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EMS/Innovative Regulatory Approaches

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EXECUTIVE SUMMARY

Rather than simply applying existing legal authority and regulatory approaches directly to nanotechnology in all respects, an innovative approach may be needed for several reasons. Potential accountability mechanisms include corporate stewardship, voluntary programs, flexible and performance-based standards, tailored monitoring and reporting, and proactive public education and dialogue. While the protection of human health and the environment is important, the evaluation of standards and approaches should be done within the appropriate context of the material in question, its setting, and the actual risks posed so as not to raise concerns where impacts are unlikely or to unduly restrict economic development. The unique nature of nanotechnology may also require an innovative approach to industry's concerns related to potential liability and confidentiality. Reference to foreign efforts may help guide the U.S. Environmental Protection Agency's (EPA) efforts toward consistency, efficiency, and effectiveness. Above all, the emergence of the nanotechnology industry requires EPA to think of environmental management as a systematic approach where regulation is only one of many possible tools to deal with potential environmental and public health issues.

I. INTRODUCTION

Because the environmental and exposure issues related to nanotechnology may be different in kind from technologies with which regulators are more familiar, an innovative approach to environmental management may be needed. Historically, the United States and many other countries have relied on a government-based regulatory system that has focused primarily on controlling workplace exposures, reducing end-of-the pipe and fence-line emissions from larger industrial facilities, management standards for hazardous wastes, and information disclosure and risk analysis for new chemicals and pesticides as the principal methods of holding industries accountable for the workplace, environmental, and public health consequences of their activities and products. As one commentator has noted, at least with respect to air, water, and waste standards, environmental regulators have applied 20th century approaches (primarily command and control regulations) to regulate 19th century technologies (such as industrial

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boilers, metal plating operations, and wastewater treatment plants). The historical approach has been successful in dealing with some of the most significant water, air, and soil pollution problems of the past. This may not be the most advantageous approach for nanotechnology for several reasons, however, including:

- the speed at which nanotechnologies are developing;
- the competitive pressures to move technology quickly into the marketplace;
- the limited resources available to government regulators;
- the difficulty in enacting new federal environmental legislation;
- the level of scientific uncertainty and the complex risks involved with nanotechnology;
- the difficulty in monitoring nanoscale releases; and
- the importance to the industry of maintaining public confidence.

Government agencies, the nanotechnology industry, advocacy organizations, individuals, and other relevant stakeholders may wish to consider employing an innovative range of management systems and accountability mechanisms to create a more sustainable and reliable system that assures public health and environmental protection while facilitating the growth of this fledgling, but potentially transformative, industry. The goal would be to avoid the rote application of existing regulatory approaches to these 21st century technologies if a better way exists.

The purpose of this paper is to provide some general thoughts and identify potential issues for consideration, but not to offer specific recommendations. Other briefing papers will focus on the issues related to nanotechnology in the context of specific environmental statutes and regulatory programs.

II. ENVIRONMENTAL ACCOUNTABILITY

"Environmental accountability" is a concept that incorporates a broad range of mechanisms designed to subject the environmental behavior of organizations to public scrutiny. The goal would be to encourage individual members of industry to engage in preferable environmental behavior by a systematic approach that uses a variety of mechanisms to foster a sense of responsibility, provide economic incentives, and establish certain legal obligations. Such mechanisms may include:

- the traditional regulatory and enforcement system;

- new approaches to regulation, including more flexible performance-based standards;
- economic instruments and product standards;
- enhanced monitoring and required public reporting;
- liability standards;
- voluntary industry leadership programs and public reporting protocols;
- improved public education;
- corporate social responsibility programs; and
- relevant stakeholder dialogues

Instead of relying solely or even primarily upon regulations, an environmental accountability regime would employ a variety of mechanisms. Some would be imposed by government, while others would be voluntarily adopted (or acquiesced to) by affected organizations based on self-interest or individual or organizational values. Still other mechanisms may result from economic pressure from customers, investors, and the public at large.

