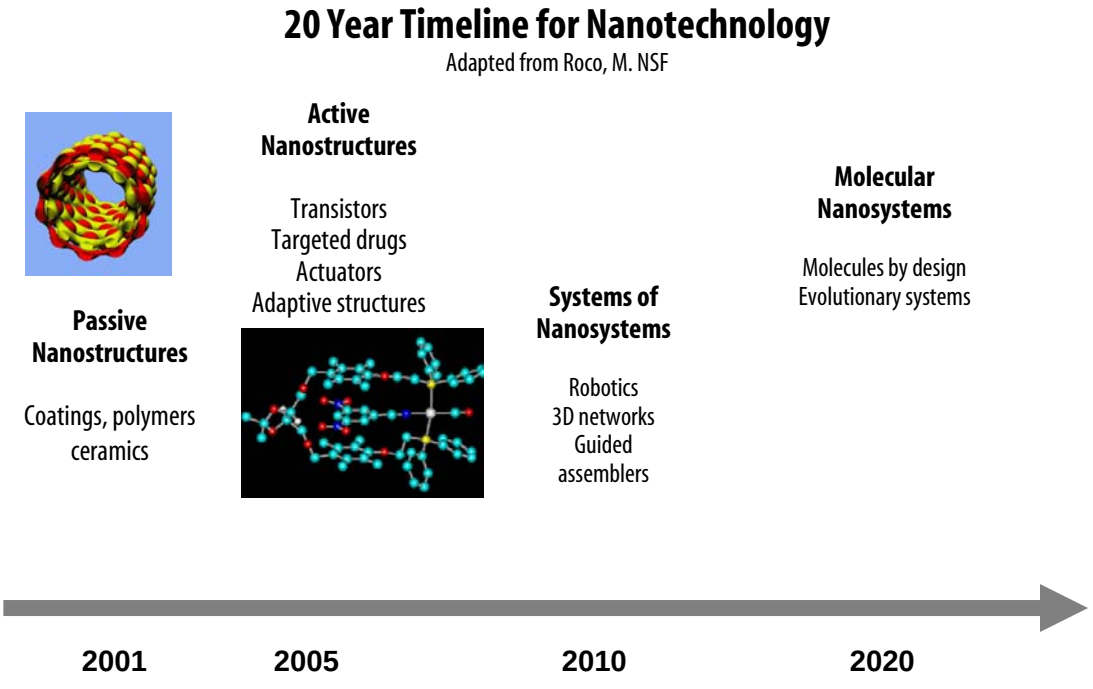
From an environmental perspective, nanomaterials offer both opportunities and challenges. The potential environmental benefits of nanotechnology include remediation, monitoring, and green production. For example, field tests indicate that iron nanoparticles can be used to clean up soil by neutralizing contaminants such as polychlorinated biphenyls, DDT, and dioxin.[10] But the greatest promise that nanotechnologies holds for the environment may be in the manner they could

[9] Lux Research, Inc., *Revenue from Nanotechnology-Enabled Products to Equal IT and Telecom by 2014, Exceed Biotech by 10 Times* (Oct. 25, 2004), *at* http://luxresearchinc.com/press/RELEASE_SizingReport.pdf

[10] Hood, *supra* note 1 at A744.

fundamentally change the way goods are manufactured. Traditional manufacturing requires large amounts of raw materials generating waste and hazardous byproducts in the process. Nanotechnology allows for building from the bottom up using only those molecules that are needed for the product, thereby eliminating waste at the source.[11]

Even as nanotech products find their way to store shelves, little is known about the risks associated with their manufacture, use, and disposal. There are only minimal data at this juncture on the effects of exposure to nanomaterials on human health and the environment. Furthermore, the methods and protocols needed to detect, measure, and characterize nanomaterials are in many cases only in the process of being developed.[12] The sheer variety of applications, properties expressed, routes of exposure and means of disposal makes it particularly challenging to identify, predict, and manage any risks posed by nanotechnologies. Knowledge of the chemical properties of a substance when in bulk may not help predict how that substance will behave at the nanoscale. For example, aluminum is inert when it takes the form of a soda can, but is highly explosive in nanoform.[13] The research addressing the health risks of exposure to nanomaterials is just beginning. Recent studies indicate some nanomaterials can penetrate individual cells, deposit in organ systems, and trigger inflammatory responses. For example, studies indicate that inhaled nanoparticles accumulate in nasal passages, lungs, and brains of rats. Studies also indicate inflammation and damage in the brains of large mouth bass as a result of exposure to aqueous fullerenes.[14]



