

**Comments of the Environmental Law Institute
on the Environmental Protection Agency's Nanotechnology White Paper
External Review Draft**

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I. Introduction and Background

The Environmental Law Institute (ELI) is an independent, non-partisan education and policy research center committed to improving environmental law and governance and promoting innovative solutions. ELI's Nanotechnology Initiative (<http://www2.eli.org/research/nanotech.htm>) seeks to respond to the pressing need to develop an effective environmental, health, and safety governance structure for nanotechnologies.

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 the U.S. Environmental Protection Agency (EPA) must place a high priority on answering the legal and policy questions central to creating an effective governance approach.

The EPA White Paper recommendations, however, do not address the development of a governance structure. Instead, the recommendations focus on steps that the Agency can take "to help ensure that society accrues the important benefits to environmental protection that nanotechnology may offer and that the Agency understands potential risks from environmental exposure to nanomaterials." (White Paper at 82). These are both laudable goals and, in particular, an understanding of potential risks is essential to the development of an effective governance structure in the long term. At the same time, the White Paper virtually ignores the actions that may need to be taken to address any risks identified. In particular, the White Paper does not discuss the steps needed to foster the legal and policy research and analyses that will lay the foundation for an effective governance structure. In fact, the White Paper devotes only 9 of its 123 pages to a discussion of risk management and statutory authorities. Although the White Paper is not limited to scientific research and data issues, it only tangentially addresses governance issues in its recommendations by presenting proposals for pollution prevention, stewardship and sustainability, and a cross agency workgroup that would "foster information sharing regarding risk assessment or regulatory activities for nanomaterials across program offices and regions."

Similarly, the White Paper narrative fails to identify the tremendous amount of work that is needed to determine whether and how the framework of environmental statutes it outlines will function effectively. For example, the White Paper does not address, in any meaningful way: whether authorities under the various laws can be used

in a coordinated manner; whether additional legal authorities are needed; and the extent to which policies and regulations will need to be modified.

Despite the lack of attention paid in the White Paper to governance issues, the need for an immediate investment in the development of a governance structure is critical and should be conducted in tandem with research and data collection efforts. 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.

ELI and the Woodrow Wilson Center for International Scholars, Project on Emerging Nanotechnologies convened a two-day dialogue in May 2005 entitled *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 not only highlighted the need for scientific research but the critical need for 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 may be posed by nanotechnologies are appropriately and proactively addressed in ways that both protect the public and enhance industry competitiveness. A summary of the Dialogue is available online at http://www.elistore.org/reports_detail.asp?ID=11116.

The following Sections outline the themes that ELI believes should guide the development of a governance structure and provide recommendations for specific areas of research and policy analyses. Unless EPA places a priority in the near term on addressing governance issues, it will fail to meet the challenge it identifies in its White Paper – “to allow full realization of the societal benefits of nanotechnology, while identifying and minimizing any adverse impacts to humans or ecosystems from exposure to nanomaterials.”

II. Governance Structure Themes

Concurrent with its efforts to conduct research and fill the data gaps outlined in the White Paper, EPA should promptly initiate the work that is needed to lay the foundation for an effective environmental, health, and safety governance structure. Several central themes should direct EPA’s effort.

Research and Data Development Should Be Principal Goals: As recognized in the White Paper, research and data will inform the identification of appropriate regulatory safeguards. The more information on eco-toxicity and health impacts that is developed, the more effective regulatory oversight and stewardship will be in the long

term. The science and data necessary for understanding the risks posed by nanotechnology, however, may not be reliable for many years. The White Paper takes steps toward prioritization of data collection and research efforts, but it does not address how to develop the data as quickly and efficiently as possible and, in the interim, how to manage risks in the face of uncertainty.

Similarly, the White Paper does not address how to allocate the burden of developing data between the public and private sectors and potentially among the major countries investing in the development of nanotechnologies. The White Paper refers to the desirability of collaboration on “burden-sharing and harmonized approaches for generating data and assessing nanomaterials.” (White Paper at 80). This is an issue that EPA should address with the Organization for Economic Cooperation and Development’s Chemicals Committee at its February 2006 meeting.

In a separate proposal, EPA has proposed a voluntary initiative that seeks to have major companies in the emerging nanotechnology industry generate data, as well as develop good practices for their supply chains. (White Paper at 14). This effort is more likely to succeed in attracting volunteers if there is a well-defined research agenda and an efficient and equitable allocation of responsibilities between public and privately funded research.

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 and should 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.

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 environmental, health, and safety is unlikely, at least in the near term, it will be necessary to use existing legal authorities and adapt current programs to regulate nanotechnologies. Reliance on a single statute such as the Toxic Substances Control Act (TSCA), however, is unlikely to suffice. A multi-statute approach that draws on both product-based and facility-based laws may be needed. As noted in the White Paper, to use existing authorities effectively, amendments to regulations and the issuance of new policies and guidance may be necessary.

The White Paper recognizes the importance of life cycle analysis and recommends creating “policy, program and research designs that encourage an environmental stewardship ethic and behaviors throughout the complete life cycle of nanomaterials and products.” (White Paper at 25, 73). The White Paper does not, however, consider life cycle analysis from a governance perspective. EPA also should consider the laws it implements to determine the extent to which they provide the basis for a life cycle approach. The governance structure itself should reflect a full life cycle

perspective, employing various statutory tools depending on the particular stage in the life cycle of nanotechnologies.