Implementation of environmental accountability regimes can vary greatly. Some examples may be useful. In 2005, Environmental Defense (ED) and DuPont entered into a partnership to develop a joint framework for the responsible development, production, use, and disposal of nanoscale materials. The ED-DuPont Responsible Nanotechnology Standards initiative will develop principles and processes for evaluating risks associated with nanoscale materials; developing risk management approaches for the manufacture, use, and disposal of nanoscale materials; and communicating risk identification and risk management decisions to stakeholders, such as consumers, regulators, and the public.

In addition to the ED-DuPont initiative, many other self-governance and best practices initiatives have been launched by various organizations. Some of these initiatives include the International Council on Nanotechnology, managed by Rice University's Center for Biological and Environmental Nanotechnology, the ASTM International's Committee E56 on Nanotechnology, and the International Organization for Standardization's Technical Committee on Nanotechnologies (TC 229).

The implementation of the self-governance initiatives will generate information on logistical and economic feasibility of these mechanisms, and can help develop critical information to understand whether and what type of dedicated regulatory program may be necessary. These initiatives could serve as the basis for the broad application of voluntary programs that will provide the emerging nanotechnology industry with the necessary flexibility to adjust to the market while providing sufficient safeguards to protect human health and the environment. Moreover, as the EPA has successfully demonstrated under the National Environmental Performance Track Program, environmental management systems can be used as a voluntary regulatory tool, and the standardization of a nanotechnology management system could serve as the basis for providing accountability and transparency to a voluntary nanotechnology management program.

III. LEADERSHIP INCENTIVES

Another example of environmental accountability is leadership incentives. 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 non-governmental organizations (NGO) 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, often addressing unregulated matters, committing to emission reductions that could not be required under existing regulations, or adopting preventive approaches that are not required by law.

Programs such as the Occupational Safety and Health Administration's (OSHA) Star Program, EPA's Performance Track, the Green Tier in Wisconsin, and the Clean Corporate Citizen Program in Michigan are examples of well-developed leadership programs. EPA's Energy Star 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 historically expressed concerns that leadership programs can be resource intensive, diverting government resources away from other important efforts such as strengthening inspection and enforcement efforts. In addition, some NGOs believe that leadership programs do not focus on priority environmental problems. Another concern raised by some NGOs is that some companies have been allowed to remain in EPA's Performance Track program despite what may be seen as a poor compliance record.

EPA should consider working with members of the nanotechnology industry, NGOs, and other relevant 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 created to take advantage of the incentives for better performance available through these programs. Participation by a broad range of stakeholders in the consideration and design of leadership programs may help to limit future problems and concerns.

IV. LIABILITY CONCERNS

Environmental accountability and voluntary management systems also relate to liability concerns. Common law and statutory liability for nanotechnology, as with any new technology or product entering the marketplace, will depend upon the factual context. In general, however, liability for very fine particulates and persistent pollutants has historically pushed the boundaries of the "failure to warn" doctrine, as the harm caused may take years to materialize as a measurable problem traceable to particular activities. Companies seeking a suitable liability prevention approach could use processes like environmental management systems and related product liability prevention oriented toward disposal risks, and control the long-term risks of nanoscale particulate matter.

Through environmental management systems, companies must identify activities that "touch" the environment. Where a regulatory framework is conditioned upon such releases through reporting requirements that have a threshold level which does not require reporting of de minimis quantities, there may be a need for environmental management that goes beyond (or operates in lieu of) regulatory requirements. Small quantities of persistent pollutants could accumulate in a manner that leads to long-term liability risks, but not where a sound environmental management system monitors this risk.

One approach may be for EPA to encourage the establishment of stewardship standards that attempt to foresee and avoid potential liabilities. In this manner, the environmental management system can operate as a liability prevention measure, and also create a feedback loop that aids the regulatory community in determining the proper threshold to use and test to require reporting or other waste management requirements. In other new technology settings (*e.g.,* pest-resistant biotech crops under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA worked with industry to create voluntary environmental management system approaches that were incorporated into permits -- and imposed via contract on the chain of commerce. EPA took the data obtained in practice and tailored the program to optimize it. Similar approaches could be used in nanotechnology to attempt to reach an optimum balance between beneficial innovation and the regulatory oversight that controls environmental liability risks.