[11] Bergeson, *supra* note 1 at 32; Hood, *supra* note 2 at A744.
[12] Denison, *supra* note 5 at 4.
[13] *Id*.
[14] Hood, *supra* note 2 at A745-A746.

It is important to understand that the nanotech revolution is just beginning. Over the next two to five years a transition from passive nanoparticles to more active nanostructures is expected and an increasing convergence of nanotechnology and biotechnology. As these transitions occur, risk will change, both qualitatively and quantitatively. A long-term timeline is above (previous page).

Numerous nanotechnology-related initiatives and activities are underway in the U.S. and abroad. Examples include, but are not limited to, the following:

- U.S. Government

  - **The National Nanotechnology Initiative (NNI).** This initiative, started in Fiscal Year 2001, is composed of 24 federal agencies managed under the Nanoscale Science Engineering and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC), which is appointed by the President.[15] The NNI coordinates research and development of its constituent agencies, provides funding to university laboratories, and supports U.S. companies pursuing commercial applications of nanotechnology. Since FY 2001, the federal government has spent over $4 billion on research and development in nanotechnology, and the President has called for over $1 billion in his FY 2006 budget.[16] The 21st Century Research and Development Act, passed in 2003, recognized and defined the role of the National Nanotechnology Coordination Office as the secretariat of the NSET Subcommittee managing its day-to-day activities and required that a National Nanotechnology Advisory Panel (NNAP) be created to review periodically the work of the NNI.[17] The President's Council of Advisors on Science and Technology (PCAST) was designated to serve as the NNAP and has recently released its first review.[18]
  - **EPA Research Programs.** The U.S. Environmental Protection Agency, through grants from its Science to Achieve Results (STAR) and Small Business Innovation Research programs, funds research to develop nanotech applications that protect the environment. The STAR program has funded 32 grants for $11 million. The EPA, along with the National Institute for Occupational Safety and Health and the National Science Foundation, also funds grants to institutions studying the potential harmful effects of nanotechnology.[19] The EPA's Science Policy Council is currently in the process of developing a white paper addressing the various issues related to nanotechnology and the environment.

- Private Sector Initiatives

  - **Nanoparticle Benchmarking Occupational Health Safety and Environment Program.** A consortium of companies has convened to address common analytical needs to measure airborne concentrations and particle sizes and to assess effectiveness of controls. Three work products are planned: a chamber test to define aerosols and monitor aerosol behavior as a function of time; a prototypical instrument to measure particle concentration in workplace ambient air in discrete particle size range; and the ability to measure penetration of nanoparticles from an air stream through filters, gloves, or protective clothing.

[15] For more information on the NNI, please visit www.nano.gov

[16] PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY, THE NATIONAL NANOTECHNOLOGY INITIATIVE AT FIVE YEARS: ASSESSMENT AND RECOMMENDATIONS OF THE NATIONAL NANOTECHNOLOGY ADVISORY PANEL 6 (2005), *available at* http://www.ostp.gov/pcast/PCASTreportFINAL5-17-05.pdf [hereinafter PCAST REPORT].

[17] Public Law 108-153.

[18] PCAST REPORT, *supra* note 15, at 1.

[19] For more information on EPA's activities in nanotechnology, see http://es.epa.gov/ncer/nano/index.html.

