12-2006

ELR NEWS & ANALYSIS

36 ELR 10943

Keeping Pace With Nanotechnology: A Proposal for a New Approach to Environmental Accountability

by Lee Paddock

Editors' Summary: The rapid growth of the nanotechnology industry that challenges traditional governance structures also calls for new approaches to accountability. Accountability mechanisms would help avoid adverse effects of the evolving technologies, foster public confidence in nanotechnology, and encourage the development of new, beneficial technologies. In this Article, Prof. Lee Paddock illustrates some of the tools of environmental accountability that may be employed in the context of nanotechnology. He discusses how traditional accountability mechanisms already inherent in the federal environmental statutes may be applied, and emphasizes the need for flexibility in permitting, public involvement, voluntary accountability programs, and opportunities for industry self-regulation. He concludes by suggesting the creation of a Nanotechnology Council to bring stakeholders together to address accountability issues.

I. Introduction

Among the many unique aspects of nanotechnology are its rapid evolution, the anticipated industry growth rate, the massive investments in research and development, and the almost visceral sense that no country and no company wants to be left behind in the nanotechnology revolution. These characteristics, along with the fact that it is still not possible to routinely monitor releases of nanoscale materials, create serious challenges in designing an environmental governance system. An effective system must be capable of identifying and avoiding adverse consequences of a rapidly advancing industry; maintaining public confidence in the industry; and facilitating, or at least not unnecessarily inhibiting, the growth of potentially transformative technologies.

Part of the answer to this dilemma is reliance on a much broader set of accountability tools embedded in a new system of environmental governance. This new system should include traditional regulatory tools, but with more focus on products, pollution prevention, and more flexible regulatory mechanisms, rather than end-of-the-pipe discharge limitations. It also must rely on a series of newer tools including robust public involvement and public dialogue, expanded information disclosure safeguarding confidential business data, involvement in government and industry leadership programs, a liability system that checks irresponsible behavior, effective self-regulation mechanisms, and adherence to clear and effective industry codes.

II. Background

Nanotechnologies include a broad array of materials with diverse characteristics, only the first generation of which has reached the market.[1] The International Risk Governance Council observed that

> [n]anoscience is the result of interdisciplinary cooperation between physics, chemistry, biology, biotechnology, material sciences and engineering in studying assemblies of atoms and molecules. . . . Applications of nanotechnology will penetrate and permeate through nearly all sectors and spheres of life (e.g. communication, health, labour, mobility, housing, relaxation, energy and food) and will be accompanied by changes in the social, economic, ethical and ecological spheres.[2]

The International Risk Governance Council recognizes four generations of nanotechnologies:

- First generation *passive nanostructures* have stable behavior and quasi-consistent properties during their use. These nanostructures have been in existence since about the year 2000.

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1. Dep't of Trade and Industry, New Dimensions for Manufacturing, A U.K. Strategy for Nanotechnology 17, fig.1 (June 2002).

2. International Risk Governance Council, Nanotechnology Risk Governance 19-20 (2006), *available at* http://www.irgc.org/irgc/_b/contentFiles/IRGC_white_paper_2_PDF_final_version.pdf.

- Second generation *active nanostructures* have properties that are expected to change during operation, so behavior is variable and potentially unstable. These nanostructures are beginning to emerge.
- Third generation *integrated nanosystems* are systems in which passive or active nanostructures are integrated into systems using nanoscale synthesis and assembling techniques. These systems will develop based on the convergence of nanotechnology, biotechnology, information technology, and the cognitive sciences. Nanosystems are expected to be in use by 2010.
- Fourth generation *heterogeneous molecular nanosystems* allow engineered nanosystems and architectures to be created from individual molecules or supramolecular components, each of which have a specific structure and are designed to play a particular role. Fundamentally new functions and processes begin to emerge with the behavior of applications being based on that of biological systems. Heterogeneous systems are anticipated in 2015.[3]

In less than 10 years, nanomaterials are expected to evolve from today's stain-resistant fabric treatment, carbon fibers that strengthen golf clubs, and titanium oxide particles in sunscreens, to nanoscale genetic therapies and molecules designed to self assemble. The anticipated scale of the nanotechnology industry is exceptional. This 2001 *Science* magazine "breakthrough of the year" technology may produce $1 trillion in goods and services by 2015.[4] The International Risk Governance Council notes that

> [n]anotechnology has the potential to become one of the defining technologies of the 21st Century. Based on the ability to measure, manipulate and organise material on the nanoscale—it is set to have significant implications—envisaged breakthroughs for nanotechnology include order-of-magnitude increases in computer efficiency, advanced pharmaceuticals, bio-compatible materials, nerve and tissue repair, surface coatings, catalysts, sensors, telecommunications and pollution control.[5]

Not surprisingly, governments and companies have invested heavily in nanotechnology research and development. More than 30 countries have nanotechnology initiatives, including many traditional industrial powers as well as less likely candidates such as Mexico and Ukraine. Figures 1 and 2 illustrate the rapid acceleration in government investment.

Figure 1[6]

Worldwide government funding for nanotechnology R&D, US$M, (April 2002)

Area	1997	1998	1999	2000	2001	2002	2003
W. Europe	126	151	179	200	225	~400	
Japan	120	135	157	245	465	~650	
USA*	116	190	255	270	422	604	710
Others	70	83	96	110	380	~520	
Total	432	559	687	825	1502	2174	
(% of 1997)	100%	129%	159%	191%	348%	503%	

From a briefing note: Nanotechnology Funding: The International Outlook by Mihail C. Roco, Chair, White House/National Science and Technology Council/Nanoscale Science, Engineering and Technology Subcommittee, and Senior Advisor, US National Science Foundation, May 2002.

