Governing Uncertainty: The Nanotechnology Environmental, Health, and Safety Challenge

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INTRODUCTION

The nano-revolution is upon us. Nanotechnology, the science and technology of controlling matter at the nanoscale,[1] promises to have far reaching impacts on the economy in areas ranging from consumer products to health care to transportation.[2] According to the National Science Foundation, nanotech is likely to exceed the impact of the Industrial Revolution and may represent a $1 trillion market by 2015.[3] In fact, over 200 products that use nanomaterials

1. Lynn L. Bergeson & Bethami Auerbach, *Reading the Small Print*, Mar./Apr. ENVTL. F. 30, 31 (2004).

2. Nanotechnology Workgroup, U.S. Envtl. Prot. Agency (EPA), *Nanotechnology White Paper—External Review Draft* 1, 3 (December 2, 2005), *available at* http://es.epa.gov/ncer/nano/publications/whitepaper12022005.pdf.

3. NATIONAL SCIENCE FOUNDATION, SOCIETAL IMPLICATIONS OF NANOSCIENCE AND NANOTECHNOLOGY 3 (Mihail C. Roco & William S. Bainbridge Eds. 2001), *available at* http://www.wtec.org/loyola/nano/societalimpact/nanosi.pdf; *cf.* Press Release, Lux Research, Inc., Revenue from Nanotechnology-Enabled Products to Equal IT and Telecom by 2014, Exceed Biotech by 10 Times (Oct. 25, 2004), *available at* http://luxresearchinc.com/press/RELEASE_SizingReport.pdf (estimating that by 2014 products that incorporate nanotechnology will constitute 15% of global manufacturing output and will total $2.6 trillion).

are already in the marketplace.[4] There are only minimal data at this juncture, however, on the effects of exposure to nanomaterials on human health and the environment. Moreover, initial studies indicate some cause for concern.[5] Thus, the nano-revolution brings with it the challenge of developing a governance structure that will address potential risks effectively, but at the same time will allow for the realization of the societal benefits associated with nanotechnologies.

The first Part of this Article provides background on nanotechnologies, including the benefits and potential environmental, health, and safety concerns. The second Part sets out several themes and principles that should guide the effort to develop an environmental, health, and safety governance structure for nanotechnologies. The third Part examines the questions that are raised in considering how to develop an effective governance structure for nanotechnologies and looks statute-by-statute at the key issues to consider. This Part also outlines a research agenda that, if implemented, will lay a solid foundation for the development of an effective governance structure.

I. BACKGROUND

A. The Technology

Nanomaterials have at least one dimension of 100 nanometers or less.[6] A nanometer is a billionth of a meter—approximately 1/100,000 the width of a human hair.[7] Manipulating material at the nanoscale can change the electronic, magnetic, mechanical

4. Project on Emerging Nanotechnologies, A Nanotechnology Consumer Products Inventory, http://www.nanotechproject.org/index.php?id=44 (last visited Mar. 20, 2006).

5. Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCIENCE 622, 622 (2006); Richard A. Denison, Environmental Defense, A proposal to increase federal funding of nanotechnology risk research to at least $100 million annually (Apr. 2005), http://www.environmentaldefense.org/documents/4442_100milquestionl.pdf; John Balbus et al., *Getting Nanotechnology Right the First Time*, ISSUES IN SCIENCE AND TECHNOLOGY 65 (Summer 2005), *available at* http://www.environmentaldefense.org/documents/4816_nanotechstatementNAS.pdf.

6. *See* National Nanotechnology Initiative, What is Nanotechnology? http://www.nano.gov/html/facts/whatIsNano.html (last visited Nov. 13, 2006); *see also* Ernie Hood, *Nanotechnology: Looking as We Leap*, 112 ENVTL. HEALTH PERSP. A741, A741 (2004).

7. Bergeson & Auerbach, *supra* note 1, at 31.

and other properties of a substance;[8] the smallest change in the structure of the nanoparticle can significantly impact the functional properties that are exhibited.[9] This emerging technology could significantly affect many industries, including computer science, energy, pharmaceuticals, transportation and others.

Although there are many applications of nanotechnology that have yet to become commercially available, there are over 200 products[10] already in the marketplace today that use nanomaterials, including paints, glare-reducing coating 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.[11] A recent survey found that there are already 1645 nanotech companies—about one half of which are small businesses—operating in the United States, but that number will likely increase substantially.[12]

Nanotechnology is what some term a "general purpose technology" much like the Internet, electricity, or steam power.[13] As such, it will have broad impacts across multiple industrial sectors and products, and these impacts may be difficult to predict in advance.

8. Nel et al., *supra* note 5, at 622; Hood, *supra* note 6, at A741 (citing Kristen Kulinowski, Executive Director for Education and Policy at Rice University Center for Biological and Environmental Nanotechnology).

9. Denison, *supra* note 5, at 4; Nel et al., *supra* note 5, at 622.

10. Project on Emerging Nanotechnologies, *supra* note 4.

11. National Nanotechnology Initiative, Applications/Products, http://www.nano.gov/html/facts/appsprod.html (last visited Nov. 13, 2006); Hood, *supra* note 6, at A741; Bergeson & Auerbach, *supra* note 1, at 30; JANE MACOUBRIE, WOODROW WILSON CENTER FOR INTERNATIONAL SCHOLARS, INFORMED PUBLIC PERCEPTIONS OF NANOTECHNOLOGY AND TRUST IN GOVERNMENT 1 (2005), *available at* http://www.wilsoncenter.org/news/docs/macoubriereport1.pdf; *see also* National Nanotechnology Initiative, More Products, http://www.nano.gov/html/facts/MoreProds.htm (last visited Nov. 7, 2006).

12. Lynn L. Bergeson, *EPA Considers How Best to Regulate Nanoscale Materials*, 15 ENVTL. QUALITY MGMT. 81 (2005); *see also infra* note 128.

13. Mike Treder, Center for Responsible Nanotechnology, *Bridges to Safety, and Bridges to Progress*, Nov. 2004, http://www.crnano.org/Bridges.htm.

The table[14] below outlines some of the existing and near-term applications across different sectors:

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

14. Table adapted from INDUSTRIAL APPLICATION OF NANOMATERIALS: CHANCES AND RISKS, FUTURE TECHNOLOGIES DIVISION, VDI TECHNOLOGIEZENTRUM 16 (Wolfgang Luther ed. 2004), *available at* http://www.zukuenftigetechnologien.de/11.pdf.

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.[15] Possibly the greatest promise that nanotechnologies hold for the environment, however, may be the manner in which 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. Nanotechnology allows for building from the bottom up using only those molecules that are needed for the product, thereby eliminating waste at the source.[16]

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 available on the effects of exposure to nanomaterials on human health and the environment,[17] and the methods and protocols needed to detect, measure, and characterize nanomaterials in many cases are only in the process of being developed.[18] The sheer variety of applications, properties expressed, routes of exposure and means of disposal make it particularly challenging to identify, estimate, 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.[19]

Although the research addressing the health risks of exposure to nanomaterials is just beginning, a recent article in *Science* described some of the initial work conducted, noting that the studies suggest that nanomaterials "are not inherently benign and that they affect

15. Hood, *supra* note 6, at A744.

16. Bergeson & Auerbach, *supra* note 1, at 32; Hood, *supra* note 6, at A744.

17. Bergeson & Auerbach, *supra* note 1, at 37; Lux Research, Inc., *Taking Action on Nanotech Environmental, Health, and Safety Risks* at 5 (May 2006) ("Of the 81,334 peer-reviewed journal articles on toxicology since 2000, just 0.6% mention nanomaterials-compared with 12% for polymers, a much better-known class of materials.").

18. Denison, *supra* note 5, at 4; *see also* Renewable Natural Resources Foundation, *Environmental Impacts of Emerging Contaminants*, 24 RENEWABLE RES. J. 1, 21 (2006).

19. Denison, *supra* note 5, at 4.

biological behaviors at the cellular, subcellular, and protein levels."[20] In addition, the article notes that "some nanoparticles readily travel throughout the body, deposit in target organs, penetrate cell membranes, lodge in mitochondria, and may trigger injurious responses."[21] For example, a 2004 study conducted by Gunter Oberdorster, an environmental toxicologist at the University of Rochester, indicated that inhaled nanoparticles accumulate in nasal passages, lungs, and brains of rats.[22] A study by David Warheit, a researcher at Dupont, found immune cells gathering around clumps of nanotubes in rats' lungs. At the highest dose used in the study, the animals suffocated due to the clumping of nanotubes, which blocked their bronchial passages.[23] Another study conducted in 2004 at Southern Methodist University by Eva Oberdorster reportedly found inflammation and "significant damage" in the brains of large mouth bass as a result of exposure to nanomaterials called aqueous fullerenes.[24]

20-YEAR TIMELINE FOR NANOTECHNOLOGY

Passive Nanostructures	**Active Nanostructures**	**Systems of Nanosystems**	**Molecular Nanosystems**
Coatings, Polymers, Ceramics	Transistors, Targeted Drugs, Actuators	Robotics, 3D Networks, Guided Assemblers	Molecules by Design, Evolutionary Systems
2001	**2005**	**2010**	**2020**

It is important to understand that the nanotech revolution is just

20. Nel et al., *supra* note 5, at 622.

21. *Id.*

22. Hood, *supra* note 6, at A745-A746; G. Oberdörster et al., *Translocation of Inhaled Ultrafine Particles to the Brain*, 16 INHALATION TOXICOLOGY 437, (2004); Bergeson & Auerbach, *supra* note 1, at 37.

23. David B. Warheit et al., *Comparative Pulmonary Toxicity Assessment of Single-wall Carbon Nanotubes in Rats*, 77 TOXICOLOGICAL SCIENCES 117 (2004); Hood, *supra* note 6, at A745-A746; Bergeson & Auerbach, *supra* note 1, at 37. *See also* Project on Emerging Nanotechnologies, Nanotechnology: Health and Environmental Implications, http://www.nanotechproject.org/index.php?id=18&action=view&dbq=warheit.

24. Hood, *supra* note 6 at A745-A746; Eva Oberdörster, *Manufactured nanomaterials (Fullerenes, C_{60}) Induce Oxidative Stress in Brain of Juvenile Largemouth Bass,* 112 ENVTL. HEALTH PERSPECTIVES 1058 (2004).

beginning. As indicated on the long-term timeline above, over the next two to five years a transition is likely to occur from passive nanoparticles to more active nanostructures.[25] Citing Mihail Roco of the U.S. National Nanotechnology Institute, a *Science* article notes that "[t]he current era is that of passive nanostructures, materials designed to perform one task. The second phase will introduce active nanostructures for multitasking, for example, actuators, drug delivery devices, and sensors."[26] The article further explains that "the third generation is expected to emerge around 2010 and feature nanosystems with thousands of interacting components. A few years after that, the first integrated nanosystems, functioning much like a mammalian cell with hierarchical systems within systems, are expected to evolve." Similarly, EPA recognizes that "[i]n the long term nanotechnology increasingly will likely be discussed within the context of the convergence, integration, and synergy of nanotechnology, biotechnology, information technology and cognitive technology."[27] For example, the convergence of nanotechnology and biotechnology "will result in the production of novel nanoscale materials."[28] As these transitions occur, risk will change, both qualitatively and quantitatively.[29]

B. Governance Activities

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

1. U.S. Government

Numerous federal agencies are involved in nanotechnology issues, many in a research and development capacity. The following are highlights of some of these nanotechnology activities and initiatives, with an emphasis on those related to environmental,

25. Adapted from Mihail C. Roco, National Science Foundation, Presentation at the National Nanotechnology Initiative 2004 Conference: National Nanotechnology Initiative: Planning for the Next Five Years, (Apr. 1, 2004) (citing M.C. Roco, AIChE Journal 2004), *available at* http://www.nsf.gov/crssprgm/nano/reports/nni_04-0401_futurenni_roco @Infocast.pdf.