V. MONITORING, REPORTING, AND PERMITTING

Tensions may arise between (1) the desire of nanotechnology companies to bring their products to market quickly; (2) the limited data which currently exist on potential exposures and risk related to nanotechnology; (3) the goal of protecting the environment and public well-being; and (4) the desire to reasonably accommodate relevant stakeholders while not unduly stifling economic potential. While regulations have played an important role in evaluating certain risks which are more readily assessable and less reliant on contextual (rather than more theoretical) exposures and risks, the existing framework may not be best suited to nanotechnology. That said, it is important to note that the last several years have seen an evolution in the driving forces for testing, monitoring, and reporting potential risks.

The roles of individuals, NGOs, and political leaders have increased significantly in securing the development and disclosure of additional data related to potential environmental and exposure risks in addition to (or in lieu of) more demanding regulation. Consumer acceptance or rejection of new products can clearly sway industry behavior. In addition, manufacturers and investors may be driven by self-interest to evaluate and limit workplace exposures, environmental risks, and product liability claims. When viewed in this light, the development of reporting monitoring and reporting requirements through a collaborative approach of qualified stakeholders may significantly reduce the tensions noted above.

The unique and varied nature of the nanotechnology industry may require an even stronger reliance on the involvement of relevant stakeholders in the development and evolution of formal or informal government or industry standards through the following efforts:

- Developing monitoring and reporting guidelines through a high level panel composed of scientists, regulators, environmental and safety NGOs, and nanotechnology industry representatives convened by the government, organizations such as ISO, or through a dialogue process such as those convened by organizations such as the Meridian Institute.

- Developing and funding a research regime aimed at rapid “ramp up” of the assessment and identification of nano-size industrial products, byproducts, and releases.

- Quickly developing monitoring technology needed to assess realistic releases, exposures, and risks involving nanomaterials.

- Recognizing that the potential exposures, pathways, and risks must be evaluated in the appropriate context and setting throughout the process.

Several examples from the permitting context are pertinent. One readily available model for flexibility is the “plant-wide applicable limits” approach developed under the Clean Air Act 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 its 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.

A second model for flexibility is the cap and trade system used to regulate sulfur dioxide emissions from coal-fired power plants. Because the primary concern about sulfur dioxide emissions was that they generated acid rain over wide areas of the country, Congress established a ceiling (a cap) on sulfur dioxide emissions from coal-fired power plants at a level substantially lower than existing emissions. After allocating emissions allowances to all of the regulated facilities, Congress authorized the facilities to trade emissions allowances among each other so long as a plant held at the end of each year one allowance for each ton of sulfur it emitted. This system allowed the plants wide latitude in choosing how to control emissions, stimulated innovation, and substantially reduced the cost of compliance.

The point of these two examples is not that they necessarily have specific applicability to nanotechnology. Rather, the examples demonstrate that imaginative regulatory approaches can be devised in the context of open stakeholder negotiations.

Two elements were essential to the success of the more flexible approach used in the Intel situation: enhanced monitoring and public reporting, along with earlier and 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.

VI. ADAPTABLE RULES

A threshold issue is to distinguish between “pollutants” or “waste” on the one hand, and manufacturing “products” or “tools” on the other. It would seem that if the manufacture and use of nanomaterials are properly managed in a reasonably controlled environment, then it may be appropriate to limit or avoid the regulation of such materials and uses. For example, EPA policy or guidance could establish handling criteria that would exempt certain products or activities from the application of certain regulatory requirements (*e.g.*, the use of carbon nanotubes within an enclosed structure). Compliance with those criteria would allow a company to avoid regulation within that context. This approach is similar to the way infectious waste has been controlled. The primary problems with infectious waste are proper isolation, packaging, storage, and disposal to prevent exposure. Rather than adopt a full-scale, RCRA-like program to deal with what was primarily an occupational exposure issue, many states opted for narrower standards that focused on improved waste handling.

Applying this approach to the management of nanomaterials, more tailored command and control requirements would be triggered in the event of an exposure-relevant release or non-compliance with the established criteria. Such an approach may alleviate industry concern about potential permitting requirements, citizen suits, etc., while providing a contextual framework for EPA and the public to appropriately assess and respond to actual risks.