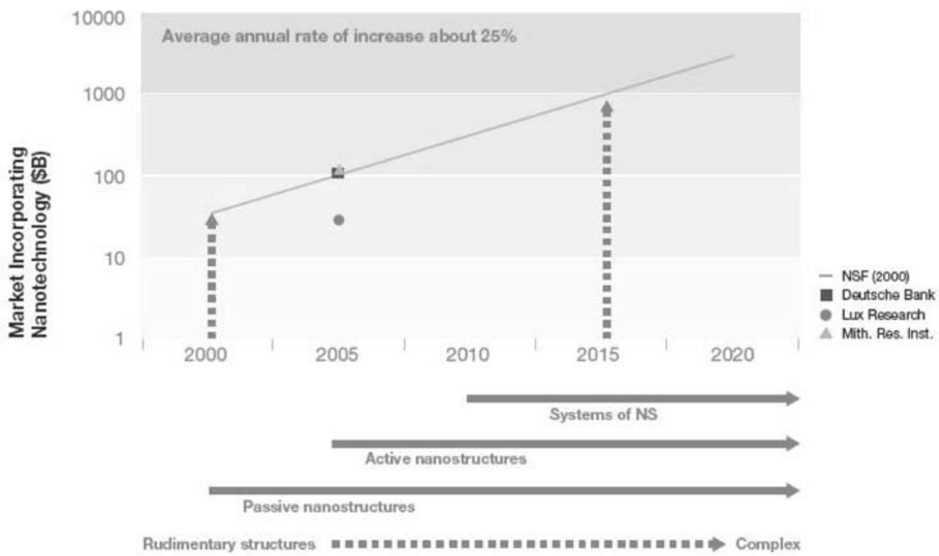
* excluding non-federal spending eg California

"Others" include Australia, Canada, China, Eastern Europe, FSU, Korea, Singapore, Taiwan and other countries with nanotechnology R&D

3. *Id.* at 14.
4. J. Clarence Davies, Woodrow Wilson Int'l Ctr. for Scholars, Project on Emerging Nanotechnologies, Managing the Effects of Nanotechnology 8 (2006), *available at* http://www.wilsoncenter.org/events/docs/Effectsnanotechfinal.pdf.
5. International Risk Governance Council, *supra* note 2, at 21.
6. New Dimensions for Manufacturing, *supra* note 1, at 21.

Figure 2[7]

Figure 2: Worldwide Market Affected by Nanotechnology (NSF estimation made in 2000, the estimation holds in 2006)



Research and development investments by industry worldwide are currently at about the same level as government investment, but these private investments are increasing at a higher annual rate.[8] Nanotechnology development appears to have become a race in which no nation, state, or major company wants to be left behind.

The United Kingdom's (U.K.'s) Strategy for Nanotechnology concluded that "the field of nanotechnology and its applications is crucial to the future competitiveness and productivity of the U.K. economy, and to the well being and prosperity of its people."[9] The U.S.-based Nanotechnology Alliance observed:

> [T]he countries that demonstrate the highest level of innovation and capture the most value from nanotech progress will exert a very significant level of influence on the global geopolitical landscape. For us to maintain our quality of life and global leadership position, the U.S. must play, not just to participate in, but to win the international nanotechnology race.[10]

State after state has enacted legislation trying to secure a competitive advantage in the industry through tax credits,[11] emerging technology funds,[12] direct appropriation to university research centers,[13] authorizing access to funding from Economic Development Banks,[14] or creating cabinet-level positions to help the state cultivate and expand growth industries such as nanotechnology.[15]

The breadth of nanotechnologies, the rate of development, and the race to be first with the next nano-breakthrough present government with a significant challenge. In its study on *Managing the Effects of Nanotechnology*, the Woodrow Wilson International Institute for Scholars pointed out that

> [t]he rapid development of [nanotechnology] also means that government managers always will be operating with outdated information, and data about [nanotechnology] effects will lag behind commercial applications. Priorities for research and for regulation will need to shift constantly. We have moved into a world which is, as David Rejeski states, "dominated by rapid improvements in products, processes, and organizations, all moving at rates that exceed the ability of our traditional governing institutions to adapt or shape outcomes." He warns: "If you think that any existing regulatory framework can keep pace with this rate of change, think again."[16]

It seems clear that the regulatory system alone cannot be relied upon to manage the environmental and public health consequences of nanotechnology. Nor can it create the level of public confidence needed to ensure the viability of the industry, even if the regulatory system were to be seen as the most desirable method for assuring environmental and health protection.

Industry, too, faces a significant problem. Regulatory systems not only punish wrongdoing; they help build public confidence in an industry, especially an industry that may involve significant risks. Over the last decade, a number of industries have faced public confidence challenges with varying results. In the United States, the use of bovine growth hormones (BGH) became a significant issue in the 1990s. While the controversy has largely subsided, a number of milk products are now labeled "BGH Free" to address concerns of some consumers.[17] Genetically modified organ-

7. International Risk Governance Council, *supra* note 2, at 21.
8. *Id.*
9. New Dimensions for Manufacturing, *supra* note 1, at 11.
10. Nanobusiness Alliance, Nanotechnology: A Roadmap to Leadership 2 (2006).
11. Ark. Code Ann. §15-4-2104(a) (West 2006).
12. Mass. Gen. Laws Ann. ch. 23G, §27(a), (c) (West 2006).
13. 2003 Or. Laws 725 (§11(4)(b)).
14. Tex. Gov't Code Ann. §489.0296(a) (Vernon 2006).
15. Va. Code Ann. §2.2-225 (West 2006).
16. Davies, *supra* note 4, at 9.
17. *See, e.g.*, Biotechnology Information Series, *Bovine Somatotropin (bST)*, http://www.biotech.iastate.edu/biotech_info_series/bio3.html#anchor346047 (last visited Oct. 30, 2006).