26. Nel et al., *supra* note 5, at 622.

27. Nanotechnology Workgroup, EPA, *supra* note 2, at 7.

28. *Id.*

29. *Id.*

health and safety issues.

The National Nanotechnology Initiative (NNI). This initiative, started in fiscal year 2001, involves 25 federal agencies[30] managed under the Nanoscale Science Engineering and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC), which is appointed by the President.[31] The NNI coordinates research and development by its constituent agencies, provides funding to university laboratories, and supports U.S. companies pursuing commercial applications of nanotechnology. The President's FY 2007 Budget provides over $1.2 billion for nanotechnology research and development, bringing the federal government's total investment since FY 2001 to over $6.5 billion.[32] The 21st Century Research and Development Act,[33] passed in 2003, recognized and defined the role of the National Nanotechnology Coordination Office as the secretariat of the NSET Subcommittee, managing the NSET Subcommittee's day-to-day activities. The Act also required that a National Nanotechnology Advisory Panel (NNAP) be created to review periodically the work of the NNI. The President's Council of Advisors on Science and Technology (PCAST) was designated to serve as the NNAP, and it released its first review in May 2005.[34] A Nanotechnology Environmental and Health Implications Working Group was established under the NSET Subcommittee.[35] The Working Group is charged with providing for the exchange of information among research and regulatory agencies, facilitating the identification, prioritization, and implementation of research, and promoting communication of information related to research on environmental and health implications of nanotechnologies to governmental and non-

30. *Developments in Nanotechnology: Hearing before the Senate Commerce, Science, and Transportation Comm.*, 109th Cong. (Feb. 15, 2006) (statement of E. Clayton Teague, Director, National Nanotechnology Coordination Office), *available at* http://commerce.senate.gov/pdf/teague-021506.pdf.

31. National Nanotechnology Initiative, About the NNI, http://www.nano.gov/html/about/home_about.html (last visited Mar. 8, 2006).

32. National Nanotechnology Initiative, Funding, http://www.nano.gov/html/about/funding.html (last visited Nov. 13, 2006).

33. 21st Century Nanotechnology Research and Development Act, Pub. L. No. 108-153, 117 Stat. 1923 (2003) (codified at 15 U.S.C. §§ 7501-7509).

34. 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, 1 (2005), *available at* http://www.nano.gov/html/res/FINAL_PCAST_NANO_REPORT.pdf [hereinafter PCAST REPORT].

35. *Id.* at 36.

governmental entities. The Working Group also helps to develop "information and strategies for the drafting of guidance toward safe handling and use of nanoproducts by researchers, workers, and consumers and supports the development of nanotechnologies standards, including nomenclature and terminology, by consensus-based standards organizations."[36]

U.S. Environmental Protection Agency (EPA) Programs:

Research Programs. EPA, through grants from its Science to Achieve Results (STAR) and Small Business Innovation Research programs, funds research to develop nanotech environmental applications. Since 2001, the STAR grants program has funded 39 grants totaling $11 million for research on nanotechnology applications. In addition to research on applications, 14 recent STAR program projects focus on understanding the possible harmful effects or implications of engineered nanoparticles. To date, EPA has awarded or selected 32 grants on nanotechnology implications totaling $10 million. EPA recently partnered with the National Institute for Occupational Safety and Health, the National Institute for Environmental Health Sciences, and the National Science Foundation to solicit jointly a research proposal.[37]

EPA Voluntary Stewardship Program. In May 2005, EPA 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.[38] At a June 2005 public meeting to discuss the program, EPA received comments covering all aspects of the voluntary pilot program.[39] EPA's Interim *Ad Hoc* Work Group on Nanoscale

36. National Nanotechnology Initiative, Interagency Working Group on Nanotechnology Environmental and Health Implications (NEHI WG), http://www.nano.gov/html/society/NEHI.htm (last visited Nov. 16, 2006); *see also* National Nanotechnology Initiative, Responsible Development and International Cooperation, http://www.nano.gov/html/society/Responsible_Development.htm (last visited Mar. 8, 2006).

37. National Center for Environmental Research, EPA, Nanotechnology Research Grants Investigating Environmental and Human Health Effects of manufactured Nanomaterials: a Joint Research Solicitation—EPA, NSF, NIOSH, NIEHS, http://es.epa.gov/ncer/rfa/2005/2005_star_nano.html (last visited Nov. 13, 2006); Nanotechnology Workgroup, EPA, *supra* note 2, at 24-25.

38. Nanoscale Materials; Notice of Public Meeting, 70 Fed. Reg. 24574 (May 10, 2005), *available at* http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-9324.pdf.

39. Nanotechnology Workgroup, EPA, *supra* note 2, at 14.

Materials has since held two additional public meetings[40] regarding the program and has developed an overview document proposing the general parameters of a voluntary pilot program.[41] The proposed voluntary Nanoscale Materials Stewardship Program, as it has come to be known, would encourage a diverse cross-section of industry, research institutions, and other stakeholders in the emerging nanotechnology industry to provide existing data, generate new data, and develop good practices for their supply chains.[42]

EPA Science Policy Council, Nanotechnology Workgroup. The Nanotechnology Workgroup of EPA's Science Policy Council released a *Draft Nanotechnology White Paper* for public comment in December 2005.[43] The *Draft White Paper* examines potential environmental implications and applications of nanotechnology. In so doing, it describes the issues that EPA must address in order to ensure that society benefits from advances in environmental protection that nanotechnology may offer, and also to understand any potential risks posed by exposure to nanomaterials.[44] EPA has received comments on the White Paper from a number of stakeholders.[45]

National Pollution Prevention and Toxics Advisory Committee (NPPTAC). EPA's NPPTAC formed an Interim *Ad Hoc* Work Group on Nanoscale Materials in 2005.[46] The Work Group was charged with facilitating informed discussion on several topics, including the development and implementation of EPA's voluntary nanoscale materials program and issues relevant to the review of new nanoscale materials consisting of chemical substances under the Toxic Substances Control Act.

U.S. House of Representatives. In April 2003, the House

40. *Id.*

41. INTERIM AD HOC WORK GROUP ON NANOSCALE MATERIALS, EPA, DRAFT OVERVIEW OF ISSUE FOR CONSIDERATION BY NPPTAC (2005), *available at* http://www.epa.gov/oppt/npptac/pubs/nanowgoverviewdraft050921finalv2.pdf.

42. *Id.*; EPA, Nanotechnology under the Toxic Substances Control Act, http://epa.gov/oppt/nano/index.htm (last visited Nov. 16, 2006).

43. Nanotechnology Workgroup, EPA, *supra* note 2.

44. *Id.* at vii.

45. *Industry Questions EPA Focus on Preventing Nanotech Pollution*, 7 INSIDE EPA, Feb. 10, 2006.

46. NATIONAL POLLUTION PREVENTION AND TOXICS ADVISORY COMMITTEE, EPA, OVERVIEW DOCUMENT ON NANOSCALE MATERIALS 1 (2005), *available at* http://www.epa.gov/oppt/npptac/pubs/nanowgoverviewdocument20051125.pdf.

Committee on Science held a hearing on the "Societal Implications of Nanotechnology."[47] In November 2005, the House Committee on Science held a second hearing on "Environmental and Safety Impacts on Nanotechnology: What Research is Needed?"[48]

U.S. Senate. The Senate Commerce, Science and Transportation Committee held a hearing in February 2006 on "Developments in Nanotechnology" to examine the status of the nanotechnology field in the United States.[49] The U.S. Senate Committee on Environment and Public Works convened a roundtable discussion with the business sector, the environmental community, and the federal government on April 6, 2006.[50] The U.S. Senate Commerce Committee Subcommittee on Trade, Tourism and Economic Development held a hearing on May 4, 2006, which focused on economic development inspired by nanotechnology.[51] Additional hearings in both the House and Senate are expected.

National Science Foundation (NSF). NSF funds work on a wide variety of nanotechnology issues, including research on the societal implications and the environmental and human health risks associated with nanotechnology.[52] NSF also funds the National Nanotechnology Infrastructure Network, a network of 13 academic research facilities that seeks to facilitate rapid advances in the field of nanotechnology by providing efficient access to nanotechnology

47. *Societal Implications of Nanotechnology: Hearing Before the H. Comm. on Science*, 108th Cong. (2003), *available at* http://www.house.gov/science/hearings/full03/apr09/charter.htm.

48. *Environmental and Safety Impacts on Nanotechnology: What Research is Needed?: Hearing Before the H. Comm. on Science*, 109th Cong. 1 (2005), *available at* http://www.house.gov/science/hearings/full05/nov%2017/charter.pdf; Press Release, House Committee on Science, More Research on Environmental, Safety Impacts on Nanotechnology is Critical to Success of the Industry, Witnesses Say (Nov. 17, 2005), *available at* http://www.house.gov/science/press/109/109-165.htm.

49. *Developments in Nanotechnology: Hearing Before the Senate Comm. on Commerce, Science and Transportation*, 108th Cong. (Feb. 2006) (statement of Sen. Ted Stevens, Chairman, Sen. Comm. on Commerce, Science and Transportation), *available at* http://commerce.senate.gov/hearings/testimony.cfm?id=1736&wit_id=3971.

50. Press Release, Senate Environment and Public Works Committee, Senator Jeffords's Statement on Nanotechnology (Apr. 6, 2006), *available at* http://epw.senate.gov/pressitem.cfm?party=dem&id=253725.

51. *Promoting Economic Development Opportunities Through Nano Commercialization: Hearing Before the Senate Comm. on Trade, Tourism, and Econ. Dev.*, 108th Cong. (May 4, 2006), *available at* http://commerce.senate.gov/hearings/witnesslist.cfm?id=1867.