- Non-profit Organizations

  - **Woodrow Wilson International Center for Scholars.** In collaboration with the Pew Charitable Trusts, the Woodrow Wilson Center recently launched the Project on Emerging Nanotechnology. "The project plans to bring together leaders from industry, government, research, and other sectors to take a long-term view of what is known and unknown about potential health and environmental challenges posed by emerging nanotechnologies, and to develop recommendations to manage them."[20]
  - **Center for Biological and Environmental Nanotechnology (CBEN).** The CBEN, funded by the National Science Foundation and housed at Rice University, "fosters the development of this field through an integrated set of programs that aim to address the scientific, technological, environmental, human resource, commercialization, and societal barriers that hinder the transition from nanoscience to nanotechnology."[21]
  - **Environmental Defense.** Environmental Defense is a national non-profit organization that brings science, economics, and the law together to find solutions to environmental problems. One of its projects is to work with government and industry to development nanotechnology responsibly. It has called for an increase in federal funding to research the potential risks of nanomaterials.[22]
  - **Meridian Institute.** The Meridian Institute is a non-profit organization that "helps decision makers and diverse stakeholders solve some of society's most contentious public policy issues."[23] One of its current projects is to convene a "Global Dialogue on Nanotechnology and the Poor" to identify ways in which nanotechnology might play a role in the development process.[24]
  - **Action Group on Erosion, Technology and Concentration (ETC).** ETC is a non-profit organization "dedicated to the conservation and sustainable advancement of cultural and ecological diversity and human rights."[25] In the past, ETC has called for a moratorium on the use and introduction of synthetic nanoparticles until governments adopt "best practices" standards to ensure the safety of those working in nanotech laboratories. ETC also advocates for an international, legally-binding mechanism based on the Precautionary Principle to regulate nanotechnology.[26]
  - **National Nanotechnology Infrastructure Network (NNIN).** The NNIN is a network of 13 academic research facilities funded by the National Science Foundation to facilitate rapid advances in the field of nanotechnology.[27]

- International

[20] Foresight and Governance Project, Woodrow Wilson International Center for Scholars, *Wilson Center Launches New Project on Emerging Nanotechnologies*, *at* http://wwics.si.edu/index.cfm?topic_id=1414&fuseaction=topics.item&news_id=120312 (last visited May 19, 2005).
[21] For more information about the Center for Biological and Environmental Nanotechnology, see http://www.cben.rice.edu.
[22] For more information about Environmental Defense's work on nanotechnology, see http://www.environmentaldefense.org/subissue.cfm?subissue=2&linkID=latestnews.
[23] For more information on the Meridian Institute, see http://www.merid.org/about.html.
[24] For more information about Meridian Institute's Global Dialogue on Nanotechnology and the Poor, see http://www.nanoandthepoor.org.
[25] For more information about the Action Group on Erosion, Technology and Concentration, see http://www.etcgroup.org/about.asp.
[26] ETC's response to the Woodrow Wilson Center's paper, *Nanotechnology and Regulation*, can be found at http://www.environmentalfutures.org/Images/nanoetccomments.pdf (last visited May 19, 2005).
[27] For more information about the National Nanotechnology Infrastructure Network, see http://www.nnin.org.

- **International Council on Nanotechnology (ICON).** Managed by CBEN, ICON is composed of representatives from government, academia, and industry around the world, whose mission is to "assess, communicate, and reduce nanotechnology environmental and health risks while maximizing its societal benefit."[28]
- **United Kingdom.** The Royal Society, the UK National Academy of Science, the Royal Academy of Engineering, and the UK National Academy of Engineering released a report, commissioned by the UK Government, in July 2004 entitled, "Nanoscience and Nanotechnologies: Opportunities and Uncertainties."[29]
- **European Union.** The European Commission released its planned budget for the Seventh Framework Programme for Research and Technological Development (FP7), which will fund research in nine different areas from 2007 to 20012. One of the nine areas is nanotechnology, with the third largest budget of just under 5 billion euros.[30] The EU also sponsors the Nanoforum, a website that provides information to industry, academia, and the public.[31]

Several organizations have begun developing voluntary guidelines, standards, and programs:

- **EPA Voluntary Program.** The U.S. EPA recently published a notice in the Federal Register announcing that it was considering a voluntary pilot program for existing nanoscale chemical substances listed under the Toxic Substances Control Act.[32]
- **Foresight Institute Voluntary Guidelines.** A nonprofit organization whose goal is to ensure that nanotechnology improves the human condition, has issued guidelines for nanotech professionals, industry, and government regulators.[33]
- **ASTM International.** In January 2005, ASTM International, a voluntary standards development organization, created Committee E56 to develop standards and guidelines for nanotechnology with the following subcommittees: Terminology & Nomenclature, Characterization, Environmental & Occupational Health & Safety, International Law & Intellectual Property, Liaison & International Cooperation, and Standards of Care/Product Stewardship.[34]
- **American National Standards Institute (ANSI).** ANSI is a non-profit organization that administers and coordinates the U.S. voluntary standardization and conformity assessment system.[35] In August 2004, ANSI established the Nanotechnology Standards Panel to bring together industry, academia, and government entities to develop and adopt voluntary standards including nomenclature/terminology; materials properties; and testing, measurement and characterization procedures.[36] ANSI recently submitted an application for accreditation for a proposed U.S. Technical Advisory Group (TAG) to the International Organization for Standardization's (ISO) new Technical Committee (TC) in Nanotechnologies, and for approval as the U.S. TAG Administrator. The ISO Nanotechnology TC is expected to be approved at the end of May.

[28] For more information about ICON, see http://icon.rice.edu.
[29] THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES (2004), *available at* http://www.nanotec.org.uk/finalReport.htm.
[30] Community Research and Development Information Service, European Union, *at* http://dbs.cordis.lu/fep-cgi/srchidadb?CALLER=EN_NEWS&ACTION=D&SESSION=&RCN=EN_RCN_ID:23629.
[31] The Nanoforum can be found at www.nanoforum.org.
[32] Nanoscale Materials; Notice of Public Meeting, 70 Fed. Reg. 24,574 (May 10, 2005).
[33] Foresight Institute's voluntary guidelines can be found at http://www.foresight.org/guidelines/current.html.
[34] For more information on ASTM International's committee on nanotechnology, see http://www.astm.org/COMMIT/COMMITTEE/E56.htm.
[35] For more information about ANSI, see http://www.ansi.org/about_ansi/overview/overview.aspx?menuid=1.
[36] For more information regarding ANSI's committee on nanotechnology, see http://www.ansi.org/standards_activities/standards_boards_panels/nsp/overview.aspx?menuid=3.

II. Issues

This workshop is designed to address the legal framework for regulating nanotechnology in the United States. The following briefly addresses the principal issues and questions likely to be discussed by the conference participants. The intent is not to limit the participants' discussion to the issues and questions identified below, but to provide a starting point for framing the workshop discussions. The outline is based in large part on issues highlighted by conference participants.

A. Hazard and Exposure

Risk Assessment Tools: Limited information exists about the potential hazards of and exposures to nanoscale materials. The environmental and human health impacts of nanotechnology manufacturing processes or of using any specific nanotechnology product are not fully known. Knowledge on the short- and long-term impacts of exposure and effects of nanomaterials on the environment, including the ability of nanoparticles to accumulate in the food chain, is limited. Progress may require that conventional risk assessment methods be modified and further developed. For example, the toxicity paradigms used in both the environmental and worker exposure areas are mass-based and mass-driven. The toxicity of nanoparticles and materials, on the other hand, is more dependent on surface area, surface chemistry, structure and number of particles. There are few tools and techniques for measuring these characteristics at the nanoscale. Reliable measurement techniques will be needed for effective nanomaterials regulation. According to a recent report by the NNAP, the NNI plans to invest about half the budget allocated to the relevant program component area, or four percent of the total budget, for research and development that is aimed primarily at understanding and addressing the potential risks posed by nanotechnology.