EPA may also consider the implementation of pilot programs, temporary requirements or voluntary programs to evaluate the efficacy of certain approaches before promulgating mandatory and enforceable regulations. This approach may need to be revisited should a loss of public or regulatory confidence arise due to the perception of a serious threat, government inaction, or industry shortcomings. This may be viewed as a potential risk of the "wait and see" approach, however.

VII. CLEAR ENFORCEMENT PRIORITIES

The future development and commercialization of nanotechnology in the United States could significantly depend upon the effective formulation and implementation of clear federal and state environmental and worker safety enforcement priorities. Enforcement priorities should reflect the lessons learned from existing environmental and worker safety programs. More than 30 years of empirical evidence demonstrates that effective enforcement is a function of clarity, predictability, and rationality (CPR). First, enforcement agencies should set clear and generally applicable workplace and environmental performance standards. Legal uncertainty, whether due to the lack of clarity or inconsistent state and federal requirements, is the enemy of environmental and worker safety, economic development, and technological growth.

Second, enforcement should be predictable. Enforcement in some programs may appear to some to be dependent on the individual preferences and perceptions of field and program personnel. In some cases, a condition or practice that one inspector or agency views as a significant violation proves to be of little or no concern to another inspector or agency in a different jurisdiction. To the extent possible and at the outset of the development of management requirements, it may be advantageous to implement one consistent, performance-based compliance and enforcement standard, applicable to as many companies as possible.

Third, enforcement priorities would preferably be rationally based and rationally applied. It is not at all clear that existing enforcement priorities and paradigms, designed to address the environmental and workplace safety problems associated with older manufacturing processes and technology, will have salience with the newer manufacturing processes, technologies, and products that are on the horizon. Rote reliance on existing enforcement priorities and approaches could at once cripple progress and prevent useful products from reaching the market, while at the same time simply missing opportunities to address potentially new environmental and/or workplace risks. On the other hand, the hasty development of a nanotechnology-specific enforcement program -- even if legally supportable -- could prove counterproductive. This suggests that a more cautious approach would be appropriate.

Relying on the range of compliance tools available to EPA and the states may also be important. These include compliance training programs, technical assistance, environmental auditing, encouraging the use of environmental management systems and participation in environmental leadership programs. Compliance training may be somewhat difficult at the outset depending upon the nature of nanotechnology regulation and the expertise of state and federal regulators and their contractors. Still, compliance assistance may be important for new, smaller entrants into the industry. Promoting the use of environmental auditing and environmental management systems may stimulate more careful self-regulation from the outset and limit the need for enforcement actions. Finally, finding a place for nanotechnology companies within corporate leadership programs could help establish a standard for excellence in environmental management among companies involved with nanotechnology.

VIII. BALANCE BETWEEN CONFIDENTIALITY AND PUBLIC DISCLOSURE

Regulated businesses typically provide both routine and episodic reports to state and federal agencies regarding environmental releases and chemical management. Consideration should be given by both government and the regulated community about what portions of these reports should be submitted and maintained subject to confidentiality claims based on public safety concerns rather than trade secret/confidential business information or national security grounds. Currently, most environmental reporting programs do not, or do not adequately, provide for confidentiality claims by regulated entities based on public safety concerns. The federal Freedom of Information Act does exempt documents in government files from mandatory public disclosure on public safety grounds, but only in connection with documents related to law enforcement. Further refinements to state and federal “freedom of information” laws may be deemed necessary to address the need to exempt certain information from pubic disclosure on public safety grounds.

Nanotechnology’s risks may arise in the setting of confidential research relating to adverse effects. At one level, material information about environmental risks can trigger SEC reporting and tort law obligations, even where the material information was generated from unpublished research that reveals not only the risk, but confidential aspects of the technology. The decision to disclose such research may also present complex questions of law and scientific ethics where there is a question as to whether the research was performed in accordance with accepted scientific principles, whether the results are statistically significant, and whether the study adequately controlled for confounding factors. Moreover, under one statute applicable to some nanotech (FIFRA), there is a data compensation program that applies to confidential information from which EPA and other companies benefit. Original data submitters have 15 years in which other registrants must compensate them for use of their data.