52. *See generally* National Science Foundation, NSF National Nanotechnology Initiative (NNI), http://www.nsf.gov/crssprgm/nano/ (last visited Mar. 13, 2006).

research infrastructure.[53]

The Food and Drug Administration (FDA). FDA regulates a wide range of products, such as foods, cosmetics, drugs, devices, and veterinary products. Some of these products may contain or utilize nanomaterials. To facilitate the regulation of nanotechnology products, the Agency has formed a NanoTechnology Interest Group (NTIG), which is made up of representatives from all the FDA Centers that may be involved in the regulation of nanotechnologies.[54] In the fall of 2006, FDA will hold a public meeting designed to gather information about current developments in uses of nanotechnology materials in FDA-regulated products. FDA states that it is:

> holding this meeting to further its understanding of developments in nanotechnology and, more specifically, to hear: About the new types of nanotechnology products under development in the areas of foods (including dietary supplements), food and color additives, animal feeds, cosmetics, human and animal drugs and human biologics and medical devices; About any specific scientific issues related to the development of these products relevant to FDA's regulation of them; Any other issues about which regulated industry, academia, and the interested public may wish to inform FDA concerning the use of nanotechnology in FDA-regulated products; and If there are opportunities for the agency to address hurdles that may be inhibiting the use of nanotechnology in medical product development.[55]

The National Institute for Occupational Safety and Health (NIOSH). In late 2005, NIOSH stated that it intended to form an interdisciplinary team of nanotechnology researchers.[56] The team will partner with employers and others in conducting field studies to observe and assess occupational health and safety practices in facilities where nanotechnology processes and applications are used.[57] The team will assess and obtain insight on materials,

53. *See generally* National Nanotechnology Infrastructure Network, http://www.nnin.org (last visited Mar. 13, 2006).

54. U.S. Food & Drug Administration, Nanotechnology, http://www.fda.gov/nanotechnology/index.html.

55. Press Release, U.S. Food & Drug Administration, FDA Announces Plan for Nanotechnology Public Meeting (April 13, 2006), *available at* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01356.html.

56. Press Release, National Institute for Occupational Safety and Health, U.S. Centers for Disease Control and Prevention, Focus on Nanotechnology: NIOSH to Form Field Research Team for Partnerships in Studying, Assessing Nanotechnology Processes (Dec. 27, 2005), *available at* http://www.cdc.gov/niosh/topics/nanotech/newsarchive.html#fieldteam.

57. *Id.*

processes, current and potential worker exposures, work practices, control procedures, and medical monitoring in nanotech operations.[58] The agency will use the information to create a worker exposure database and to update periodically an interim, on-line NIOSH guidance document entitled *Approaches to Safe Nanotechnology*.[59]

2. Private Sector Initiatives

The business community has formed trade groups and other consortia and initiated a variety of efforts:

American Chemistry Council (ACC) Chemstar Nanotechnology Panel. The ACC's Chemstar Nanotechnology Panel consists of producers that are engaged in the manufacture, distribution, and/or use of chemicals and that have a business interest in nanotechnology products. The panel is developing recommendations for EPA and the chemical industry regarding environmental, health, and safety issues and regulatory guidelines for nanomaterials.[60]

NanoBusiness Alliance. The NanoBusiness Alliance is an industry association that seeks to advance the emerging business of nanotechnology and microsystems. The Alliance is engaged in a number of initiatives including research and education, public policy, and public awareness.[61]

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.[62] Three work products are being developed: a chamber

58. *Id.*

59. NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH), APPROACHES TO SAFE NANOTECHNOLOGY: AN INFORMATION EXCHANGE WITH NIOSH, *available at* http://www.cdc.gov/niosh/topics/nanotech/safenano/pdfs/approaches_to_safe_nanotechnology.pdf.

60. *See generally* American Chemistry Council, CHEMSTAR Panels, http://www.americanchemistry.com/s_acc/sec_employment.asp?CID=371&DID=1252 (last visited Mar. 20, 2006); *Environmental and Safety Impacts of Nanotechnology: What Research is Needed? Hearing Before the H. Comm. on Science*, 108th Cong. (Nov. 2005) (statement of Krishna Doraiswamy, DuPont Central Research & Development), *available at* http://www.house.gov/science/hearings/full05/nov%2017/Doraiswamy.pdf.

61. NanoBusiness Alliance, Mission, http://nanobusiness.org/ (follow "About the Alliance" hyperlink) (last visited Nov. 13, 2006).

62. *See* Michele L. Ostraat, Presentation on the Nanoparticle Occupational HS&E

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.[63]

3. Non-Governmental Organizations

Both advocacy and non-advocacy organizations are engaged in nanotechnology issues. Some of their initiatives address environmental, health, and safety issues.

Action Group on Erosion, Technology and Concentration (ETC Group). ETC Group is a non-profit organization "dedicated to the conservation and sustainable advancement of cultural and ecological diversity and human rights."[64] ETC Group 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.[65] ETC Group also advocates for an international, legally binding mechanism based on the Precautionary Principle to regulate nanotechnology.[66]

Center for Biological and Environmental Nanotechnology (CBEN). CBEN, funded by the National Science Foundation and housed at Rice University, fosters the development of nanoscience "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."[67]

Center on Nanotechnology and Society (Nano & Society). Nano & Society is an affiliate of the Institute on Biotechnology and the

Consortium (Oct. 6, 2005), *available at* http://www.cce.umn.edu/pdfs/cpe/conferences/nano/Michele_Ostraat.pdf.

63. *See id.*

64. Action Group on Erosion, Technology and Concentration, About ETC Group, http://www.etcgroup.org/en/about (last visited Nov. 13, 2006).

65. ETC Group, *No Small Matter! Nanotech Particles Penetrate Living Cells and Accumulate in Animal Organs*, 76 ETC COMMUNIQUÉ 1 (2002), *availabe at* http://www.etcgroup.org/upload/publication/192/01/comm_nanomat_july02.pdf.

66. ETC Group, ETC Group response to the Woodrow Wilson Center's paper, Nanotechnology and Regulation, http://www.environmentalfutures.org/Images/nanoetccomments.pdf (last visited Mar. 10, 2006).

67. Center for Biological and Environmental Nanotechnology, Center Vision, http://www.cben.rice.edu/about.cfm?doc_id=4998 (last visited Mar. 8, 2006).

Human Future at Chicago-Kent College of Law in the Illinois Institute of Technology.[68] Nano & Society seeks to "catalyze informed interdisciplinary research, education and dialogue on the ethical, legal, policy, business, and broader societal implications of nanoscale science and technology–all with a special focus on the human condition."[69] Nano & Society hosts the Chicago Nano Forum and sponsors national symposia on related topics.[70]

Center for Nanotechnology in Society (CNS). Funded by the NSF for five years beginning in 2005, the CNS at the University of California, Santa Barbara is designed to serve as a "national research and education center, a network hub among researchers and educators concerned with nanotechnologies' societal impacts, and a resource base for studying these impacts."[71]

Center for Responsible Nanotechnology (CRN). CRN is a non-profit research and advocacy organization that seeks to raise awareness of both the benefits and dangers presented by nanotechnology and the possibilities for responsible use of nanotechnology.[72]

Environmental Defense. Environmental Defense, a national non-profit organization, has called for an increase in federal funding to research the potential risks of nanomaterials.[73] Environmental Defense and DuPont have reached an agreement "to collaborate on a framework for the responsible development, production, use and disposal" of nanomaterials.[74] In addition, Environmental Defense and the American Chemistry Chemstar Nanotechnology Panel developed a Joint Statement of Principles in which each organization agreed on "several fundamental principles on which a governmental program for addressing potential risks of nanoscale materials should be premised."[75]

68. Center on Nanotechnology and Society Home Page, http://nano-and-society.org/index.html (last visited Nov. 13, 2006).

69. *Id.*

70. *Id.*

71. Center for Nanotechnology in Society, University of California, Santa Barbara, About CNS-UCSB, http://www.cns.ucsb.edu/about.html (last visited Nov. 13, 2006).

72. Center for Responsible Nanotechnology, CRN's Vision, Mission, & Purpose, http://www.crnano.org/index.html (last visited Mar. 13, 2006).

73. Denison, *supra* note 5.

74. Environmental Defense, Environmental Defense and DuPont: Global Nanotechnology Standards of Care Partnership, http://www.environmentaldefense.org/article.cfm?contentID=4821 (last visited Nov. 13, 2006).

75. Environmental Defense and American Chemistry Council Nanotechnology Panel,

Environmental Law Institute (ELI). ELI is an independent non-partisan environmental education and policy research center. Through a variety of activities, ELI's Nanotechnology Initiative promotes the adoption of an effective environmental, health, and safety governance structure for nanotechnologies. To that end, ELI has convened two multi-stakeholder symposia on nanotechnologies. In May 2005, ELI and the Woodrow Wilson Center's Project on Emerging Nanotechnologies convened a dialogue on "Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up To the Job?"[76] Dialogue participants included noted scientists, lawyers, and policymakers, and the proceedings were published in a report.[77] In May 2006, ELI co-sponsored with the Vanderbilt Center for Environmental Management Studies a symposium on "Nanotechnology Governance: Environmental Management from an International Perspective." The Symposium brought together over 40 key stakeholders including corporate, government, academic, nonprofit, and law firm practitioners. The purpose of the Symposium was to address from an environmental management perspective the desirability of and potential for an internationally harmonized approach to nanotechnology environmental, health, and safety governance. The Symposium will serve as a launching point for several articles in the November 2006 issue of ELI's Environmental Law Reporter that will focus on nanotechnology governance from an international perspective.[78]

Friends of the Earth (FOE). Founded in 1969, FOE "defends the environment and champions a healthy and just world,"[79] serving as the "voice of an influential, international network of grassroots

Joint Statement of Principles: Comments on EPA's Notice of a Public Meeting on Nanoscale Materials (June 23, 2005), *available at* http://www.environmentaldefense.org/documents/4857_ACC-ED_nanotech.pdf (last visited Mar. 10, 2006).

76. Environmental Law Institute, Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up to the Job?, http://www2.eli.org/research/events/nanotech5.25.05.cfm (last visited Mar. 10, 2006).

77. See the articles published in 36 Envtl. L. Rep. News & Analysis (Envtl. Law Inst.) (Dec. 2006), *available at* http://www.elr.info/NewsAnalysis/index.cfm.

78. Environmental Law Institute, Nanotechnology Governance: Environmental Management from a Global Perspective—Agenda, http://www2.eli.org/research/events/nanotech5.19.06.htm (last visited Nov. 13, 2006).

79. Friends of the Earth, Who We Are, http://www.foe.org/about/whoweare.html (last visited Nov. 13, 2006).

groups in 70 countries."[80] Its nanotechnology project "aims to catalyze debate on what is set to be one of the defining issues of our time." [81] In a report entitled *Nanomaterials, Sunscreens and Cosmetics: Small Ingredients, Big Risks*, FOE calls for a "moratorium on the further commercial release of personal care products that contain engineered nanomaterials, and the withdrawal of such products currently on the market, until adequate, publicly available, peer-reviewed safety studies have been completed, and adequate regulations have been put in place to protect the general public, the workers manufacturing these products and the environmental systems in which waste products will be released."[82] In conjunction with its report, FOE, with the International Center for Technology Assessment and a coalition of consumer, health, and environmental groups, filed a legal petition that asks FDA to take several actions, including but not limited to: classify sunscreens made with nanoscale ingredients as an imminent hazard to public health and recall them until the Agency has developed regulations for products made with nanotechnologies; conduct an environmental impact statement under the National Environmental Policy Act to determine how the policies FDA will use to address nanotechnologies would affect the environment; require toxicity tests for nanomaterials; and mandate that products such as cosmetics that contain nanoparticles be labeled. Additional organizations on the petition included Greenpeace International, The Action Group on Erosion, Technology, and Concentration (ETC Group), Clean Production Action, The Center for Environmental Health (CEH), Our Bodies Ourselves, and The Silicon Valley Toxics Coalition (SVTC).[83]

International Risk Governance Council (IRGC). IRGC, an independent foundation, is a public-private partnership that supports governments, businesses, and other organizations

80. Friends of the Earth, About, http://www.foe.org/about/index.html (last visited Nov. 13, 2006).

81. Friends of the Earth, Campaigns, http://www.foe.org/camps/comm/nanotech/index.html (last visited Nov. 13, 2006).

82. FRIENDS OF THE EARTH, NANOMATERIALS, SUNSCREENS AND COSMETICS: SMALL INGREDIENTS, BIG RISKS, 2 (2006), *available at* http://www.foe.org/camps/comm/nanotech/execsummaryappendix.pdf.