isms (GMOs), including such products as seed that can tolerate certain herbicides, have been similarly controversial. Concerns range from GMO "out-crossing," in which GMOs cross breed with non-GMOs, changing the non-GMO plant's characteristics, to fears about the potential effect of GMO foods on health, to the impact that patented GMO seeds may have on the cost of seed for farmers in developing countries.[18] Although GMO companies have overcome these concerns in the United States, political concerns driven by the public reaction in the European Union resulted in a long delay in introducing GMO seeds in Europe.[19] Problems of public acceptance can arise even in the absence of scientific facts substantiating the fears.[20]

Nanotechnologies face a similar risk, in significant part because so little is known about the effects of these technologies.[21] Issues have been raised in several quarters about the potential impact of nanotechnologies. The Natural Resources Defense Council and Environmental Defense staff observed that the novel properties of nanotechnologies

> pose new risks to workers, consumers, the public, and the environment. The few data now available give cause for concern: Some nanomaterials appear to have the potential to damage skin, brain, and lung tissue, to be mobile or persistent in the environment, or to kill microorganisms (potentially including ones that constitute the base of the food web). The trickle of data highlights how little is known about the environmental and health effects of engineered nanomaterials.[22]

The president of Consumers Union recently noted, "concerns abound that nanoparticles can behave in unpredictable ways: They go places in the body previously off-limits to their clunky cousins; they might have altered magnetic properties; they might be able to move from package to person in a way we just don't yet understand."[23]

While a biotechnology-type backlash has not yet affected nano-manufacturers, the level of uncertainty about effects, the dearth of public understanding, the lack of a clear management approach, and the potential health and environmental effects of some nanomaterials all create the setting for a nano-backlash.[24] It certainly appears to be in the best interest of the industry to work quickly with government, nongovernmental organizations (NGOs), and others to create and implement a credible accountability system that can build and maintain public confidence in the industry.

III. Environmental Accountability

For the last decade, government agencies have recognized the need for a systems approach to achieve broader compliance with environmental laws. Agencies have created compliance management systems that incorporate both compliance assistance as well as enforcement mechanisms to produce desired environmental outcomes using limited resources.[25] Environmental accountability extends the compliance management systems approach beyond the typical compliance assistance and enforcement tools of the regulatory system.[26] The concept incorporates a broad range of mechanisms designed to subject the environmental behavior of organizations to public scrutiny. These mechanisms include:

- traditional regulatory, compliance and enforcement tools;
- new approaches to regulation incorporating more flexible, performance-based standards, economic instruments, and product standards;
- stakeholder dialogues supported by better information and new public education strategies;
- voluntary industry leadership programs and public reporting protocols;
- the possibility of liability in circumstances where products are prematurely or inappropriately introduced into the market place; and
- corporate self-regulation and social responsibility programs.

Instead of relying solely or even primarily upon government-imposed, post-production regulations, these accountability mechanisms take advantage of a variety of behavioral motivators including requirements imposed through the regulatory system and activities encouraged by economics and values. Some mechanisms would be voluntarily adopted (or acquiesced to) by affected organizations based on self-interest or individual or organizational values, some may be based on economic pressure from customers, investors, the public, or economic opportunity created by incentives, while still others will continue to rely on government mandates and enforcement.[27]

While each of these mechanisms can enhance public accountability for environmental outcomes, it is critical that they be deployed in a systematic way. Each of these accountability mechanisms, much like each of our major environmental statutes, has been developed independently, rather than as an element of a comprehensive strategy to enhance public accountability to maximize environmental outcomes.

Using the full range of accountability tools more systematically—creating an environmental accountability system

18. *See, e.g.*, University of Georgia Research Magazine, *Viewpoint: The GMO Controversy and the Ivory Tower*, http://www.ovpr.uga.edu/researchnews/winter2000/viewpoint.html (last visited Oct. 30, 2006).

19. Sylvie Bonny, *Why Are Most Europeans Opposed to GMOs? Factors Explaining Rejection in France and Europe*, 6 Electronic J. Biotech. 50, 53 (2003).

20. Gregory N. Mandel, *Technology Wars: The Failure of Democratic Discourse*, 11 Mich. Telecomm. & Tech. L. Rev. 117, 119-20 (2005).

21. *Id.* at 119.

22. John Balbus et al., *Getting Nanotechnology Right the First Time*, Issues in Sci. & Tech. 65 (Summer 2005).

23. Jim Guest, *A Small Matter of Great Concern*, Consumer Reps., Oct. 2006, at 5.

24. The Royal Society and the Royal Academy of Engineering, Nanoscience and Nanotechnologies: Opportunities and Uncertainties 61 (2004), *available at* http://www.nanotec.org.uk/finalReport.htm.

25. *See* Suellen Keiner & LeRoy Paddock, *Mixing Management Metaphors: The Complexities of Introducing a Performance-Based State/EPA Partnership Into an Activities-Based Management Culture*, *in* Environment.gov: Transforming Environmental Protection for the 21st Century 11.51, 11.51-11.52 (2000).

26. LeRoy Paddock, *Environmental Accountability and Public Involvement*, 21 Pace Envtl. L. Rev. 243 (2004).

27. American Bar Association, Section on Environment, Energy, and Resources (ABA-SEER), Briefing Paper on EMS/Innovative Regulatory Approaches, 4-5 (2006) [hereinafter Briefing Paper], *available at* www.abanet.org/environ/nanotech/pdf/EMS.pdf.

similar to, but much broader than, the compliance management system now used by the U.S. Environmental Protection Agency (EPA)—could significantly improve the effectiveness of environmental programs and improve environmental results. This will require government agencies, environmental organizations, and others concerned with environmental progress to analyze more carefully how the various mechanisms can be linked in a strategic fashion.

IV. A Proposed Environmental Accountability System for Nanotechnology

Because of the speed at which the industry is growing and the range of materials and technologies that are part of the nano-revolution, a systematic approach to environmental accountability is particularly important. If traditional government mechanisms cannot keep up with the industry, the environment and public health must be protected and public confidence must be created through a more comprehensive approach.