Other concerns must be addressed in balancing the desire for public disclosure while maintaining confidentiality. Unlike potential risks to health and safety, which arise in the context of security/vulnerability assessment and workplace/end-user exposure, these other concerns are purely economic, but of significant importance in encouraging the development of nanotechnology products and applications.

Protection of intellectual property rights and proprietary business information is crucial to fostering an environment which encourages capital expenditure to develop nanotechnology products and markets. When dealing with disclosure of sensitive nanotechnology information, those who engage in nanotechnology businesses also have legitimate concerns for the protection of proprietary information so as not to enable reverse engineering or unfair competition in world markets, and to shield themselves from presently unforeseen, unspecified, and unregulated liability. Although the Freedom of Information Act provides certain protection for proprietary information, additional innovative protections will need to be addressed and implemented such as the use of panel science-law judges, among others, to protect the propriety or intellectual property of the creators of innovative technology from unfair competition, and to limit the mechanism and availability of citizen suits which such otherwise unshielded mandatory disclosures would invite.

Finally, a mechanism for risk assessment must be crafted to permit the controlled but necessary sharing of confidential information with insurers and others who furnish acceptable risk shifting mechanisms, such as private or federally funded liability insurance, to be utilized for the benefit of all -- nanotechnology businesses as well as workplace and end-user exposures.

These confidentiality issues must be addressed in the context of the need for good information to allow government to design appropriate management approaches and the need for sufficient information about both the risks and benefits of nanotechnologies to build public confidence in the industry. A dialogue among relevant stakeholders on information confidentiality and disclosure that carefully parcels out what information must be maintained as confidential to protect legitimate trade secrets, security issues, and the need for transparency could be an important early step in making progress on this critical issue.

IX. PROMOTION OF NANOTECHNOLOGY FOR ENVIRONMENTALLY BENEFICIAL USES

Environmentally friendly nanotechnology (EFNT) has potential application in manufacturing through reducing waste, replacing toxic materials with less toxic alternatives, and requiring less resources and energy. EFNT also has applications in green energy, waste treatment and remediation, and environmental sensors. This section offers some thoughts on how EPA could further its underlying goal of protecting human health and the environment by encouraging the development and use of EFNT. These suggestions are generally aimed at furthering EPA's ongoing efforts; most would avoid substantial additional cost or rulemaking.

Elements of public education and dialogue efforts may include:

- Providing context under realistic scenarios for the use of and potential exposure to EFNT.
- Publicizing technical reviews, guidance, and success stories related to EFNT.
- Encouraging similar efforts by state environmental agencies.
- Informing governmental entities and industry about EFNT means for reducing waste, reducing resource use, and saving energy.

- Hosting forums and conferences on EFNT technologies for governmental entities and industry.

- Seeking input from industry on how its EFNT products could be utilized and promoted.

- Advising industry of less toxic EFNT alternatives to other materials.

With respect to remediation techniques utilizing EFNT, EPA may consider:

- Prioritizing more research and use toward a variety of regulated sites and conditions over more relevant time periods.

- Encouraging their use at sites where the known risks from existing conditions considerably outweigh the potential risks from EFNT.

- Encouraging the use of experimental EFNT at portions of sites as appropriate.

- Providing flexibility and other incentives for the use of experimental ENFT remediation techniques (*e.g.*, more flexible timelines and conditions).

- Using it at sites managed by EPA and other federal facilities.

- Creating a registry of sites where EFNT has been used successfully, and information about EFNT use at those sites.

- Establishing defined and feasible metrics for demonstrating acceptable fate and transport, toxicity, and exposure risks related to the introduction of nanomaterials into the environment.

EPA may also create incentives for using EFNT products and technology by:

- Encouraging the purchase and use of EFNT by public entities (federal, state, local).

- Discounting permit and application fees.

- Prioritizing permit and approval processing.

- Considering the beneficial use of EFNT in the context of enforcement actions (*e.g.*, supplemental environmental projects; offsets for penalties or consideration of the calculated economic benefit of noncompliance).

A promotional program for EFNT could be developed in the context of a wider analysis of the role that EPA should play in publicizing both the benefits and the risks of nanotechnologies. This approach could allow EPA to identify and promote the environmental benefits without running the risk of losing credibility by over-promotion without adequately taking into account certain risks involved.