83. The International Center for Technology Assessment v. Von Eschenbach, Docket No. 2006p0210, (May 2006), *available at* http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf.

worldwide.[84] IRGC aims to help improve the anticipation and governance of global, systemic risks.[85] With respect to the development of nanotechnology and nanoscale products, IRGC is developing frameworks for adequate risk governance approaches at the national and international levels.[86] IRGC is conducting surveys on the role of governments, non-governmental organizations, industry, and research organizations in nanotechnology risk governance. Findings from the surveys that have been completed, reports on two expert workshops, and an IRGC white paper will be used to develop its initial risk governance recommendations, which are expected to be published in July 2006.[87]

Meridian Institute. The Meridian Institute is a non-profit organization that convenes decision makers and diverse stakeholders to address public policy issues.[88] One of its current projects is a "Global Dialogue on Nanotechnology and the Poor," which will identify ways in which nanotechnology might play a role in the development process.[89]

Woodrow Wilson International Center for Scholars. In collaboration with the Pew Charitable Trusts, the Woodrow Wilson Center launched the Project on Emerging Nanotechnology in April 2005. The project aims to help "ensure that as nanotechnologies advance, possible risks are minimized, public and consumer engagement remains strong, and the potential benefits of these new technologies are realized."[90] The Project has compiled and made publicly available a global inventory of current government-funded research into the human health, safety, and environmental

84. International Risk Governance Council, About the IRGC, http://www.irgc.org/ (last visited Mar. 13, 2006).

85. *Id.*

86. INTERNATIONAL RISK GOVERNANCE COUNCIL, SURVEY ON NANOTECHNOLOGY GOVERNANCE: VOLUME A. THE ROLE OF GOVERNMENT 5 (2005), *available at* http://www.irgc.http://www.irgc.org/irgc/projects/nanotechnology/_b/contentFiles/Survey_on_Nanotechnology_Governance_-_Part_A_The_Role_of_Government.pdf.

87. IRGC WORKING GROUP ON NANOTECHNOLOGY, SURVEY ON NANOTECHNOLOGY GOVERNANCE, Volume D. The Role of NGOs 4 (2006), *available at* http://www.irgc.org/irgc/projects/nanotechnology/_b/contentFiles/Survey_on_Nanotechnology_Governance_-_Part_D_The_Role_of_NGOs.pdf.

88. Meridian Institute, About Meridian, http://www.merid.org/about.html (last visited Mar. 10, 2006).

89. Meridian Institute, Global Dialogue on Nanotechnology and the Poor, http://www.meridian-nano.org (last visited Mar. 10, 2006).

90. Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, http://www.wilsoncenter.org/nano (last visited Mar. 8, 2006).

implications of nanotechnology.[91] The Project also has released a report on nanotechnology governance by J. Clarence Davies, which describes "the menu of possibilities for government action to deal with the adverse effects of nanotechnology" and provides "evidence relevant for determining what needs to be done to manage nanotechnology."[92] Also, the Project on Emerging Nanotechnologies has recently launched a GreenNano series to highlight efforts to ensure that the environmental and health risks posed by nanotech products are minimized during both production and consumption.[93]

4. International

Several international initiatives are underway to address nanotechnology-related issues, some of which focus on environmental, health, and safety concerns.

European Union (EU). The European Commission, the Executive body of the EU, 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 2013. One of the nine areas is nanotechnology, which has the fourth largest budget of just under 5 billion euros.[94] The EU also sponsors nanoforum.org, a website that provides information to industry, academia, and the public.[95] The European Commission issued a Communication in 2004 entitled: *Towards a European Strategy for Nanotechnology*. The Communication highlights the need: "(a) to identify and address safety concerns (real or perceived) at the earliest possible stage; (b) to reinforce support

91. Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, Nanotechnology Health and Environmental Implications: An inventory of current research, http://www.nanotechproject.org/index.php?id=18 (last visited Nov. 13, 2006).

92. J. CLARENCE DAVIES, WOODROW WILSON INTERNATIONAL CENTER FOR SCHOLARS, MANAGING THE EFFECTS OF NANOTECHNOLOGY 1 (2006).

93. Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Green Nanotechnology: What Does it Mean to be Green?, http:// www.nanotechproject.org/ index.php?id=42 (last visited Mar. 10, 2006).

94. COMMUNITY RESEARCH AND DEVELOPMENT INFORMATION SERVICE, EUROPEAN UNION, PROPOSAL FOR A DECISION ON THE EUROPEAN PARLIAMENT AND THE COUNCIL CONCERNING THE SEVENTH FRAMEWORK PROGRAMME OF THE EUROPEAN COMMUNITY FOR RESEARCH, TECHNOLOGICAL DEVELOPMENT AND DEMONSTRATION ACTIVITIES (2007-2013) 48 (2005) *available at* http://ica.cordis.lu/documents/documentlibrary/2461EN.pdf.

95. nanoforum.org, http://www.nanoforum.org (last visited Mar. 20, 2006).

for the integration of health, environmental risk, and other related aspects in R&D activities together with specific studies; [and] (c) to support the generation of data on toxicology and ecotoxicology (including dose response data) and evaluate potential human and environmental exposure."[96]

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 "develop and communicate information regarding potential environmental and health risks of nanotechnology, thereby fostering risk reduction while maximizing societal benefit."[97] In August 2005, ICON released an online database[98] of scientific findings related to the environmental, health, and safety impacts of nanoparticles.[99]

Organisation for Economic Co-operation and Development (OECD). The OECD has held a series of sessions and workshops on the environmental, health, and safety implications of nanomaterials. A recent OECD workshop (hosted by the United States) on the "Safety of Manufactured Nanomaterials" was held under the auspices of the OECD's Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.[100] The OECD and Allianz published a report in 2005 on the "Opportunities and Risks of Nanotechnologies."[101]

United Kingdom (UK). The Royal Society, the UK National Academy of Science, the Royal Academy of Engineering, and the

96. EUROPEAN COMMISSION, TOWARDS A EUROPEAN STRATEGY FOR NANOTECHNOLOGY 20 (2004) *available at* http://ec.europa.eu/research/industrial_technologies/pdf/nanotechnology_communication_en.pdf.

97. International Council on Nanotechnology, Mission and Strategy, http://icon.rice.edu/ about.cfm?doc_id=4379 (last visited Mar. 20, 2006).

98. International Council on Nanotechnology, ICON EHS Database, http://icon.rice.edu/research.cfm (last visited Mar. 9, 2006).

99. Press Release, International Council on Nanotechnology, Nano Coalition Unveils Environmental, Health and Safety Database—ICON Collects Diverse Scientific Findings (Aug. 19, 2005).

100. Organisation for Economic Co-operation and Development [OECD], OECD Workshop on the Safety of Manufactured Nanomaterials, Description of the Workshop (2005) (on file with author); OECD, ENVIRONMENTAL DIRECTORATE, JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS, PESTICIDES, AND BIOTECHNOLOGY, REPORT OF THE OECD WORKSHOP ON THE SAFETY OF MANUFACTURED NANOMATERIALS: BUILDING CO-OPERATION, CO-ORDINATION AND COMMUNICATION (2006).

101. OECD AND ALLIANZ, SMALL SIZES THAT MATTER: OPPORTUNITIES AND RISKS OF NANOTECHNOLOGIES (2005), *available at* http://www.oecd.org/dataoecd/4/38/35081968.pdf.

UK National Academy of Engineering released a report commissioned by the UK Government in July 2004 entitled *Nanoscience and Nanotechnologies: Opportunities and Uncertainties.*[102]

5. Voluntary Guidelines and Standards

Several efforts are underway to develop standards related to nanotechnologies.

American National Standards Institute (ANSI). ANSI is a non-profit organization that coordinates "the development and use of voluntary consensus standards in the United States and represents the needs and views of U.S. stakeholders in standardization forums around the globe."[103] 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.[104] ANSI also accredited a U.S. Technical Advisory Group (TAG) to the International Organization for Standardization's Nanotechnologies TC-229 (see below). The TAG is responsible for formulating U.S. positions on nanotechnology standardization and includes more than 45 representatives from academia, government, industry, non-government, and standards developing organizations.[105]

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

102. THE ROYAL SOCIETY & THE ROYAL ACADEMY OF ENGINEERING, NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES (2004), *available at* http://www.nanotec.org.uk/finalReport.htm.

103. American National Standards Institute, About ANSI Overview, http://www.ansi.org/about_ansi/overview/overview.aspx?menuid=1 (last visited Mar. 15, 2006).

104. American National Standards Institute, ANSI Nanotechnology Standards Panel, http://www.ansi.org/standards_activities/standards_boards_panels/nsp/overview.aspx?menuid=3 (last visited Nov. 13, 2006).

105. Press Release, American National Standards Institute, Report from the inaugural meeting of the U.S. TAG to ISO TC 229-*Nanotechnologies* (2005), *available at* http://public.ansi.org/ansionline/Documents/Standards%20Activities/ANSI-NSP/Report%20-%20TC%20229%20Meeting.pdf.

Cooperation, and Standards of Care/Product Stewardship.[106]

Foresight Nanotech Institute. Foresight is a nonprofit organization whose goal is to ensure that nanotechnology improves the human condition.[107] In an attempt to ensure safer development of nanotechnology, the Foresight Institute has issued voluntary guidelines in the form of self-assessment scorecards for nanotech professionals, industry, and government regulators.[108]

International Organization for Standardization (ISO). ISO is a network of the national standards institutes of 157 countries.[109] ISO's Technical Committee (TC) 229, on Health, Safety, and Environmental Aspects of Nanotechnologies is tasked with "classification, terminology, and nomenclature, basic metrology, characterization (including calibration and certification), risk, and environmental issues."[110] The Committee includes 28 participating countries and 8 observer countries. [111]

II. GOVERNANCE STRUCTURE THEMES

Nanotechnologies present an important opportunity to rethink governance options, explore innovative ways to apply environmental law to emerging technologies, and build public and investor confidence that the risks will be adequately managed. To do this, EPA and other agencies with responsibility for addressing the potential risks posed by nanotechnologies must place a high priority on answering the legal and policy questions central to creating an effective governance approach. This Part outlines the themes that should guide the development of a governance structure.

The themes set forth are based on the collective experience of the authors in their decades of working on environmental

106. ASTM International, Committee E56 on Nanotechnology, http://www.astm.org/COMMIT/COMMITTEE/E56.htm (last visited Mar. 20, 2006).