A. Government Regulation

Government regulation must be part of the accountability system both to assure that the environment and public health are protected and to build and maintain public confidence in the industry. Given the political stalemates that have occurred on environmental issues over the past few years, it is unlikely that major new legislation addressing nanotechnology will be adopted in the United States in the foreseeable future absent a dramatic incident involving nanomaterials.[28]

Several environmental statutes including the Clean Water Act (CWA),[29] the Clean Air Act (CAA),[30] the Toxic Substances Control Act (TSCA),[31] the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[32] the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA),[33] and the Resource Conservation and Recovery Act (RCRA),[34] may apply to nanomaterials, although each of the statutes has limitations in the context of nanotechnology. Further, the inability to detect and monitor many nanoscale materials complicates the use of existing regulatory programs. Given the pace at which the industry is evolving, reliance on traditional permitting approaches—which may take months or even years to complete in the context of a new industrial process—could adversely affect competitiveness in a rapidly developing global market and therefore may be strongly resisted.

The American Bar Association, Section on Environment, Energy, and Resources (ABA-SEER) Nanotechnology Project[35] examined how each of the federal environmental statutes might apply in the context of nanotechnology.

1. CWA

EPA would likely be required to demonstrate that regulation through the CWA is appropriate due to specific nanocompounds or classes or categories of nanoparticles having a potential adverse effect on human health or the environment. Furthermore, technology must be developed that would allow nanoparticles to be accurately monitored, measured, and controlled.[36]

2. CAA

EPA must identify forms of nanoparticles that pose actionable risk; must develop appropriate methods of sampling, analysis, and control sufficient for nanoparticles; must base its standards on a measure other than mass, since nanoparticles typically have low mass; and must develop an efficient method to assess the risk created by engineered nanoparticles.[37]

3. TSCA

Nanomaterials include chemical substances and mixtures that EPA can regulate under TSCA. If a chemical substance is manufactured at the nanoscale, it is subject to the same premanufacture notification review that is applicable to any new chemical; however, there is no agreement on whether nanoscale versions of existing chemicals qualify as new chemicals. EPA may have the authority under TSCA to require health and environmental testing of nanomaterials, collect data on the production of nanomaterials, and promulgate rules regulating manufacture, processing, distribution, and use of nanomaterials.[38]

4. FIFRA

EPA is able to regulate nanopesticides, although questions do arise as to whether the use of nanoscale material already registered under FIFRA results in a new pesticide. EPA may prohibit the use of nanopesticides presenting unreasonable adverse effects, and may restrict other nanopesticides so as to ensure that risks do not become unreasonable.[39] Here again, detection and monitoring, as well as the question of whether a risk exists and is unreasonable, are important unresolved issues.

5. RCRA

To date, neither EPA nor state waste management programs have offered regulations or guidances that expressly address the management or disposal of nanoscale wastes. EPA has noted, "[n]anomaterials that meet the definition of RCRA

28. Linda K. Breggin, Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up to the Job? 8 (Envtl. Law Inst. ed., 2005).
29. 33 U.S.C. §§1251-1387, ELR Stat. FWPCA §§101-607.
30. 42 U.S.C. §§7401-7671q, ELR Stat. CAA §§101-618.
31. 15 U.S.C. §§2601-2692, ELR Stat. TSCA §§2-412.
32. 7 U.S.C. §§136-136y, ELR Stat. FIFRA §§2-34.
33. 42 U.S.C. §§9601-9675, ELR Stat. CERCLA §§101-405.
34. 42 U.S.C. §§6901-6992k, ELR Stat. RCRA §§1001-11011.
35. ABA-SEER, Section Nanotechnology Project (2006), *available at* http://www.abanet.org/environ/nanotech/.
36. ABA-SEER, Nanotechnology Briefing Paper: Clean Water Act 3 (2006), *available at* http://www.abanet.org/environ/nanotech/pdf/CWA.pdf.
37. ABA-SEER, CAA Nanotechnology Briefing Paper 4 (2006), *available at* http://www.abanet.org/environ/nanotech/pdf/CAA.pdf.
38. ABA-SEER, Regulation of Nanoscale Materials Under the Toxic Substances Control Act 3-4 (2006), *available at* http://www.abanet.org/environ/nanotech/pdf/TSCA.pdf.
39. ABA-SEER, The Adequacy of FIFRA to Regulate Nanotechnology-Based Pesticides 3-4 (2006), *available at* http://www.abanet.org/environ/nanotech/pdf/FIFRA.pdf.

hazardous wastes would be subject to these regulations."[40] The exemption from the definition of "hazardous waste" for household hazardous wastes may pose a problem given the growing use of nanomaterials in household items. The fact that nanomaterials may also exhibit special characteristics that are not listed among the four RCRA hazardous characteristics is also a potential issue.[41]

6. CERCLA

The current state of knowledge concerning the environmental and health effects of nanomaterials poses practical difficulties in applying CERCLA. Most scientific and technical predicates for applying CERCLA to nanomaterials do not yet exist. However, CERCLA was purpose-built to cope with unanticipated adverse consequences of previously accepted practices and its liability and cleanup scheme fits the paradigm of adverse consequences that may arise in the future from as-yet-unknown properties of nanomaterials.[42]

The ABA-SEER analysis of existing environmental statutes, as well as analyses by other organizations such the Environmental Law Institute (ELI),[43] indicates that these statutes are useful but imprecise mechanisms for dealing with various aspects of nanotechnologies. Regulation of nanotechnology, given the rapid changes within the industry, is likely to be an ongoing process, with approaches evolving over time.[44] EPA, in its White Paper on Nanotechnology,[45] suggests a more product-oriented rather than emissions-related approach to managing the potential impacts of nanotechnologies:

> Pollution prevention is a critical area to engage EPA resources and expertise as nanotechnology industries form and develop. It is critical that EPA apply the principles developed for green chemistry, green engineering, and environmentally benign manufacturing in EPA's approach to nanotechnology. EPA has the opportunity to work with stakeholders to apply approaches of pollution prevention and product stewardship to nanotechnology development, so that emissions and risks are reduced as productivity and the economy grow.[46]

B. Flexible Permitting

Given the limitations on the ability to detect and monitor nanoscale materials and the questions about the health effects of these materials, initial efforts must be directed at preventing releases into the environment. Still, at least some manufacturing operations are likely to need traditional EPA permits for environmental releases. Typically, changes in industrial operations that result in changes in type or quantity of emissions require a new permit. In the context of a rapidly evolving industry, this requirement is likely to be seen as stifling innovation and hindering competitiveness. At the same time, industry regulations must be stringent enough to reasonably protect human health and the environment.