Questions:

- *What considerations should be taken into account in using existing data to evaluate the toxicology and eco-toxicology of nanomaterial?*
- *To what extent will new nanotech-specific data need to be generated on toxicology and eco-toxicology and who will generate these data?*
- *How can the development of new risk assessment tools be fostered?*
- *Do assessment methods and protocols for conducting material characterization, human and environmental toxicity and fate and transport testing of nanoscale materials need to be revised (e.g., inhalation toxicity protocols)?*

Life Cycle Assessments: A Royal Society & Royal Academy of Engineering 2004 study recommended that an independent body undertake a series of life cycle assessments for the applications and product groups arising from existing and expected developments in nanotechnologies to ensure that savings in resource consumption during the life of the product are not offset by increased consumption during manufacture and disposal. In addition, Environmental Defense

has recommended that studies be undertaken to investigate potential risks throughout the entire product lifecycle and take into account worker safety, consumer use, and the ecological effects from product disposal.

Questions:

- *What are the challenges associated with conducting life cycle assessments in an area in which the technology is currently emerging and the data are limited?*
- *Are existing tools sufficient or are new tools and approaches needed? If tool development is required, who will fund such work?*
- *What funding mechanisms could be used to support life cycle assessments?*

B. Regulation

The Existing Legal Framework: No current U.S. laws or regulations are specifically designed to regulate nanotechnology. Similarly, it is not clear any existing law or regulation is ill-suited or incapable of addressing the risks and benefits of nanotechnology. Several statutes, most notably the Toxic Substances Control Act, could be used to regulate nanomaterials. Effective nanotechnology regulation will require an assessment of the adequacy of existing statutes and regulations and identification of any necessary statutory and regulatory modifications.

Questions:

- *How do nanomaterials differ from conventional materials for purposes of regulation?*
- *What would a rational system for nanotech regulation look like and can it be achieved within the current regulatory structure? More specifically:*
    - *Are new policies, guidance, and governance tools needed to move forward with the regulation of nanotechnology in a responsible and effective manner?*
    - *What new statutory authorities, if any, are needed?*
    - *Where should EPA focus its limited resources for purposes of regulating nanotechnology?*
- *To what extent do the media-specific and industry-specific environmental laws and programs limit EPA's ability to address effectively nanotechnology?*
- *What lessons can be learned from the experience of Europe, the U.S, and other countries with biotechnology regulation?*
- *What new information is needed to assess the adequacy of the current regulatory structure?*

Toxic Substances Control Act (TSCA)-Specific Issues: TSCA is frequently cited as the most appropriate existing statute for nanotechnology regulation. It is not viewed, however, as an ideal vehicle and many issues will need to be addressed if TSCA is to be used effectively as the principal statute for regulating nanotechnology. These issues range from fundamental questions about nomenclature to the interaction of TSCA with other environmental statutes.

Questions:

- *How should the determination of new versus existing chemicals under TSCA be applied to nanomaterials (e.g., is nanomaterial with the same molecular structure as a substance listed on the Inventory a new chemical if it has chemical, physical, and biological properties that differ)?*

- *Would specific guidelines for identifying nanoscale materials on the TSCA Inventory make the process of determining whether substances are new or existing more predictable and/or transparent?*

- *Should the current TSCA exemptions for: research and development; low volume manufacture; low environmental releases and human exposure with low volume; and limited test marketing apply to nanomaterials? For example, are the current thresholds used for the low release, low exposure substance exemption under TSCA appropriate given the higher level of activity per unit mass for nano as opposed to conventional materials?*

- *What factors should be considered and approaches used for determining whether nanomaterials constitute a significant new use under TSCA Section 5?*

- *What hazard and exposure data are needed to characterize potential risks of nanotechnologies for purposes of Premanufacture Notice (PMN)?*

- *What would be the benefits and drawbacks of issuing a TSCA Section 8(e) Rule to obtain reporting of information on the manufacture or processing of nanoscale materials consisting of existing chemicals? Under 8(e) how would "substantial risk" be determined for nanomaterials?*

- *If TSCA is used as the primary vehicle at the front end for regulating nanotechnology, how will it interface with other environmental statutes EPA administers, such as the Clean Air Act, Clean Water Act, National Environmental Policy Act, and the Resource Conservation and Recovery Act, which may also have a role in regulating nanotechnologies?*