107. Foresight Nanotech Institute, About the Foresight Nanotech Institute, http://www.foresight.org/about/index.html (last visited Mar. 20, 2006).

108. Foresight Nanotech Institute, Foresight Guidelines Version 4.0, http://www.foresight.org/guidelines/current.html (last visited Mar. 20, 2006).

109. International Organization for Standardization, Overview of the ISO system, http://www.iso.org/iso/en/aboutiso/introduction/index.html (last visited Mar. 15, 2006).

110. International Organization for Standardization, TC 229 Nanotechnologies, http://www.iso.org/iso/en/stdsdevelopment/tc/tclist/TechnicalCommitteeDetailPage.TechnicalCommitteeDetail?COMMID=5932 (last visited Mar. 15, 2006).

111. *Id.*

regulatory issues in both the private and public sectors. The themes reflect observations made over the years from both inside and outside state and federal government with respect to: the specific issues associated with developing a governance structure for new technologies; effective approaches generally for administering the major environmental laws and corresponding regulations; use of alternative governance approaches in lieu of or to augment traditional regulation; administrative agencies' strengths and weaknesses in adapting to new governance challenges; and the importance of public involvement and information dissemination.

The themes also are based, in part, on issues highlighted by participants at a dialogue that ELI and the Woodrow Wilson Center for International Scholars' Project on Emerging Nanotechnologies convened in May 2005 on "Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up To the Job?" Noted scientists, lawyers, and policymakers were asked to examine 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 implications of nanotechnologies. The workshop 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 that nanotechnologies may pose are appropriately and proactively addressed in ways that both protect the public and enhance industry competitiveness. The conclusions and recommendations presented in this paper draw in part on the workshop discussions but represent the views of the authors. This document does not represent a consensus viewpoint of the workshop participants or the views of any particular participant.[112]

A. The Need is Urgent to Develop an Effective Environmental, Health, and Safety Governance Structure for Nanotechnologies

As discussed above, nano-based products are already on the market and the numbers have increased considerably over the last

112. Environmental Law Institute, Nanotechnology Initiative, http://www2.eli.org/research/nanotech.htm (last visited Nov. 15, 2006) (summarizing the workshop discussions and presentations by some of the participants).

two years.[113] Workers in nanotech manufacturing facilities and laboratories are potentially being exposed to nanomaterials, and consumers are already using products that rely on various types of engineered nanoparticles. Even though nano-based industries are at an early stage of growth, it is likely that nanomaterials are already being emitted into the air, discharged into the water, disposed of, and shipped through the domestic and global economy with minimal, if any, federal or state review and little available research about the possible effects on human health and the environment.[114]

Unless significantly more resources are devoted to this effort in the near term, nanotechnologies could fail to realize their potential and unnecessary harm to the public and environment could result. Such a scenario would be particularly unfortunate, because nanotechnology presents the opportunity to apply lessons learned from experiences in analogous situations, such as the regulation of biotechnology, where in some countries public trust in the technology was undercut.[115] It also would be regrettable because some new nano-based products and manufacturing processes promise enormous health and environmental improvements over existing medical, energy, and industrial applications. Finally, an effective governance structure for nanotechnology also could be useful in the future when new scientific advancements and greater technological convergence, discussed above, present similar challenges.

B. Human Health and Eco-Toxicity Data Are Essential to the Development of an Effective Governance Structure

Effective regulatory oversight and stewardship depends in large part on the development of data on human health and eco-toxicity. The science and data necessary for assessing the risks posed by nanotechnology, however, may not be reliable for many years. It is necessary, therefore, to determine data generation priorities in order to ensure that data are developed as quickly and efficiently as possible, to manage risks in the interim as the data develop, and to

113. *See* PROJECT ON EMERGING NANOTECHNOLOGIES, *supra* note 4.

114. *See* Renewable Natural Resources Foundation, *supra* note 18; *see also* Pat Phibbs, *Toxic Substances Manufacturer of New Carbon Nanotube Approved by EPA Under an Exemption,* B.N.A DAILY ENVIRONMENT REPORT, Oct. 21, 2005, at A-1 (noting that this approval marks first time that EPA has approved a new chemical specifically identified as nano).

115. E. Donald Elliott, *Regulate Nano Now*, July/Aug. 2005 ENVTL. F. 43, 43.

allocate the data development burden between the public and private sectors and potentially among the major countries investing in the development of nanotechnologies.[116] Research and data collection should continually inform and proceed in tandem with efforts to develop an effective governance structure.

EPA has taken steps toward prioritizing research needs in its recent White Paper,[117] but the White Paper does not address the allocation of the research burden or how to ensure that data are developed as quickly and efficiently as possible. Furthermore, EPA's Nanoscale Materials Stewardship Program[118] will be more likely to attract volunteers if there is a well-defined research agenda and an efficient and equitable allocation of responsibilities between the public and private sectors.

C. An Integrated, Multi-Faceted Governance Structure Is Likely to Be Most Effective

A multi-pronged approach is likely to be the most effective way to address environmental, health, and safety concerns, given the complexity and likely pervasiveness of the technology, the uncertainty regarding the potential hazards, and the multimedia nature of the environmental problems that could arise. A multi-pronged approach could include elements of regulatory and voluntary programs under existing environmental statutes; corporate stewardship; tort liability; federal, state, and local legislation; voluntary standards; disclosure; liability insurance; and international measures. Developing the optimal mix of these tools is a significant aspect of the governance challenge.

D. Adaptation and Integration of Existing Laws Will Be Necessary

Because there are no nanotechnology-specific laws and regulations, and the enactment of new nanotechnology legislation related to human health and the environment is unlikely, at least in the near term, it will be necessary to use existing legal authorities

116. Environmental Law Institute, Comments of the Environmental Law Institute on the Environmental Protection Agency's Nanotechnology White Paper 3 (Jan. 21, 2006), *available at* http://www2.eli.org/pdf/research/nanotech/eli.nano.white.paper.comments.pdf (noting that this is an issue that could be addressed by the Organization for Economic Cooperation and Development's Chemicals Committee).

117. *See generally* Nanotechnology Workgroup, EPA, *supra* note 2.

118. Nanoscale Materials; Notice of Public Meeting, *supra* note 38.

and adapt current programs to regulate nanotechnologies.[119] Reliance on a single statute such as the Toxic Substances Control Act (TSCA),[120] however, is unlikely to suffice. Although TSCA is often cited as the most appropriate vehicle for addressing environmental, health, and safety concerns associated with nanotechnologies, TSCA may not be an ideal instrument.[121] Accordingly, a multi-statute approach that draws on both product-based and facility-based laws may be needed and should be explored. To use any existing authorities effectively, however, amendments to regulations and the issuance of new policies and guidance are likely to be necessary, as discussed below.

Furthermore, although enactment of new laws ultimately may be appropriate and necessary for the effective regulation of nanotechnologies,[122] a focus on how to use current statutes and regulations will facilitate the identification of gaps and needs with

119. DAVIES, *supra* note 92, at 17.

120. Toxic Control Substances Act (TSCA), Pub. L. 94-469, 90 Stat. 2003 (codified at 15 U.S.C. §§ 2601-92). As described by the Congressional Research Service: "The Toxic Substances Control Act . . . authorizes EPA to screen existing and new chemicals used in manufacturing and commerce to identify potentially dangerous products or uses that should be subject to federal control. . . . EPA may require manufacturers and processors of chemicals to conduct and report the results of tests to determine the effects of potentially dangerous chemicals on living things. Based on test results and other information, EPA may regulate the manufacture, importation, processing, distribution, use, and/or disposal of any chemical that presents an unreasonable risk of injury to human health or the environment. A variety of regulatory tools is available to EPA under TSCA ranging in severity from a total ban on production, import, and use to a requirement that a product bears a warning label at the point of sale. TSCA directs EPA to use the least burdensome option that can reduce risk to a level that is reasonable given the benefits provided by the chemical product or process." LINDA SCHIEROW, CONGRESSIONAL RESEARCH SERVICE, SUMMARIES OF ENVIRONMENTAL LAWS ADMINISTERED BY THE EPA: TOXIC SUBSTANCES CONTROL ACT, *available at* http://www.cnie.org/NLE/CRSreports/BriefingBooks/Laws/k.cfm.

121. DAVIES, *supra* note 92, at 11-12 (describing TSCA as a "weak regulatory instrument," because: the statute requires EPA to meet a variety of requirements before it can regulate a chemical; the standard of judicial review is unusually difficult for EPA to meet in litigation challenging rules it issues under the statute; and the statute implicitly assumes that "no knowledge about a chemical means there is no risk."); *see also* Renewable Natural Resources Foundation, *supra* note 18, at 21 ("delegates were concerned that current regulatory frameworks are inadequate to assess nanomaterial compounds with vastly different structures and properties than those compounds in existing regulated materials. . . .[c]obbling together pieces of existing regulatory processes is a prescription for failure."); *cf.* American Chemistry Council Nanotechnology Panel, Views of the American Chemistry Council Nanotechnology Panel on the Broad Scope of EPA's Authority Under TSCA to Address Any Potential Risks From Engineered Nanoscale Materials 2 (Mar. 2006)(concluding that "EPA has ample authority to address any potential risk that engineered nanoscale materials may pose.") (on file with author).

122. DAVIES, *supra* note 92, at 18-21.

respect to new legal authorities. In any event, a plan to regulate under existing laws is essential, as it may take many years to enact a new law.[123]

The integrated use of existing laws and programs will present substantial regulatory challenges because nanotechnologies create multi-media pollution problems; span a wide range of industries, sectors, and federal regulatory agencies; have a multitude of current and potential applications; and present cross-media trade-offs.[124] Not only will it be important to ensure the adequacy of statutory and regulatory authorities, but it will be necessary to address barriers to implementing those authorities, which include insufficient program budgets and human resources and long time frames for rulemakings.

In addition to EPA, several other federal agencies have jurisdiction over nanotechnology environmental, health, and safety issues, such as the Food and Drug Administration, the Occupational Health and Safety Administration, and the Consumer Product Safety Commission (CPSC).[125] These agencies will need to coordinate their efforts to avoid duplication, avoid gaps, and ensure consistent and complementary approaches.

Furthermore, as noted above, although EPA has recognized the importance of collaborations with other countries on harmonized approaches for data generation and assessment efforts,[126] it is also important to consider governance frameworks for nanotechnologies in the same vein. For example, the European Commission has stated that it will "promote . . . international debate or consensus on issues that are of global concern, such as public health, safety, the environment, consumer protection, risk assessment, regulatory approaches, metrology, nomenclature, and norms. . . ."[127] Similarly, J. Clarence Davies notes in a recent report

123. RICHARD JAMES LAZARUS, THE MAKING OF ENVIRONMENTAL LAW (2004) (discussing the barriers to enactment of environmental laws).

124. *See* Mark Greenwood, Presentation at the Environmental Law Institute and Woodrow Wilson International Center for Scholars dialogue "Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up to the Job?": Securing the Promise of Nanotechnology: Challenges to the Federal Regulatory System, (May 25, 2005), *available at* http://www2.eli.org/pdf/research/nanotech/Presentations/Greenwood.pdf.