This dichotomy may require stakeholders to consider more flexible regulatory approaches based on performance and transparency.[47] These types of regulatory approaches could be developed through a collaborative process involving government, industry representatives, and advocacy organizations to build confidence in the regulatory framework. One readily available model for flexibility is the "plantwide applicable limits" approach developed under the CAA and used in EPA's Project XL program. Under this program, Intel, working with its local stakeholders and EPA, was able to design a new permit that allowed its microchip production facilities to change their product mix without new permits so long as umbrella emissions limits for entire facilities were met. With a product life cycle that can be as short as eight months, the ability to change product lines without having to modify a permit was essential for Intel to remain competitive.

Two elements were vital to the success of the more flexible approach used in the Intel situation: enhanced monitoring and public reporting, and earlier, more substantial stakeholder involvement. Because flexible permits are designed to reduce delays arising from government reviews and approvals (particularly given increasingly limited government budgets), alternative accountability mechanisms would ideally be substituted to ensure that the public is adequately informed and protected. These mechanisms would include government and public access to additional information that could help track facility performance and identify problems, and more stakeholder influence at the front end of the approval process over the structure of the regulatory mechanisms. Just as it has worked for the microchip industry, a more flexible approach to permitting designed with broad stakeholder involvement and relying on enhanced monitoring and public reporting may allow the nanotechnology industry to continue its rapid growth while adequately protecting public health and the environment.[48]

C. Public Involvement and Dialogue

If the nanotechnology industry does not address issues of public confidence in the technology, it may suffer the same fate as that of genetically modified seed crops in the European Union: rejection of the crops as unsafe by the public and by public officials even though the scientific consensus identified little risk from the use of GMO seeds.[49] While regulatory schemes play a role in engendering public confidence, confidence is primarily an issue of values and political and economic power. If opinion leaders view a product

40. U.S. EPA, NANOTECHNOLOGY WHITE PAPER (INITIAL DRAFT) 25 (Nov. 2, 2005).

41. ABA-SEER, RCRA REGULATION OF WASTES FROM THE PRODUCTION, USE, AND DISPOSAL OF NANOMATERIALS (2006), *available at* http://www.abanet.org/environ/nanotech/pdf/RCRA.pdf.

42. ABA-SEER, CERCLA NANOTECHNOLOGY ISSUES 13-14 (2006), *available at* http://www.abanet.org/environ/nanotech/pdf/CERCLA.pdf.

43. BREGGIN, *supra* note 28, at 8-16.

44. Glenn Harlan Reynolds, *Environmental Regulation of Nanotechnology: Some Preliminary Observations*, 31 ELR 10681, 10685 (June 2001).

45. U.S. EPA, NANOTECHNOLOGY WHITE PAPER (EXTERNAL REVIEW DRAFT) (2005), *available at* http://www.epa.gov/osa/pdfs/EPA_nanotechnology_white_paper_external_review_draft_12-2-2005.pdf.

46. *Id.* at 73.

47. THE ROYAL SOCIETY AND THE ROYAL ACADEMY OF ENGINEERING, *supra* note 24, at 82.

48. Lee Paddock, *A New Environmental Accountability System for the Nanotechnology Industry, in* 1 NANOTECH, TECHNICAL PROCEEDINGS OF THE 2006 NSTI NANOTECHNOLOGY CONFERENCE AND TRADE SHOW ch. 8, §2.1 (2006).

49. Malcolm Grant, *2005 Kerlin Lecture*, 9 GREENLAW 7 (2006).

as antipathetic to the values they hold, products may either be banned or may not survive in the market, regardless of the actual risk involved. The specter of unfounded public rejection suggests that accountability tools must be identified that create public confidence in the industry.

The risk of public rejection is especially acute in situations where scientific uncertainty is significant and where interest groups are likely to stake out strongly held positions early in the development of the technology. As Prof. Gregory Mandel noted in his study of responses to risks posed by biotechnology and by nuclear power production, "individuals and interest groups do not revise their technology preferences in response to scientific and empirical information in the manner that such information appears to indicate."[50] Rather, a wide range of cultural factors drive and reinforce polarization. These factors include biased assimilation of new data—Professor Mandel notes that "individual beliefs are remarkably resilient to the introduction of new data that challenges the beliefs"[51]; the tendency of individuals to rapidly and automatically have a positive or negative feeling when confronted with certain ideas or concepts; cognitive dissonance avoidance which leads individuals to discount information that conflicts with their perception of risks; and group dynamics that tend to perpetuate and reinforce polarization among individuals who socialize with those holding similar views.[52] The polarization phenomenon is aggravated by the fact that moderate voices tend to be underrepresented in debates involving technological risk because moderate voices typically do not inspire a "moderate movement."