The use of existing laws and programs in an integrated fashion will present serious regulatory challenges, as 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. In addition, 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, including insufficient program budgets and human resources, as well as the 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. These agencies will need to coordinate their efforts to avoid duplication, avoid gaps, and ensure consistent and complementary approaches.

Furthermore, as noted above, the White Paper recognizes the importance of collaborations with other countries on harmonized approaches for data generation and assessment efforts; it neglects, however, to consider governance frameworks for nanotechnologies in the same vein. As recognized by participants in the dialogue hosted by ELI and the Woodrow Wilson Center for International Scholars, Project on Emerging Nanotechnologies in May 2005, international consistency and harmonization of protocols and regulations can help foster a secure business climate.¹ Similarly, in a recent report Terry Davies noted that a “regulatory regime” for nanotechnologies “should have international coordination built into it.”² ELI will hold a Symposium in Spring 2006 on the development of governance structures from an international perspective. The Symposium will consider the governance approaches likely to be taken in the U.S., Europe, and Asia and the implications for corporate environmental management if disparate governance structures emerge. The Symposium will also focus on whether coordination or harmonization is feasible and desirable.

An Interim Governance Approach Will Be Needed: The development of a multi-faceted approach may take considerable time due to data, resource, and administrative constraints. There is an immediate need, therefore, to take steps to ensure that the current manufacture, use, and disposal practices for nanoproducts 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. Again, it is crucial that this interim approach be systemic and look across programs, statutes, and potential voluntary initiatives.

¹ *Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up To the Job?: A Dialogue*, Environmental Law Institute, October 2005, http://www.elistore.org/reports_detail.asp?ID=11116 (at 24).

² *Managing the Effects of Nanotechnology*, J. Clarence Davies, Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, January 2006.

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. 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.

III. EPA's Governance Structure Research Needs

Substantial work is needed to develop a governance approach consistent with the themes outlined above. In addition to the development of human health and eco-toxicity data, considerable policy and legal analyses are needed. Without such research and policy work, an appropriate foundation will not be laid and the resulting governance structure may not be effective. Virtually all of the proposed work that follows 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. The following core areas of research are central to the development of a governance structure:

A Comprehensive Analysis of Existing Legal Authorities and Development of a Regulatory Blueprint: A thorough analysis is needed of the major *environmental, health, and safety statutes* to identify authorities to regulate nanotechnologies, as well as potential gaps in legal authorities required by federal and state agencies to regulate effectively nanotechnologies. In addition, a comprehensive analysis of EPA *regulations, policies, and guidance* issued under the major environmental statutes is needed for purposes of determining how they could be revised or interpreted to address more effectively nanotechnologies. The in-depth analysis could include, for example, suggested changes to TSCA regulations that would make volume-based exemptions more reasonable when applied to nanotechnologies or that would provide guidance as to when nanomaterials should be considered “new” chemicals or a “new use” of a chemical. The analysis could also 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. The statutory and regulatory analysis could include an assessment of the role of *state programs* in the governance structure for nanotechnology, including both delegated federal programs and state-sponsored initiatives, as well as the role of *international regulatory programs*, and the growing influence of the precautionary principle and related European-based environmental, health, and safety principles.

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. In addition, the blueprint could address issues such as ways in which regulatory programs may need to be tailored to *small and medium-sized nanotechnology companies*.

An Assessment of Alternative Governance Approaches: Non-regulatory mechanisms are likely to be an important component of the environmental, health, and safety governance structure for nanotechnologies. The White Paper addresses some of these approaches in its discussion of pollution prevention, stewardship and sustainability, but does not examine the implications of relying on these approaches. Accordingly, an analysis is needed of *private sector and public sector voluntary programs* and how they could augment traditional regulatory tools, what types of weaknesses or gaps are likely to exist in these programs, and how voluntary and mandatory programs can work together to strengthen the governance structure for nanotechnologies. Research and recommendations for how to create, design, and make publicly accessible environmental, health, and safety *databases* also are needed. In addition, 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 assessment 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*. Such disclosure programs could seek from nanotechnology facilities permitted under the Clean Water and Clean Air Acts, or subject to Toxic Release Inventory reporting requirements, for example, disclosure of information about air emissions, water discharges, consumer exposures, and waste disposal practices to the public.

Development of Public Information and Involvement Tools and Mechanisms: Because of the importance of both public opinion and stakeholder involvement in the development of an effective governance structure, a *long-range action plan* is needed 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 are not typically at the table for federal environmental policy discussions, such as startups and non-U.S. manufacturers. 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 would also 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 should also 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 also 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 structured in a variety of ways, but 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.

An Examination of Management and Implementation Approaches: 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, Alar and similar regulatory efforts could facilitate implementation. In addition, 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 would also 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.

Effective development and implementation of a governance structure also will depend heavily upon *governmental coordination* at the federal-state, intra-agency, inter-agency, and international levels. 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. Issues to consider include ways 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, as would an analysis of possible mechanisms for coordinating international research efforts.

IV. Conclusion

The White Paper provides a valuable review of research needs for the environmental applications and implications of nanotechnologies. It does not, however, adequately recognize the critical importance of taking prompt action to address the research and policy analyses needed to foster the development of an optimal environmental, health, and safety governance structure. It is hoped that the themes and research agenda set out in these comments will help inform EPA's efforts as it moves

forward on the challenging path toward developing an effective governance structure that will allow for the full realization of the societal benefits of nanotech, while at the same time minimizing any adverse impacts to human health and ecosystems.