125. The CPSC has issued a statement on nanotech. CPSC, CPSC Nanomaterial Statement, *available at* http://www.cpsc.gov/LIBRARY/CPSCNanoStatement.pdf (last visited Nov. 15, 2006).

126. Nanotechnology Workgroup, EPA, *supra* note 2, at 80.

127. EUROPEAN COMMISSION, *supra* note 96, at 21.

that a "regulatory regime" for nanotechnologies "should have international coordination built into it."[128]

E. An Interim Governance Approach Will Be Needed

The development of a multi-faceted approach may take considerable time due to data limitations, resource deficits, and administrative constraints. There is an immediate need, therefore, to take steps to ensure that the current manufacture, use, and disposal practices for nanomaterials and products containing them are protective of human health and the environment. Thus, the development of an interim governance approach, in addition to a permanent long-term structure, is essential. It is crucial that this interim approach be systemic and look across programs, statutes, and potential voluntary initiatives.

F. The Governance Structure Must Be Developed in a Manner That Informs the Public and Meaningfully Involves Stakeholders

Because of the technical nature of nanotechnologies, the rapid introduction of nanoproducts into the market, and the limited data on environmental, health, and safety effects, the potential exists for public controversy that could impede unnecessarily the development and deployment of nanotechnologies.[129] The delivery of accurate information to the public is critical. Whether an independent dialogue is convened or stakeholders participate in private and public initiatives as they arise, it is important to ensure the representation of a wide range of interests. It is especially important to consider the needs of small businesses and start-up firms in the development of such a governance framework.[130]

128. DAVIES, *supra* note 92, at 1.

129. MACOUBRIE, *supra* note 11, at 8 ("[M]ost people participating in the study had little initial awareness of nanotechnology. . . . [A]sked if nanotechnology is predicted to become another industrial revolution (true), 75% said 'don't know' and 24% answered 'true.'"); Balbus et al., *supra* note 5, at 70 ("government and industry need to engage . . . stakeholders and consider their views in deciding how to develop and manage this promising technology in a way that maximizes benefits and minimizes it risks").

130. As explained in EPA's Small Business Strategy: "Small businesses stated that they face many challenges in their attempt to be good, responsible environmental stewards. The biggest concern small businesses expressed to the Agency is that they do not know what requirements apply to them, whom to contact, or how to comply. If and when they do find out what is required, they stated that they are frequently confused by duplicative, overlapping or conflicting requirements, many of which have been designed for larger entities with no down-scaling options. Because small businesses fear being targeted, they are

III. A NANOTECHNOLOGY GOVERNANCE RESEARCH AGENDA

This Part outlines the principal issues and questions that arise with respect to the development of a nanotechnology governance structure that is based, at least in part, on existing U.S. laws. This initial set of issues and questions highlights the need for a comprehensive, integrated research agenda that will serve as a basis for developing a governance structure. It is clear that substantial work is required to lay this foundation and that, in addition to the development of human health and eco-toxicity data, considerable policy and legal analyses should be conducted.

A. Regulation Under Existing Major Environmental Statutes

Although no current U.S. laws or regulations are specifically designed to regulate nanotechnology, several statutes, most notably TSCA, possibly could be used to regulate nanomaterials. Effective regulation will require an assessment of the adequacy of existing statutes and regulations and the identification of any necessary statutory and regulatory modifications.

In addition to statute-specific questions, myriad over-arching issues will need to be addressed, including: whether nanomaterials differ from conventional materials for purposes of regulation; what a rational system for nanotech regulation would look like; and whether regulation can be achieved within the current regulatory structure. Additional issues to address include: whether new policies, guidance, and governance tools are needed to move forward with the regulation of nanotechnology in a responsible, efficient, and effective manner; whether new statutory authorities, if any, are needed; where EPA should focus its limited resources for purposes of regulating nanotechnology; to what extent media-specific and industry-specific environmental laws and programs

reluctant to call environmental agencies for more information. Small businesses stated that they need short, clear, concise, easy-to-read and easy-to-find information both in hardcopy and on-line. Additionally, many small businesses believe that the cost of compliance for them provides a disadvantage compared to the same costs applied to large entities." Unifying EPA's Small Business Activities: A Strategy to Meet the Needs of Small Businesses (June 27, 2003), *available at* http://www.epa.gov/sbo/pdfs/strategyfinal2003.pdf; *see also* Richard J. Pierce, Jr., *Small is Not Beautiful: The Case Against Special Regulatory Treatment of Small firms*, 50 ADMIN. L. REV. 537, 559 (1998) (noting that small firms are "responsible for a massively disproportionate share of water and air pollution," in part because they are not subject to the same regulatory controls as large firms).

limit EPA's ability to address effectively nanotechnology; whether lessons can be learned from the experience of Europe, the U.S, and other countries with biotechnology regulation; and whether new information is needed to assess the adequacy of the current regulatory structure.

The remainder of this Part looks at each of the major environmental statutes that EPA administers to identify issues and questions that should be addressed in an effort to assess the applicability of existing laws for purposes of addressing environmental, health, and safety concerns.

1. Toxic Substances Control Act

As noted above, TSCA is frequently cited as the most appropriate existing statute for nanotechnology regulation. It is not viewed as an ideal vehicle, however, and many issues will need to be addressed if TSCA is to be used effectively as the principal statute for regulating nanotechnology. These issues include: approaches for making determinations with respect to "new" versus existing chemicals under TSCA (i.e., is nanomaterial with the same molecular structure as a substance listed on the TSCA Inventory a new chemical if it has chemical, physical, and biological properties that differ?); whether specific guidelines for identifying nanoscale materials on the TSCA Inventory would make the process of determining whether substances are "new" or "existing" more predictable and/or transparent; and whether the current TSCA exemptions for research and development, low volume manufacture, low environmental releases and human exposure with low volume, and limited test marketing should apply to nanomaterials—given the higher level of activity per unit mass for nano as opposed to conventional materials.[131]

In addition, it is important to consider the factors and approaches for determining whether nanomaterials constitute a

131. Karen Florini, Presentation at the Environmental Law Institute and Woodrow Wilson International Center for Scholars dialogue: No Small Matter: Can TSCA Get Nano Right the First Time? (May 25, 2005), *available at* http://www2.eli.org/pdf/research/nanotech/Presentations/Florini_A.pdf; Lynn L. Bergeson, Presentation at the Environmental Law Institute and Woodrow Wilson International Center for Scholars dialogue: Applicability of U.S. Environmental Laws to Assess, Prevent, and Control Risks of Nanotechnology: TSCA, (May 25, 2005), *available at* http://www2.eli.org/pdf/research/nanotech/Presentations/Bergeson.pdf (last visited Mar. 20, 2006); *cf.* American Chemistry Council Nanotechnology Panel, *supra* note 121.

significant new use under TSCA Section 5.[132] For example, it is critical to identify the hazard and exposure data needed to characterize potential risks of nanotechnologies for PMN purposes. Furthermore, it would be useful to review the benefits and drawbacks of issuing a TSCA Section 8(a) Rule[133] in order to obtain reporting of information on the manufacture or processing of nanoscale materials consisting of existing chemicals. The basis for determining "substantial risk" under Section 8(e) with respect to nanomaterials is also a key consideration.

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,[134] none of which exists as applied to nanoscale materials. It is important to consider whether, absent export notification, nanoscale materials could be exported for use, processing, or disposal anywhere in the world without any tracking ability and, if so, whether this is desirable or should be addressed in some manner.[135]

Finally, if TSCA is used as the primary vehicle at the front end for regulating nanotechnology, it is critical to consider how it will interface with the other core environmental statutes EPA administers, such as the Clean Air Act, Clean Water Act, Comprehensive Environmental, Response, Compensation and Liability Act, and Resource Conservation and Recovery Act, which also may have a role in regulating nanotechnologies.

2. Resource Conservation and Recovery Act (RCRA)[136] & Comprehensive Environmental Response, Compensation,

132. 15 U.S.C. § 2604.

133. *Id.* § 2607(a).

134. *Id.* § 2611(b).

135. Bergeson, *supra* note 131.

136. 42 U.S.C. §§ 6901-6992k (2006); JAMES E. MCCARTHY AND MARY TIEMANN, CONGRESSIONAL RESEARCH SERVICE, SUMMARIES OF ENVIRONMENTAL LAWS ADMINISTERED BY THE EPA: SOLID WASTE DISPOSAL ACT/RESOURCE CONSERVATION AND RECOVERY ACT (2006), *available at* http://www.cnie.org/NLE/CRSreports/BriefingBooks/Laws/h.cfm ("The Resource Conservation and Recovery Act of 1976 (RCRA) established the federal program regulating solid and hazardous waste management. RCRA actually amends earlier legislation (the Solid Waste Disposal Act of 1965), but the amendments were so comprehensive that the Act is commonly called RCRA rather than its official title.").

and Liability Act (CERCLA)[137]

In its 2004 study, the Royal Society and Royal Academy of Engineering concluded that the risk of releasing nanomaterials would be highest during disposal, destruction, or recycling.[138] Waste from nanotechnology facilities could be regulated under RCRA if such wastes meet the applicable criteria (e.g., are listed or characteristic wastes).[139] CERCLA also may provide authority to impose liability for releases of nanomaterials.

In considering these statutes, the following issues, among others, should be considered: whether RCRA is sufficiently flexible to allow for regulation of any new or currently-unknown hazards associated with nanowaste; whether RCRA waste identification rules could be modified with sufficient clarity in the foreseeable future to capture specific nanowaste streams (listed wastes) or through a narrative standard to capture the "characteristic" of a nanohazard; the role of state waste programs in regulating nanotechnology, either as a complement to or in lieu of federal regulation; whether some nanomaterials will constitute "hazardous substances" under CERCLA; and whether CERCLA cleanup standards and processes effectively can address hazardous substances that are nanoscale in dimension.[140]

3. Clean Air Act and Clean Water Act

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

137. 42 U.S.C. §§ 9601-9675; MARK REISCH, CONGRESSIONAL RESEARCH SERVICE, SUMMARIES OF ENVIRONMENTAL LAWS ADMINISTERED BY THE EPA: SUPERFUND, Congressional Research Service Report RL30022 (2006), *available at* http://www.cnie.org/nle/crsreports/briefingbooks/laws/j.cfm ("CERCLA authorizes the federal government to respond to spills and other releases (or threatened releases) of hazardous substances, as well as to leaking hazardous waste dumps.").

138. THE ROYAL SOCIETY & THE ROYAL ACADEMY OF ENGINEERING, *supra* note 102.

139. Under RCRA, there are two ways that a solid waste can qualify as a hazardous waste: the solid waste exhibits one or more of the characteristics of hazardous waste described in EPA regulations or the solid waste specifically is listed in EPA regulations. 40 C.F.R. §§ 261.21-.24, .31-.33.