A systematic approach to environmental accountability requires constructive contact among the industry, government, advocacy organizations, and other public stakeholders. Professor Mandel espouses a concept he calls "dialogue and deliberation," in which representatives of all of the interest groups (including moderates) engage in a culture-conscious dialogue that focuses on values, not just competing scientific claims about benefits and risks. "The goal of the dialogue would be to help different groups learn about each other and each other's views, with a goal of cultural accommodation and understanding. Once these objectives have been achieved, a substantive policy deliberation can begin, aimed at developing widely-acceptable policy solutions."[53] The Royal Society and Royal Academy of Engineering issued a similar call for public dialogue and debate on nanotechnology issues in its groundbreaking 2004 study of the industry:

> The general case for wider societal dialogue about novel technologies, and with its greater openness about science policy, rests on three broad sets of argument. . . . The normative argument proposes that dialogue is a good thing in and of itself and as such forms a part of the wider democratic processes through which controversial decisions are made. . . . The instrumental argument suggests that dialogue, as one means of rendering decision-making more open and transparent, will increase the legitimacy of decisions and through this generate secondary effects such as greater trust in the policy-making process. . . . Finally, the substantive argument is that dialogue will help generate better quality outcomes. In the field of environmental risk, non-technical assessments and knowledge have been shown to provide useful commentary on the validity or otherwise of the assumptions made in expert assessments.[54]

The Royal Society noted that with many mature technologies, public dialogue has often happened too little and too late to be effective.[55] With nanotechnology, there is a unique opportunity to avoid the problem of too little, too late.

Both the Meridian Institute and ELI have convened policy dialogues related to nanotechnology to launch the deliberation process, but a much more robust dialogue involving many more stakeholders and more approaches to assure environmental accountability will be needed as the industry continues to evolve.[56] The Natural Resources Defense Council and Environmental Defense have called upon both government and industry to do a better job of "engaging the broad array of stakeholders outside government and industry—labor, health organizations, consumer advocates and environmental NGOs—whose constituencies stand to be both beneficiaries of this new technology and those most likely to bear any risks that arise."[57]

EPA, industry organizations and interested NGOs should act with a sense of urgency in creating new forums for public dialogue and debate on nanotechnology. There are several types of dialogue that may contribute to the rationale and safe development of the industry. One model is a company-by-company dialogue, similar to the collaboration between Environmental Defense and Dupont, designed to create a framework for the responsible development, production, use, and disposal of nanoscale materials.[58] Another approach is a government-convened, ongoing dialogue among major stakeholders similar to the process EPA used in its Common Sense Initiative in the mid-1990s.[59] The lessons learned about how to conduct an effective, industry-focused, multistakeholder dialogue through the Common Sense Initiative, taken together with advances in understanding multistakeholder dialogues over the past decade and the fact that the nanotechnology industry is still in its infancy, could make a Common Sense type of dialogue far more effective today than it was 10 years ago. A third approach is a dialogue convened by a well-regarded neutral facilitation organization, perhaps funded by a combination of government, industry, and foundation support.

Dialogues engage surrogates for the general public, but it is also important to find ways to engage interested members of the general public directly. Better public education is an important element of a new public dialogue on nanotechnology. Education in this context cannot simply be a one-

50. Mandel, *supra* note 20, at 141.

51. *Id*. at 159.

52. *Id.* at 159-63.

53. *Id.* at 178.

54. The Royal Society and the Royal Academy of Engineering, *supra* note 24, at 63.

55. *Id.* at 64.

56. Meridian Institute, *Dialogue Series on Nanotechnology and Federal Regulations* http://www.merid.org/showproject.php?ProjectID=9233.0 (last visited Sept. 21, 2006); *see* Breggin, *supra* note 28.

57. Balbus et al., *supra* note 22, at 70.

58. *See* Environmental Defense, *Environmental Defense and DuPont: Global Nanotechnology Standards of Care Partnership*, http://www.environmentaldefense.org/article.cfm?contentID=4821 (last visited Sept. 21, 2006).

59. *See* U.S. EPA, Lessons Learned About Protecting the Environment in Common Sense, Cost Effective Ways (1998), *available at* http://www.epa.gov/sectors/pdf/pubs_lessons.pdf.

way effort to convince the public that nanotechnology has important societal benefits and is safe. Instead, the education process must be part of the dialogue requiring "innovative approaches to information provision, ones that involve a genuine two-way engagement between scientists, stakeholders and the public."[60]

Engaging a broad public in an esoteric issue like nanotechnology is difficult. Still, the Internet offers intriguing possibilities for a new form of two-way dialogue with the broader public. Such a dialogue could start with a website on which the best and most credible information on the developments in nanotechnology is regularly posted. This should include up-to-date information on both the risks and benefits of nanotechnologies, information about developments in government regulations, and information about industry standards and self-regulation approaches. The broader public could then use the site to comment on proposed regulations or on issues that could be addressed by members of the industry.[61]

Credibility and responsiveness are key issues for this idea to succeed. A government-managed site is one option, but given the role governments are playing in supporting nanotechnology development and the skepticism among many about government credibility, this may not be the best option. Other options include a neutral organization with experience in nanotechnology, such as the Meridian Institute, or a combination of well-regarded NGOs and broadly representative industry groups working together. One small-scale model of the later type of arrangement can be found in the innovative website jointly maintained by the Minnesota Center for Environmental Advocacy (MCEA) and Flint Hills Resources, a large oil refiner, on which emissions data is available to the public, which has an opportunity to comment directly to both MCEA and Flint Hills.[62]

Finally, a successful dialogue will require better information on the risks and benefits of nanotechnology. To date, most nanotechnology funding has been spent on technology development rather than on environmental health and safety research, or detection and monitoring technology.[63] One estimate by environmental organizations indicated that of the roughly $1 billion that the federal government spends annually on nanotechnology, environmental and health research constitutes less than 1%.[64] Assuring that adequate information is developed and disseminated on the health and environmental impacts of nanotechnology is critical to public credibility and an essential element of environmental accountability, as is better detection and monitoring technology.

