ENVIRONMENTAL LAW INSTITUTE ISSUE PAPER

Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up to the Job?
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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
$>10^4$	**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.

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

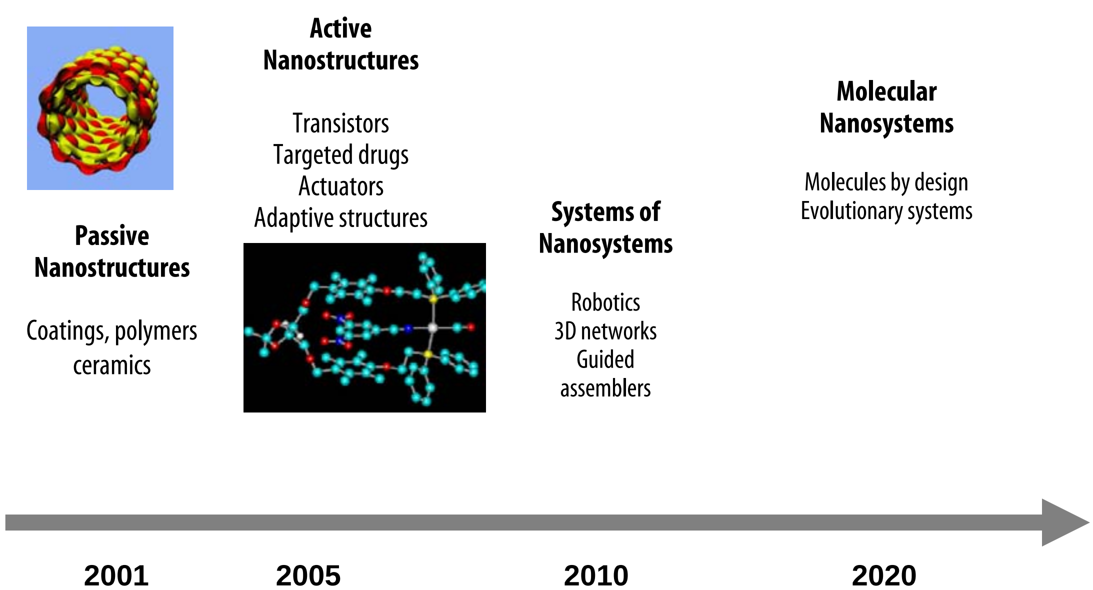
[9] Lux Research, Inc., *Revenue from Nanotechnology-Enabled Products to Equal IT and Telecom by 2014, Exceed Biotech by 10 Times* (Oct. 25, 2004), *at* http://luxresearchinc.com/press/RELEASE_SizingReport.pdf
[10] Hood, *supra* note 1 at A744.

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]

20 Year Timeline for Nanotechnology

Adapted from Roco, M. NSF



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[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.

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[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

  - **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]

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[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.
[28] For more information about ICON, see http://icon.rice.edu.

- **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.

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[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.