140. *See, e.g.*, Tracy Hester, Presentation at the Environmental Law Institute and Woodrow Wilson International Center for Scholars dialogue: RCRA and CERCLA in the New World of Nanoscale Materials (May 25, 2005), http://www2.eli.org/pdf/research/nanotech/ Presentations/Hester.pdf (last visited Mar. 20, 2006).

potential regulatory vehicles.[141] For example, EPA has established National Ambient Air Quality Standards for fine particulates of less than 2.5 micrometers.[142] It is possible that these standards, as 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.[143] Potential authorities under the Clean Water Act include but are not limited to: technology-based and water quality-based effluent limitations for sources requiring national pollutant discharge and elimination system permits, and pretreatment standards for other sources.[144]

In considering the use of these statutes, issues to address include: the provisions of the Clean Air and Clean Water Acts that could be used most effectively to regulate nanotechnologies; the benefits and drawbacks of using these statutory authorities (e.g., the discretionary or inflexible nature of authorities); whether certain authorities should be modified to apply more effectively to nanoscale materials; whether monitoring could be accomplished using existing techniques, given the size and other characteristics of nanoparticles; and how to develop new technologies and methods, if needed.

4. The Path Forward

The breadth and depth of the issues outlined above indicate the need for a comprehensive analysis of existing legal authorities and the development of a regulatory blueprint. Specifically, the major environmental, health, and safety statutes should be analyzed to identify authorities to regulate nanotechnologies, as well as to identify potential gaps in the legal authorities needed by federal and state agencies to regulate effectively. In addition, a comprehensive analysis of EPA regulations, policies, and guidance issued under the major environmental statutes would help determine how they could be revised or interpreted to address

141. *But see* DAVIES, *supra* note 92, at 14-15 (concluding that "it is hard to imagine how these laws could be used to manage the adverse effects of NT products" due to detection problems among others.).

142. 40 C.F.R. § 50 (2006).

143. 42 U.S.C. § 7409 (2006).

144. 33 U.S.C. §§ 1313, 1317(a), 1342 (2000).

nanotechnologies more effectively. The analysis could include, for example, suggested changes to TSCA regulations that would make volume-based exemptions more appropriate when applied to nanotechnologies, as all current exemptions clearly apply to conventional "macro" chemical substances. It also could provide guidance as to when a nanomaterial is a "new" chemical or constitutes a "new use" of a chemical. In addition, the analysis could highlight data and disclosure-related authorities under environmental, health, and safety laws and regulations that could be used or modified to foster the development and dissemination of environmental, health, and safety data.

Based on the statutory and regulatory analysis, a blueprint for an integrated, multi-statute approach for regulating nanotechnologies could be developed. The blueprint would draw on the strengths of the various programs and address the advantages and disadvantages of reliance on particular statutes and regulations. The blueprint should be designed to incorporate into the nanotechnology governance structure a full life cycle perspective that includes, for example, basic research and development, manufacturing, and product use and disposal. Ideally, the research would examine how various statutory tools could apply at each stage in the life cycle of nanotechnologies. The blueprint also could identify ways in which regulatory programs may need to be tailored to small and medium-sized nanotechnology companies.

In addition, effective management and implementation of any legal authorities and administrative tools will be essential to the development of an effective governance structure. An analysis of lessons learned from experiences with biotech, PCBs, DDT, and similar regulatory efforts could facilitate implementation. Furthermore, an assessment of administrative barriers to using existing legal authorities should be conducted and could address administrative, budgetary, planning and similar constraints in implementing an effective governance approach. The effort to develop an effective governance structure also would benefit from an analysis of available funding mechanisms to support research, data collection, and data evaluation, and from estimates of cost and resource burdens on agencies and businesses.

B. Alternatives to Traditional Regulation

Non-regulatory mechanisms such as voluntary programs are likely

to be an important component of the environmental, health, and safety governance structure for nanotechnologies. Non-regulatory mechanisms can temporarily fill gaps in current regulatory authorities, they can address some regulatory concerns with a minimum of cost, and they can address potential information asymmetries between industry and government agencies, particularly in the early stages of the development of nanotechnologies. Furthermore, because of the fast pace at which nanotechnologies are developing, it may be difficult, if not impossible, for traditional regulatory mechanisms to keep up. Traditional notice and comment rulemaking and other regulatory approaches often take considerable time to develop; non-regulatory programs, in most cases, can evolve more quickly.

1. Governmental Non-Regulatory and Information-Based Tools

Several governmental alternatives to traditional regulation could be explored for purposes of addressing the environmental and human health risks that may be associated with nanotechnologies. These could include, but are not necessarily limited to, economic incentives,[145] insurance,[146] tort liability,[147] pollution prevention and

145. For a discussion of economic incentives: NATIONAL CENTER FOR ENVIRONMENTAL ECONOMICS, EPA, THE UNITED STATES EXPERIENCE WITH ECONOMIC INCENTIVES IN ENVIRONMENTAL POLLUTION CONTROL POLICY (2001) (concluding that the number and diversity of economic incentives for environmental pollution control is growing rapidly at the state and local level and that incentives are: particularly useful in controlling pollution that has not already been subjected to traditional forms of regulation; in many cases may generate benefits beyond what is possible with traditional regulations; are sometimes applied where traditional regulations might not be possible; can be particularly useful for small and geographically dispersed sources; can provide impetus for technological change; can provide cost savings relative to traditional regulatory approaches; and have wide applicability to specific environmental problems).

146. *See generally* Benjamin J. Richardson, *Mandating Environmental Liability Insurance*, 12 DUKE ENVTL. L. & POL'Y F. 295 (2002) ("Insurance functions to spread the economic consequences of individual events across many parties, and, thereby, reduce the potentially catastrophic effects of unforeseen events on individuals by having those consequences absorbed by a third-party (the insurer) . . . [t]hrough the setting of premiums and coverage conditions, insurance markets may induce improved safety measures and offer effective protection against the financial consequences of such accidents, which is particularly important where the responsible party is impecunious.").

147. *See generally* MARK WILDE, CIVIL LIABILITY FOR ENVIRONMENTAL DAMAGE, COMPARATIVE ANALYSIS OF LAW AND POLICY IN EUROPE AND THE UNITED STATES (2002) (addressing whether, through increased protection of private interests, tort has the ability to provide a useful additional means of environmental protection). *See also* Center for Progressive Regulation, Tort Reform, http://www.progressiveregulation.org/perspectives/tortReform.cfm (last visited Mar. 20, 2006) ("The adverse publicity and financial

voluntary data collection programs, and disclosure.[148] As noted above, EPA recently announced its interest in pursuing a Nanoscale Materials Stewardship Program for certain nanoscale materials. The Program will seek to have major companies in the emerging nanotechnology industry report and generate data and develop good practices for their supply chains.[149]

The use of alternative governance approaches requires consideration of the following types of issues: whether models exist that could inform the use of non-regulatory approaches for nanotechnologies, the considerations and assumptions that could inform the selection of the various non-regulatory approaches, the limitations associated with using alternatives to regulation; the types of economic incentives that could be used in lieu of or as a complement to traditional regulations (e.g., financial incentives for toxicity testing), and whether a voluntary EPA program on nanotechnology would be useful and, if so, the objectives, design, and scope of such a voluntary program.

2. Industry Voluntary Standards

As discussed, several efforts are underway to develop standards related to nanotechnologies: ISO's Technical Committee on Health, Safety, and Environmental Aspects of Nanotechnologies (TC 229); [150] ASTM International's Committee E56;[151] and ANSI's Nanotechnology Standards Panel[152] and its work on the U.S. Technical Advisory Group to ISO's TC-229.[153]

To understand the role of voluntary standards in a nanotech governance structure, the following issues should be addressed: the benefits and limitations of voluntary standards or guidelines; how voluntary standards can be used effectively in combination with

consequences of tort liability can provide powerful incentives for actors to change their behavior, ultimately resulting in far less damage to the environment and to the health and livelihood of human beings.").

148. For a discussion of the potential role of disclosure in regulating nanotech, see generally William F. Pedersen, *Regulating Nanotechnology by Information Disclosure* (2005), *available at* http://www2.eli.org/pdf/research/nanotech/Presentations/pedersen.pdf.

149. INTERIM AD HOC WORK GROUP ON NANOSCALE MATERIALS, *supra* note 41.

150. International Organization for Standardization, TC 229 Nanotechnologies, http://www.iso.org/iso/en/stdsdevelopment/tc/tclist/TechnicalCommitteeDetailPage.TechnicalCommitteeDetail?COMMID=5932 (last visited Nov. 13, 2006).

151. ASTM International, *supra* note 106.

152. American National Standards Institute, *supra* note 104.

153. *Id.*

regulatory approaches; and the development of models that could be used to assess the potential effectiveness of nanotech-related voluntary standards or guidelines.

3. The Path Forward

There is a need for an analysis of private sector and public sector voluntary programs and how they could augment traditional regulatory tools, the types of weaknesses or gaps that are likely to exist in these programs, and how voluntary and mandatory programs can work together to strengthen the governance structure for nanotechnologies. In addition, there is a need for research and recommendations on how to create, design, and make publicly accessible environmental, health, and safety databases. An assessment of the effects of tort liability on the behavior of nanotechnology firms with respect to environmental, health, and safety, including an examination of causation issues, would help inform the development of a governance structure. In a similar vein, an evaluation of the influence of insurance products on the environmental, health, and safety-related behavior of nanotech manufacturers including, for example, the role of incentives such as premium amounts and level of insurer monitoring in determining the level of care used would be valuable. Finally, research and policy work is needed on the potential role of facility-based disclosure programs. Disclosure programs could seek disclosure of information to the public about air emissions, water discharges, consumer exposures, and waste disposal practices from nanotechnology facilities permitted under the Clean Water and Clean Air Acts, or subject to Toxic Release Inventory reporting requirements.

C. The Role of Governmental Entities

Effective development and implementation of a governance structure will depend heavily upon governmental coordination at the local, state, federal, intra-agency, inter-agency, and international levels.

1. State and Local Government

Lux Research estimates that state and local governments invested

more than $400 million in nanotechnology research, facilities, and business incubation programs in 2004.[154] Although several states have enacted legislation encouraging or promoting nanotechnologies,[155] no states have enacted regulatory authorities.

154. *Nanotechnology: Where Does the U.S. Stand? Hearing Before the Research Subcomm. of the H. Comm. on Science*, 109th Cong. (June 29, 2005) (statement of Matthew M. Nordan, Vice President of Research, Lux Research Inc., at 8), *available at* http://www.house.gov/science/hearings/research05/june29/nordan.pdf.