D. Voluntary Programs

Industry leadership programs can play an important part in environmental accountability. Recognizing that environmental behavior is driven by factors beyond command and control regulations, EPA and many states have developed voluntary environmental leadership programs. The incentives for participating in these programs may include public recognition, improved working relationships with government agencies, penalty avoidance through auditing and self-reporting, and regulatory flexibility. As an emerging industry, it may be useful for EPA, industry leaders, and NGOs to consider the role that leadership programs could play in motivating desired environmental behavior.

Typical elements of environmental leadership programs include:

- a good compliance record;
- the existence of a company environmental management system that sets goals for environmental performance, maintains careful records, establishes employee training programs, requires periodic audits, provides for management review of the audits, and encourages continuous improvement in operations based on the management review; and
- reporting and prompt correction of violations that are identified through the environmental audits.

The goals established through leadership programs are often expected to go beyond mere compliance with the law to address unregulated matters, commit to emissions reductions that could not be required under existing regulations, or adopt preventive approaches that are not required by law.

Programs such as the Occupational Safety and Health Administration's Star Program,[65] EPA's Performance Track,[66] the Green Tier[67] in Wisconsin, and the Clean Corporate Citizen[68] program in Michigan are examples of well-developed leadership programs. EPA's Energy Star[69] program is another example of a leadership program, although one that exists in an area entirely unregulated by EPA. While these programs generally have broad support, some NGOs have expressed concerns that leadership programs can be resource-intensive, diverting government resources away from other important work, such as strengthening inspection and enforcement efforts. In addition, some NGOs feel that leadership programs do not focus on priority environmental problems. Yet another concern raised by some NGOs is that some companies have been allowed to remain in EPA's Performance Track program despite what the organizations see as a poor compliance record.

EPA should consider working with stakeholders to determine whether a special leadership program for nanotechnology companies or companies that use nanotechnologies in their products could be added to the Performance Track or a separate nanotechnology leadership program. Participation by a broad range of stakeholders in the consideration and design of leadership programs may help to limit future concerns with this approach to environmental accountability.[70]

60. The Royal Society and the Royal Academy of Engineering, *supra* note 24, at 66.

61. Briefing Paper, *supra* note 27, at 16.

62. *See* Flint Hill Resources and Minnesota Center for Environmental Advocacy, *Environmental Reporting Made Easy*, http://www.fhrpinebend.com/ (last visited Sept. 21, 2006).

63. *See* Davies, *supra* note 4, at 29.

64. Balbus et al., *supra* note 22, at 67.

65. *See* U.S. Dep't of Labor, *OSHA Voluntary Protection Program*, http://www.osha.gov/dcsp/vpp/index.html (last visited Sept. 21, 2006).

66. *See* U.S. EPA, *National Environmental Performance Track*, http://www.epa.gov/performancetrack (last visited Sept. 21, 2006).

67. *See* Wis. Dep't of Natural Resources, *Green Tier*, http://www.dnr.state.wi.us/org/caer/cea/environmental (last visited Sept. 21, 2006).

68. *See* Mich. Dep't of Envtl. Quality, *Clean Corporate Citizen*, http://www.michigan.gov/deq/0,1607,7-135-3307_3666_4134—-,00.html (last visited Sept. 21, 2006).

69. *See* Energy Star, http://www.energystar.gov (last visited Sept. 21, 2006).

70. Briefing Paper, *supra* note 27, at 6-7.

E. Liability

Nanotechnologies will face the threat of legal liability under nuisance, negligence, or strict liability theories if their use causes harm to public health or the environment. The potential for civil liability is a key element of accountability because government resources to deal with environmental problems are shrinking while environmental threats are increasing. The civil liability system plays a critical role in tempering corporate decisions to introduce potentially risky products into the market prematurely.

Companies should be able to mitigate their liability exposure by incorporating aspects of environmental accountability into the way they do business.[71] Liability can be mitigated by a robust regulatory regime that will encourage courts to view compliance with the regulatory scheme as establishing reasonable care on the part of the industry. The risks of civil liability can also be minimized by increased transparency. The worst-case scenario for companies is demonstrated by the fate of the asbestos industry and, more recently, by litigation related to anti-inflammatory drugs. A key factor in both liability situations is that information about the adverse impact of asbestos and the drugs was available to the manufacturer but was not disclosed to the public or regulatory authorities. Prompt disclosure of information about adverse impacts of a product does not immunize a company from legal liability. However, it can reduce the potential of legal liability in several ways.

First, the prospect of disclosure can provide the impetus for a company to modify its product, withhold, or temporarily remove it from the market until the impact can be better understood or the public can be more clearly warned. Second, disclosure can prompt regulatory action including additional studies, product warnings, or market restrictions. Third, disclosure allows consumers to make more informed choices in the use of a product. Finally, wider stakeholder involvement with access to more complete information early in the approval process may raise issues or problems that could be resolved before a product reaches the market, avoiding potential mishaps.

The prospect of liability for harm to public health or the environment will be an important accountability tool for the nanotechnology industry. Of equal importance is industry's opportunity to minimize that liability by employing accountability mechanisms such as public reporting and early public involvement.

F. Industry Codes and Self-Regulation

Industries have increasingly turned to codes of conduct and industry self-regulation as means of assuring compliance with environmental laws, maintaining their reputation, reducing the risk of legal liability, enhancing relationships with government agencies, minimizing exposure to penalties, and building public confidence. These codes and self-regulatory mechanisms are important accountability tools, especially if the codes or self-regulatory mechanisms increase the amount of information available to the public. Modern industry environmental codes trace their origin to the Coalition for Environmentally Responsible Economies (CERES) and its CERES Principles adopted in response to the *Exxon Valdez* disaster.[72] The American Chemistry Council (ACC), then the Chemical Manufacturers Association) adopted its Responsible Care©[73] program in part to deal with increasing public concern about the role of discarded chemicals in groundwater contamination during the late 1980s. Responsible Care© is a mandatory program for all ACC members and is practiced in 52 countries.[74] The Forest Stewardship Council, an NGO, developed a code for sustainable forestry practices and certifies compliance with its code to deal with the fact that forest management practices were rarely regulated.[75]

In the mid-1990s, the International Organization for Standardization (ISO) began work on a standard for what constitutes a quality environmental management program based on its early quality management standard.[76] The environmental management standard—ISO 14001—now in wide use around the world, provides a template for identifying the environmental aspects of an organization, setting goals for reducing those impacts, monitoring the goals, reporting results to management, and adjusting business practices based on the information—often referred to as the "plan, do, check, act" model. The most recent ISO 14001 survey shows that at the end of 2005, 111,162 facilities held ISO 14001 certificates (up from 36,464 in 2001) in 138 countries.[77] A significant number of companies use the ISO 14001 management standard but do not take the additional steps necessary to qualify for formal certification.