X. CONSIDERATION OF INTERNATIONAL APPROACHES

A number of reasons may exist for international coordination or consideration of nanotechnology management:

- Virtually every industrialized nation is actively pursuing scientific research and economic development of nanotechnology.

- Rapid globalization of economy, industry, and innovation systems suggest much value in consistent regulatory frameworks.

- Seeking coordinated international approaches at the outset of regulatory consideration would avoid trade and other disputes between conflicting entrenched national programs (*e.g.*, U.S./exporter vs EU/importers dispute over biotech crop approvals).

Existing international regimes, such as the Basel Convention on Hazardous Waste or the United Nations Convention on Transport of Dangerous Goods, may cover applications of nanotechnology, but require interpretation or negotiations to determine what fits where. In some instances, these Conventions may drive the adoption of nanotechnology as substituting for more hazardous technologies in electronic waste.

Formal international regulations or treaties specific to nanotechnology would be premature at this time given nascent state of technology and uncertainties about potential risks, and the wide variety of industries and media (air, water, etc.) that can be implicated. Initial international coordination efforts should therefore focus on information sharing, confidence-building, and voluntary measures. The threat of liability exists independent of regulation, and it is already driving industry self-governance.

Rather than trying to reinvent the wheel for nanotechnology alone at the international level, emphasis should be on supporting and advancing existing international coordination initiatives, including:

- ***International Standards Organization****:* The ISO has established a Technical Committee (TC 229) to develop international standards for nanotechnology, including standards for: terminology and nomenclature; metrology and instrumentation; test methodologies; modeling and simulation; and *science-based health, safety, and environmental practices.*

- ***ASTM:*** The ASTM has established an International Committee E56 on Nanotechnology that is currently developing standards for nanotechnology, including one that addresses environmental safety issues.

- ***Meridian Institute:*** The Meridian Institute and the National Science Foundation (NSF) sponsored an international Dialogue on Responsible R&D in Nanotechnology in June 2004 attended by officials from 25 nations. The purpose of the meeting was "to bring together governmental representatives from countries with significant nanotechnology research and development (R&D) programs to enter into an informal dialogue about how best to ensure that such programs are carried out in a responsible manner." The meeting resulted in an agreement "to form a preparatory group to explore possible actions, mechanisms, timing, institutional frameworks, and principles for ongoing international dialogue, cooperation, and coordination in the area of responsible R&D of nanotechnology."

- ***International Risk Governance Council***: The IRGC has launched an initiative to develop a "conceptual risk governance framework" for nanotechnology that will be globally acceptable. It has published a comprehensive draft report entitled "Nanotechnology Risk Governance" and convened meetings in January 2006 and July 2006 to develop an international risk governance system for nanotechnology.

- ***Semiconductor Industry Trade Associations (U.S., Korea, EU, Japan, and Taiwan):*** Foresee a "post-silicon era'" in their "International Technology Roadmap for Semiconductors," which projects nanotechnology as replacing current chip-making processes in another decade or two. Molecular electronics will sustain the chip industry rule "Moore's Law," which projects a doubling of computing power in two-year timeframes. The Roadmap addresses Environmental Health & Safety as well.

- ***Institute of Electrical and Electronics Engineers***: The IEEE, which has a standard setting component, convened an international workshop to map standards for nanotechnology in 2003, attended by representatives of ten nations, and has since begun to develop standards for nanotechnology.

- ***International Association of Nanotechnology:*** IAnano is working on a roadmap and framework for nanotechnology, including developing guidelines for quality control, health and safety, and nomenclature of nanotechnology.

- ***International Council on Nanotechnology:*** One of the major activities of the ICON is "to provide a multi-stakeholder, international and neutral forum for exploring health and environmental issues."

International coordination and regulation of nanotechnology will face many challenges and obstacles, including the different political, economic, and technological perspectives and capabilities of different nations. Nevertheless, for the reasons stated above, international coordination may offer potential benefits. Given the numerous international initiatives listed above, it would be advisable for EPA, before considering unilateral U.S. regulations, to consider and participate in existing international initiatives to see if an international consensus emerges on a regulatory approach for nanotechnology. At a minimum, consideration of such approaches may provide insight and guidance on more favorable approaches.