155. ARK. CODE ANN. § 15-4-2102(f)(2) (2006) (finds that it is in Arkansas' best interest to "[e]ncourage the application of nanotechnology to: (A) Biotechnology and agriculture; (B) Manufacturing and materials; (C) Medicine and health; (D) Photonics; (E) Nanoelectronics and computer technology; (F) Environment and energy; (G) Aeronautics and space; and (H) National security"); ARK. CODE ANN. § 15-4-2104(a) (2006) (establishes a tax credit for "any Arkansas taxpayer for the cost of a facility located in Arkansas which designs, develops, or produces photovoltaic devices, electric vehicle equipment, fuel cells, microturbines, Stirling engines, or devices which are reliant upon nanotechnology"); CAL. EDUC. CODE § 88500(1) (2006) (includes nanotechnology, among other areas, to be a "strategic priority area" to be "explored if new or additional funding becomes available" as part of the California Community Colleges Economic and Workforce Development Program); MASS. GEN. LAWS ch. 23G, § 27(a)&(c) (2006) (establishes Emerging Technologies Fund and defines nanotechnology as an emerging technology industry); MASS. GEN. LAWS ch. 40J, § 4F(a) (2006) (establishes the Massachusetts Research Center Matching Fund to support Centers of Excellence "research and innovations in targeted emerging technologies. . .[i]n the first year, 3 such Centers shall target the research and development of medical devices, nanotechnology and biotechnology"); N.Y. EXEC. LAW §§ 209, 209-r (2006) (defines nanotechnology as an "enabling science" and creates Gen*NY*sis program "to assist research and technology development programs in the life sciences or in enabling sciences"); OKLA. STAT. tit. 74, § 5060.1a(A)(2) (2006) (establishes as a goal for Oklahoma Science and Technology Research and Development Board to enhance "the lives of, and expanding opportunities for, all Oklahomans through growth of information technology, biotechnology, nanotechnology and sensors industries and infrastructure throughout the urban and rural areas of the state"); 2003 Or. Laws 725 § 11(4)(b) (appropriates $500,000 for the Portland State University Center for Nanoscience and Nanotechnology); OR. REV. STAT. § 351.509 (2005) (establishes Portland State University Center for Nanoscience and Nanotechnology Account); PA. STAT. ANN. tit. 24 § 6250.902(c) (2006) (for programs to be considered "innovative programs" and eligible for Workforce Leadership Grants, "[t]he application and use of nanotechnology shall be an integral part of postsecondary instruction with exposure to this technology for students at the secondary level"); S.C. CODE ANN. § 2-75-90(A)&(B) (2005) (authorizes research universities to use matching funds from the Centers for Excellence Matching Endowment to endow professorships in the area of nanotechnology); TEX. GOV'T CODE ANN. § 481.0296(a) (2006) (establishes that the Texas Economic Development and Tourism Office "shall coordinate state efforts to attract, develop, or retain technology industries in this state in certain sectors, including. . .nanotechnology); TEX. GOV'T CODE ANN. § 489.213(b) (2006) (establishes that the Texas Economic Development Bank "shall give special preference to products or businesses in the areas of semiconductors, nanotechnology, biotechnology, and biomedicine that have the greatest likelihood of commercial success, job creation, and job retention in this state"); TEX. GOV'T CODE ANN. § 489.213(e) (2006) (authorizes the Product Development and Small Business Incubator Board to "appoint an advisory committee of experts in the areas of semiconductors, nanotechnology, biotechnology, and biomedicine to

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.[156]

Issues to consider include: the appropriate role of state governments in regulating nanotechnologies; whether states are likely to step forward to regulate nanotechnologies in the absence of pervasive and specific federal regulation and, if so, the advantages and disadvantages of such a proactive state role; and whether a federal-state dialogue would be helpful in securing the benefits of state-level thinking and minimizing later potential conflicts.

2. 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 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 Committee on Technology's Subcommittee on Nanoscale Science, Engineering, and Technology "coordinate with the agencies that have the responsibility and authority for protecting the environment and the public."[157] In addition, intra-agency coordination, particularly at EPA, will be important. EPA regulatory programs are organized around the principal environmental statutes, with separate offices

review projects and businesses seeking financing from the bank"); TEX. GOV'T CODE ANN. § 489.213(h) (2006) (establishes that "[a]ny business in this state is eligible for funding distributed through the small business incubator fund if it is determined that the business is substantially likely to develop and expand the opportunities for small businesses in the semiconductor, nanotechnology, biotechnology, or biomedicine industry in this state"); VA. CODE ANN. § 2.2-225 (2006) (creates the position of Secretary of Technology with the authority to "[e]nsure the Commonwealth remains competitive in cultivating and expanding growth industries, including life sciences, advanced materials and nanotechnology, biotechnology, and aerospace").

156. MASS GEN. LAWS ch. 21I (2006).

157. PCAST REPORT, *supra* note 34, at 43; *see also* Renewable Natural Resources Foundation, *supra* note 18, at 21 (noting the potential for inconsistencies among agencies regulating nanomaterials).

regulating air, water, site remediation, and pesticides and toxic chemicals. Nanotechnologies raise issues that cut across these intra-agency boundaries.[158]

Factors to consider include whether current federal initiatives adequately ensure cooperation and coordination among federal agencies with respect to environmental, health and safety concerns. It is also critical to consider the major impediments to intra-agency coordination and whether they can be addressed efficiently and effectively.

3. International

Several entities have recognized the importance of international coordination on nanotechnology environmental, health, and safety concerns. 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."[159] The Panel also noted that because environmental and health concerns "reach beyond borders,"[160] the NNI should coordinate with agencies and organizations that are responsible for representing the United States in international fora. The European Commission, in a 2004 Communication, concluded that international cooperation could accelerate research and development "by overcoming knowledge gaps more rapidly."[161] Recognizing the value of science and technical cooperation agreements as, for example, an implementing arrangement between the European Commission and the National Science Foundation, the Commission stated the need for reinforced international cooperation "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

158. Renewable Natural Resources Foundation, *supra* note 18, at 21 (noting that the current approach to nanotechnologies "perpetuates the media-by-media regulation of contaminants that fails to recognize the interconnectedness of air, water, and soil).

159. PCAST REPORT, *supra* note 34, at 42.

160. *Id.* at 43.

161. EUROPEAN COMMISSION, *supra* note 96, at 21; *see also* Linda K. Breggin, *Harmonization of Environmental, Health, and Safety Governance Approaches for Nanotechnology: An Overview of Key Themes*, *in* 36 Envtl. L. Rep. News & Analysis, *supra* note 77, at 10909, *available at* http://www.elr.info/articles/vol36/36.10909.pdf

knowledge apartheid)," particularly with respect to health, safety, and the environment.[162] Furthermore, as noted above, the Commission also has stated that it will promote debate or consensus on issues of global concern, such as public health, safety, the environment, and regulatory approaches, among others.[163] In addition, EPA has recognized the importance of collaborations with other countries on harmonized approaches for data generation and assessment efforts.[164]

Issues to address with respect to international coordination include: whether international consensus or debate should be promoted on issues that are arguably of global concern, such as human health and environment and regulatory approaches; the implications of a country moving aggressively to regulate nanotechnology, particularly with respect to the movement of nanomaterials and products across borders; and the implications for nanotechnology of international agreements, such as the Basel Convention.[165]

4. The Path Forward

Because governmental coordination is essential to the development and implementation of an effective governance structure, it is critical to pay attention to the challenges that such coordination efforts present. For the intra-agency effort, such coordination could be fostered substantially by an assessment of how EPA's program offices could work together to regulate nanotechnologies. One issue to consider is how to ensure that the product-based programs, such as those for toxics and pesticides, interact effectively with facility-based programs, such as those for water, air, and waste. Similarly, recommendations for how the various federal agencies with jurisdiction over nanotechnology environmental, health, and safety issues can work together in an effective manner would be useful.

The statutory and regulatory analysis and blueprint outlined above could include an assessment of the role of state programs in

162. *Id.*

163. *Id.*; *see also* DAVIES, *supra* note 92.

164. Nanotechnology Workgroup, EPA, *supra* note 2, at 13.

165. Convention on the Control of Transboundary Movement of Hazardous Wastes and Their Disposal (Basel Convention), Mar. 22, 1989, 28 I.L.M. 657, *available at* http://www.basel.int/text/con-e-rev.pdf.

the governance structure for nanotechnology, including both delegated federal programs and state-sponsored initiatives. The blueprint also could address possible mechanisms for coordinating not only research and data collection efforts on the international level, but also efforts to develop governance structures.

D. The Role of the Public

As discussed, the technical nature of nanotechnologies, the rapid introduction of nanoproducts into the market, and limited data on environmental, health, and safety effects present a particular challenge with respect to involving and informing the public. At the same time, public involvement is essential because of the potential for controversy, which could result in the failure of nanotechnology to produce myriad societal benefits.[166]

1. Information Dissemination and Public Involvement

Fostering meaningful public involvement in decisions related to the regulation of nanotechnology may be particularly difficult because of 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."[167] 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.[168]

Issues with respect to public involvement include: the ways in which EPA, other government agencies, the business community and non-profit groups can promote understanding of the human health and environmental effects of nanotechnologies; impediments to involving the public in the development of

166. *See* MACOUBRIE, *supra* note 11, at 1.

167. PCAST REPORT, *supra* note 34, at 43.

168. *See generally Environmental and Safety Impacts of Nanotechnology: What Research Is Needed? Hearing Before the H. Comm. on Science*, 109th Cong. (Nov. 17, 2005) (statement of Richard A. Denison, Senior Scientist, Environmental Defense), *available at* http://www.house.gov/science/hearings/full05/nov%2017/Denison.pdf; THE ROYAL SOCIETY & THE ROYAL ACADEMY OF ENGINEERING, *supra* note 102, at 87.

nanotechnology policy; and whether a public dialogue on regulation of nanotechnologies would be useful and, if so, in what context and fora.

2. The Path Forward

Because of the importance of both public opinion and stakeholder involvement in the development of an effective governance structure,[169] there is a need for a long-range action plan, which could be issued in conjunction with the regulatory blueprint proposed above, that identifies the wide range of non-traditional stakeholders that should be included in any processes associated with government or private sector initiatives on nanotechnology environmental, health, and safety. Many of these key nanotechnology players, such as startups and non-U.S. manufacturers, are not typically at the table for federal environmental policy discussions. In addition, the action plan should include a strategy for outreach to identified stakeholders that outlines approaches for disseminating information, answering questions, and motivating participation in initiatives. The action plan also should provide for the development and use of handbooks, research reports, and primers tailored to specific stakeholder groups, such as workers in nanotechnology manufacturing facilities, consumers, and municipal waste authorities. The tools could provide information on interim steps that can be taken in the absence of regulation or voluntary programs to help ensure that practices are protective of human health and the environment.

The action plan also should address the pivotal role of public opinion by recommending steps regulatory authorities can take to inform the public about the benefits and concerns associated with nanotechnologies. The action plan could outline tools such as guidebooks for the public on nanotechnologies and their implications for environmental, health, and safety. In conjunction with the development of an action plan, or as part of a larger effort to develop a consensus-based governance structure, a multi-stakeholder dialogue could be convened. The dialogue could be

169. Virtually all of the research proposed in this article could be conducted in conjunction with stakeholder involvement and dialogue, which would greatly enhance the quality and credibility of the product, in addition to the ultimate viability of any recommendations produced.

structured in a variety of ways, but it would allow for a diverse group of stakeholders to meet on a regular basis to explore the myriad issues surrounding the development of an effective environmental, health, and safety governance structure.

IV. CONCLUSION

Nanotechnologies not only present an important technological development; they present an important opportunity to learn from past experiences and to explore innovative ways to apply environmental law to emerging technologies. To do this effectively, a high priority must be placed on answering the legal and policy questions central to creating an effective governance approach. The importance of taking prompt action with respect to the research and policy analyses needed to foster the development of an optimal environmental, health, and safety governance structure cannot be overstated. Without timely action, nanotechnology could fail to realize its tremendous potential and efforts to minimize adverse impacts on human health and ecosystems also could fail. The themes and research agenda set out in this article should inform both private and public sector efforts to move forward on the challenging path toward developing an effective governance structure.