- *TSCA Section 12(b) requires exporters to notify EPA, in writing, if they export chemical substances or mixtures that are subject to certain TSCA rules or orders. To trigger a 12(b) notification, there must be a final Section 4 rule or a proposed or final Section 5, 6, or 7 rule, none of which exists as applied to nanoscale materials, nor is any expected any time soon. Absent export notification, could nanoscale materials be exported for use, processing, or disposal anywhere in the world without any tracking ability? Is this desirable and, if not, what can be done to address this?*

Resource Conservation and Recovery Act (RCRA) and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)- Specific Issues: In its 2004 study, the Royal Society & Royal Academy of Engineering concluded that the risk of release of nanomaterials would be highest during disposal, destruction or recycling. Waste from nanotechnology facilities could be regulated under RCRA, if such wastes meet the applicable criteria (e.g., are listed or characteristic wastes). CERCLA may also provide authorities to address disposal of nanomaterials.

Questions:

- *Is RCRA sufficiently flexible to allow for regulation of any new or now unknown hazards associated with nanowaste?*
- *Could the RCRA waste identification rules be modified with sufficient clarity in the foreseeable future to capture specific nanowaste streams (listed waste) or through a narrative standard to capture the "characteristic" of a nanohazard?*
- *What is the role of state waste programs in regulating nanotechnology, either as a complement to or in lieu of federal regulation?*
- *Can CERCLA effectively address any hazards posed by the treatment or disposal of hazardous substances that are nanoscale in dimension?*

Clean Air Act and Clean Water Act-Specific Issues: The manufacturing, use, and disposal of nanomaterials and products have the potential to result in air emissions and water discharges. Accordingly, the Clean Air and Clean Water Acts are potential regulatory vehicles. For example, EPA has established National Ambient Air Quality Standards for fine particulates of less than 2.5 micrometers. It is possible that these standards, carried out by the states through state implementation plans, could be translated into specific limitations on nanotechnology manufacturers. It is also possible that nanotechnology could be regulated under the hazardous air pollutant authorities of the Clean Air Act. Potential authorities under the Clean Water Act include but are not limited to: effluent limitations for point sources; national pollutant discharge and elimination system permits; new source performance standards; and toxic and pretreatment effluent standards.

Questions:

- *Which provisions of the Clean Air and Clean Water Acts could be used most effectively to regulate nanotechnologies?*
- *What are the benefits and drawbacks of using these statutory authorities (e.g. the discretionary or inflexible nature of authorities)?*
- *Should certain authorities be modified to apply more effectively to nanoscale materials?*
- *Given the size and other characteristics of nanoparticles, could monitoring be accomplished using existing techniques? If new technologies and methods are needed, who would develop these?*

C. Alternatives to Traditional Regulation

Non-Regulatory and Information-Based Tools: In addition to or in lieu of traditional regulation, there are several approaches that could be used to address the environmental and human health risks that may be associated with nanotechnologies. These could include, but are not necessarily limited to, economic incentives, tort liability, and disclosure. EPA recently announced a public meeting to discuss a potential voluntary disclosure pilot program for certain nanoscale materials.

Questions:

- *What models could inform the use of non-regulatory approaches for nanotechnologies?*
- *What are the considerations and assumptions that would inform the selection of the various non-regulatory approaches?*
- *What are the limitations associated with using alternatives to regulation?*
- *What types of economic incentives could be used in lieu of or as a complement to traditional regulations (e.g., financial incentives for toxicity testing)?*
- *Would a voluntary EPA program on nanotechnology be useful and, if so, what should be the objectives, design, and scope of such a voluntary program?*

Voluntary Standards: Two voluntary standards development organizations, the American National Standards Institute and ASTM International, have recently created committees to develop guidelines for companies using nanotechnology. The ISO is poised to begin a new technical committee on nanotechnologies to address nomenclature and related issues, possibly including management standards pertinent to nanomaterials. In addition, the Foresight Institute has developed a set of voluntary standards for use by researchers.