Broad adoption of ISO 14001 by companies in the nanotechnology industry could help to identify and deal with potential adverse environmental and public health impacts of nanomaterials, even in the absence of government regulations. An enhanced environmental management system (EMS) advocated by the Multi-State Working Group on Environmental Performance[78] (MSWG) could be an even better approach to self-regulation. The "External Value EMS" developed by the MSWG addresses three issues that many in government and NGOs see as major gaps in an ISO 14001 EMS. ISO 14001 does not require a company to demonstrate compliance with environmental requirements, involve stakeholders in the EMS process, or disclose information developed through the EMS to the public. The External Value EMS includes these additional requirements[79] and could be more effective than a standard EMS in building and maintaining public confidence.

Given the likely limitations on the government's ability to respond to nanotechnology, self-regulation is important

71. Mark Stallworthy, *Environmental Liability and the Impact of Statutory Authority*, 15 J. Envtl. L. 3 (2003).

72. *See* Ceres, http://www.ceres.org (last visited Sept. 21, 2006).

73. *See* Responsible Care, *The Chemical Industry's Performance*, http://www.responsiblecare-us.com/about.asp (last visited Sept. 21, 2006).

74. *Id.*

75. *See* Forest Stewardship Council, http://www.fscus.org (last visited Sept. 21, 2006).

76. *See* ISO, *ISO 9000 and ISO 14000—in Brief*, http://www.iso.org/iso/en/iso9000-14000/understand/inbrief.html (last visited Sept. 21, 2006).

77. ISO 25 (2005), *available at* http://www.iso.org/iso/en/iso9000-14000/pdf/survey2005.pdf.

78. *See* Multi-State Working Group, *Welcome to the Multi-State Working Group on Environmental Performance*, http://www.mswg.org (last visited Sept. 21, 2006).

79. Multi-State Working Group, The External Value Environmental Management System Voluntary Guidance (2004), *available at* http://www.mswg.org/documents/guidance04.pdf.

to avoiding potential adverse impacts from nanotechnology and to build public confidence in the industry. Forms of self-regulation such as the External Value EMS, which enhance public access to information, may be particularly valuable. Both the Natural Resources Defense Council and Environmental Defense have recognized the importance of corporate standards of care:

> Even under the most optimistic scenario, it appears unlikely that federal agencies will put into place adequate provisions for nanomaterials quickly enough to address the materials now entering or poised to enter the market. Out of enlightened self-interest, industry must take the lead in evaluating and managing nanomaterial risks for the near term, working with other stakeholders to quickly establish and implement life cycle-based "standards of care" for nanomaterials.
>
> These standards should include a framework and a process by which to identify and manage nanomaterials' risks across a product's full life cycle, taking into account worker safety, manufacturing releases and wastes, product use, and product disposal. Standards of care should also include and be responsive to feedback mechanisms, including environmental and health monitoring programs to check the accuracy of the assumptions about a material's risks and the effectiveness of risk management practices. Such standards should be developed and implemented in a transparent and accountable manner, including by publicly disclosing the assumptions, processes, and results of the risk identification and risk management systems.[80]

Nanotechnology industries should act now through organizations such as the ACC, the NanoBusiness Alliance, and other business entities to advance the dialogue on self-regulation in consultation with NGOs and government. Mediation organizations such as the Meridian Institute can play an important role in facilitating this dialogue.

G. Creating an Accountability System

Traditional regulatory systems are complex to develop and manage; a more inclusive environmental accountability system is likely to be even more difficult to oversee. Government controls the regulatory system, but can only influence many of the other accountability tools. Environmental accountability, especially in the context of nanotechnology, will require a new governance approach. The approach must incorporate government and its critical role in accountability, but must also engage industry and the public in a new management partnership.

A multistakeholder Nanotechnology Council could serve this function. The Council could be independently chartered or could be organized by government under the Federal Advisory Committee Act. The Council should utilize facilitated dialogue provided by a highly credible mediation/facilitation organization to identify the parties that should be at the table, the issues that are discussed by the Council, the form of deliberation, and communication links to relevant stakeholders. Among the issues that the Council should address are public education, additional mechanisms for public dialogue, research priorities, risk/benefit identification, and regulatory approaches. It should analyze how the various accountability mechanisms—the regulatory system, dialogue and information, voluntary programs, liability, and self-regulation—can be organized in a systematic way to support appropriate growth of the industry. The Council should not be a short-term project; rather, it should remain in existence as the major stages in nanotechnology reach the market and until it is clear that there are no remaining major public policy issues related to nanotechnology.

V. Conclusion

Nanotechnology presents a daunting challenge to government, industry, and the public in building a credible system of environmental governance. Stakeholders from all sectors have recognized that a new system of governance that includes and reaches beyond reliance on government agencies will be needed. To ensure that public health and the environment are protected while facilitating the development of potentially transformative products and services, businesses, governments, and NGOs must act with a sense of urgency to develop and co-manage a new system of environmental governance that can keep pace with nanotechnology.

80. Balbus et al., *supra* note 22, at 70.