Woodrow Wilson International Center for Scholars
Project on Emerging Nanotechnologies

VOLUNTARY INITIATIVES, REGULATION, AND NANOTECHNOLOGY OVERSIGHT:

Charting a Path

Daniel J. Fiorino

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ACRONYMS

DEP	Department of Environmental Protection (Massachusetts)
EMS	Environmental Management Systems
EDF	Environmental Defense Fund
EPA	Environmental Protection Agency
ERP	Environmental Results Program
FDA	Food and Drug Administration
FSC	Forestry Stewardship Council
HPV	High Production Volume
ISO	International Standards Organization
MSC	Marine Stewardship Council
NGO	Non-government organization
NIA	Nanotechnology Industries Association
NMSP	Nanoscale Materials Stewardship Program
NRDC	National Resources Defense Council
OSHA	Occupational Safety and Health Administration
PEN	Project for Emerging Nanotechnologies
RCMS	Responsible Care Management System
SFI	Sustainable Forestry Initiative
TERA	Toxicology Excellence for Risk Assessment
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
USCAP	U.S. Climate Action Partnership
VCCEP	Voluntary Children's Chemicals Evaluation Program
VPP	Voluntary Protection Programs

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PREFACE

Over the past five years, the Project on Emerging Nanotechnologies has been involved in the development of a number of voluntary initiatives, ranging from the Nano Risk Framework pioneered by the Environmental Defense Fund and Dupont, to the voluntary reporting system for nanomaterials developed by the city of Cambridge, Massachusetts. Each of these initiatives has provided important information to businesses, regulators, non-government organizations and the public, which hopefully will lead to more effective governance systems in the future.

At this time, enough of these voluntary initiatives for nanotechnology have been implemented so they can be looked at together, in a comparative sense, and historically, in terms of their relationship to programs that have preceded them. This report, by Dr. Daniel Fiorino, a scholar at American University and long-time senior manager at the Environmental Protection Agency (EPA), provides this analysis for the first time.

The report provides a taxonomy of the various types of voluntary initiatives (past and present) and the partnerships that underlie them, as well as an assessment of the factors that are most likely to contribute to program success. Against this backdrop, Dr. Fiorino then evaluates what has been done so far with nanotechnology and recommends ways to strengthen voluntary programs in the future. The report ends with specific recommendations for key stakeholders such as EPA, other federal agencies, non-government organizations and businesses.

As nanotechnologies advance, along with other emerging technologies, voluntary programs will continue to play an important role in the governance portfolio. For this reason, evaluating and learning from these endeavors will remain critical to better oversight. This report is an important contribution to that learning process.

David Rejeski
Washington, DC
November 2010

ABOUT THE AUTHOR

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Dr. Fiorino joined American University in the fall of 2009 after a career at the U.S. Environmental Protection Agency. While at EPA, he held a number of management and advisory positions, including Associate Director of the Office of Policy Analysis, Senior Advisor to the Assistant Administrator for Policy and Director of the National Environmental Performance Track. He is recognized for his expertise on environmental policy-making, innovation and analysis.

He is the author or co-author of four books: *The New Environmental Regulation; Making Environmental Policy; Environmental Governance Reconsidered;* and *Managing for the Environment.* He also is the author of more than two dozen journal articles and book chapters on such topics as risk-based planning, policy learning, environmental innovation, voluntary initiatives and democratic deliberation. His writing has been recognized with nine national awards, including (in 2007) the Brownlow Award of the National Academy of Public Administration for *The New Environmental Regulation.* In addition to American University, he has taught at Middlebury College, Johns Hopkins University, George Mason University and the University of Pittsburgh. In 2001 he was elected a Fellow of the National Academy of Public Administration.

Fiorino received his B.A. in political science from Youngstown State University and M.A. and Ph.D. degrees in political science from Johns Hopkins University. He conducted most of the research and writing for this report as a Public Policy Scholar at the Woodrow Wilson Center in the summer of 2009.