XI. EXPANDED PUBLIC EDUCATION

A public education program should be evaluated to provide the public with accessible information on the status of nano-material development, potential benefits and risks of nanomaterials, what is being done to investigate and understand the risks, what is being done by EPA and others to protect against the risks, and what individuals can do to protect themselves against any risks. Such a program could include, among others, the following elements:

- Developing pages on EPA's website that provide a variety of information, FAQ sheets, guidance, references for further information (*e.g.*, a link to the National Institute of Occupational Safety and Health webpage), examples of use, etc.
- Establishing a web-based dialogue on the benefits and risks of nanotechnology that is open to industry and the general public.
- Disseminating information and availability of information through press releases and print and other media by providing information to, and encouraging dissemination by:
    - State and local officials, such as through the National League of Cities, National Association of Counties, U.S. Conference of Mayors, etc.
    - State and local regulatory bodies.
    - Potentially related trade groups, industry organizations, and legal associations (*e.g.*, state bars or the environmental and regulatory sections of state bars).
    - Various public interest groups.
- Considering the feasibility of involving qualified stakeholders (industry, scientists, public interest organizations) in the creation of the public education materials, and highlighting the varied involvement.

In addition to the above efforts, it would be helpful to hold multi-stakeholder forums involving industry, scientists, lawyers, academics, public interest representatives, and others for insight into perceived risks, tension points, perceptions of regulatory protection, and possible ways to resolve various issues. Such forums should consider involving members of the general public in stakeholder forums and separate discussion or breakout groups to achieve same objectives.

By creating opportunities for the public to have open access to as much information on the nature of nanotechnology and its potential benefits and risks, EPA would allow open-minded participants to provide input based more on knowledge than on fear.

XII. A SYSTEMS APPROACH

The nanotechnology industry is facing at least two critical issues related to environmental management. The first is the need for a flexible and adaptive approach to environmental oversight that takes into account both the regulatory system as well as other approaches of driving desirable environmental behavior. The second is building and maintaining public confidence. 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 EU -- rejection of the crops as unsafe by the public and by public officials, even though the scientific consensus identified little if any risk from the use of GMO seeds. The specter of unfounded public rejection suggests that accountability tools must be identified that create public confidence in the industry. Both of these issues support the importance of a systems approach to environmental management.

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 Professor 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.” Rather, a wide range of cultural factors tend to drive and reinforce polarization. These factors include biased assimilation of new data -- Mandel notes that “individual beliefs are remarkably resilient to the introduction of new data that challenges the beliefs”; 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. 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.”

The risk of public rejection of nanotechnology for non-scientific reasons may be reduced if companies and government use the tools of environmental accountability early in the commercialization process. Accountability could be enhanced by providing more open access to information about the public health and environmental issues, involving a wide range of stakeholders in discussions about the appropriate approaches to regulating nanotechnology, enhancing monitoring, providing the public with credible information about both the risks and the societal benefits of the technology, and creating a process that allows regulations and industry practices to adapt to new scientific findings.

A productive systematic approach to environmental accountability requires constructive contact among the industry, government, advocacy organizations, and other public stakeholders. Mandel espouses a concept he calls "dialogue and deliberation" in which representatives of the relevant interest groups (including "moderates") engage in a "culture-conscious" dialogue that focuses on values, in addition to potentially competing claims about the scientific, economic, and social 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." Both the Meridian Institute and the Environmental Law Institute 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 may be needed as the industry continues to evolve. The earlier that these dialogues are initiated and the more open they are, the more likely that the dialogues will avoid or overcome interest group polarization. The dialogues would be most productive and useful if they focus on the real risks associated with the industry based on the best available scientific evidence, and finding ways to address the risks while allowing the industry to continue to develop. The result should be increased public confidence and reduced risk of unfounded rejection of new technology.

CONCLUSION

We believe that the issues surrounding nanotechnology provide an interesting and unique opportunity for EPA to imagine and implement a 21st century approach to environmental management. Consideration of the issues and options presented here would allow the systematic development and use of a wide range of tools to encourage desirable environmental behavior that will protect human health and the environment while allowing the industry to grow and compete globally.