Questions:

- *What are the benefits and limitations of voluntary standards or guidelines?*
- *Can voluntary standards be used effectively in combination with regulatory approaches?*
- *Are there models that could be used to assess the potential effectiveness of nanotech-related voluntary standards or guidelines?*

Public Involvement: Fostering meaningful public involvement in decisions related to the regulation of nanotechnology presents many challenges. These challenges are due in part to the highly technical nature of the issues involved. The NNAP recently concluded that the NNI should "vigorously communicate" with the public about the Government's efforts to address societal concerns and without which "public trust may dissipate and concerns based on information from other sources,

including the entertainment industry may become dominant." In addition, a national environmental group has called for increased public involvement in nanotechnology policy development in Congressional testimony, as has the Royal Society & Royal Academy of Engineering in its 2004 report.

Questions:

- *How can EPA, other government agencies, the business community and non-profit groups promote understanding of the human health and environmental effects of nanotechnologies?*
- *What are the most important challenges with respect to involving the public in the development of nanotechnology policy?*
- *Would a public dialogue on regulation of nanotechnologies be of use and, if so, in what context and fora?*

D. The Role of Governmental Entities

State and Local Governments: Lux Research estimates that in 2004 state and local governments invested more than $400 million in nanotechnology research, facilities, and business incubation programs. Although several states have enacted legislation encouraging or promoting nanotechnologies, no states have yet enacted regulatory authorities. Under most of the major environmental statutes, the states also have a potential role in regulating nanotechnologies through delegated federal programs. In addition, states may have existing statutes that could be used to regulate nanotechnologies, such as the Massachusetts Toxic Use Reduction Act. Issues with respect to preemption will also influence the role of state law in regulating nanotechnologies.

Questions:

- *What is the appropriate role of state governments in regulating nanotechnologies?*
- *In the absence of pervasive and specific federal regulation, are states likely to step forward to regulate nanotechnologies and, if so, what would be the advantages and disadvantages of a proactive state role?*
- *Would a federal-state dialogue be helpful in securing the benefits of state-level thinking and minimizing later potential conflicts?*

Federal Agencies: The regulation of nanotechnologies implicates multiple regulatory regimes depending on the context in which nanotechnologies are used. The regulatory agencies with possible jurisdiction include, but are not limited to, the U.S. Department of Agriculture, Department of Homeland Security, the Occupational Health and Safety Administration, the Food and Drug Administration, and the Consumer Product Safety Commission. Recently, the NNAP recommended that the NSTC Subcommittee on Technology, the Nanoscale Science, Engineering, and Technology "coordinate with the agencies that have the responsibility and authority for protecting the environment and the public."

Questions:

- *Do current federal initiatives adequately ensure cooperation and coordination among federal agencies?*
- *What are the major impediments to inter-agency coordination and how can they be addressed?*

International: The NNAP recently concluded that "governments around the world must take a proactive stance to ensure that environmental, health, and safety concerns are addressed as nanotechnology research and development moves forward in order to assure the public that nanotechnology will be safe." The Panel also noted that because environmental and health concerns "reach beyond borders," the National Nanotechnology Initiative should coordinate with agencies and organizations that are responsible for representing the United States in international fora. The European Commission, in a 2004 report, has concluded that international co-operation could accelerate research and development "by overcoming knowledge gaps more rapidly." Recognizing the value of science and technical cooperation agreements, such as an implementing arrangement between the European Commission and the National Science Foundation, the Commission stated that reinforced international co-operation in nanosciences and nanotechnologies is needed "both with countries that are more economically advanced (to share knowledge and profit from critical mass) and less economically advanced (to secure their access to knowledge and avoid any knowledge apartheid)," particularly with respect to health, safety, and the environment.

Questions:

- *Should international consensus or debate be promoted on issues that are arguably of global concern, such as public health and the environment, risk assessment, regulatory approaches, metrology, and nomenclature?*
- *Should there be monitoring and sharing of information related to the scientific and technological development of nanotechnologies?*
- *What are the implications of a country moving aggressively to regulate nanotechnology, particularly with respect to the movement of nanomaterials and products across borders?*
- *What issues, if any, should be addressed with respect to the nanotechnology implications of international agreements such as the Basel Convention?*

Appendix 1: Relevant Federal Authorities
Appendix 2: State Laws on Nanotechnology

These appendices can be found online at http://www2.eli.org/research/nanotech.htm.

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