EXECUTIVE SUMMARY

The rapidly growing field of nanotechnology and its products poses new and interesting challenges to environmental policy-makers and institutions. In one sense, these challenges, which include such issues as limitations in data and uncertainty about many health and environmental effects, are typical of those of earlier generations of chemicals management. At the same time, nanotechnology is representative of a newer generation of environmental issues whose consequences are difficult to predict, rapidly evolving, dependent on technology change and innovations and not usually amenable to conventional regulatory solutions and strategies.

Existing policy assessments have analyzed and offered recommendations on the available and appropriate regulatory strategies for managing potential health and environmental effects of materials, products and processes arising from nanotechnology. These assessments have made it clear that government regulation in some form will play a necessary and crucial role. Government will be involved in assessing potential risks, defining oversight structures and systems, promoting transparency, protecting workers, informing the public and generally steering the responsible development of the industry.

The thesis of this report is that non-regulatory and voluntary initiatives will play a constructive role in nanotechnology oversight as well. Voluntary initiatives are defined here as "any collective effort to improve environmental performance or manage environmental problems in ways that are not required by law." Although voluntary initiatives have been used in health and worker safety policy as well as in environmental policy, the focus in this report is their use in the environmental field. Voluntary initiatives have been applied to such issues as climate change, water and energy use, supply chain management, waste and toxics reduction and data collection, among others. They have spawned a considerable amount of literature on the strengths and weaknesses of voluntary initiatives.

Voluntary initiatives generally fall into one of three types, based on who sponsors and participates in them. In the first type, government agencies sponsor an initiative and invite others to participate. In the second, business firms organize to achieve an environmental goal or to improve their practices and performance. In the third type, business firms create partnerships with non-government organizations. Recent experience offers examples of all three types. A survey of the literature offers several lessons for their effective design.

Experience with and research on voluntary initiatives suggests they are most likely to succeed when (1) there are defined consequences if participation and results do not reach desired levels; (2) participation and achievements yield business and other organizational benefits; (3) the sponsoring organization is clearly committed to and communicates the goals and value of the initiative; and (4) public credibility is enhanced with mechanisms for monitoring performance, minimizing free-riding and applying sanctions for not meeting obligations.

Three existing voluntary initiatives illustrate each of these types as it may be applied to nanotechnology. The *Nano Risk Framework* is the product of collaboration between the Environmental Defense Fund and DuPont. Issued in 2007, the framework defines a systematic process for identifying, managing and reducing potential risks of nanomaterials throughout their life cycle. The *Responsible Nano Code*, also the result of a multi-party collaboration, set out a higher-level set of principles and operating practices to guide the industry. The U.S. Environmental Protection Agency's *Nanoscale Materials Stewardship Program*, announced two years ago, is a voluntary effort to collect data from chemical firms as a basis for making better risk management decisions and for determining further data needs and strategies. All three illustrate the strengths and limitations of voluntary initiatives; all were designed to complement, inform or prepare the ground for regulation rather than to serve as a substitute for it.

The nature of nanotechnology as a rapidly growing and constantly evolving sector makes it an excellent application for voluntary initiatives. Their role would not be to replace government regulation, however, but to inform regulation and to complement existing and future actions. The flexibility, adaptability, relative ease of implementation and potential for constructive engagement of multiple parties commend them as a part of an oversight strategy.

This analysis of voluntary environmental initiatives suggests a variety of actions for stakeholders. The Environmental Protection Agency and other agencies should develop multi-year strategies with both regulatory and voluntary actions. They should assess the experience with voluntary initiatives—on chemicals and more generally—and build any lessons into program designs. They should proceed with mandatory reporting under the appropriate legal authorities but also consider how well-designed voluntary data collection initiatives may enhance and expand upon those efforts. Government, business and non-government organizations should consider creating a multi-stakeholder Nano Stewardship Council modeled generally on such collaborative mechanisms as the Forest Stewardship Council. It would provide a neutral forum for discussing nanotechnology issues and serve as a clearinghouse for information. Nanotechnology firms and business organizations should build upon the foundations of The *Nano Risk Framework* and *Nano Risk Code* to expand and extend the capacities of the industry for managing potential risks. Investors and insurers could promote progress on voluntary initiatives by incorporating participation in and commitment to credible voluntary initiatives into their decision-making.

INTRODUCTION

The idea of generations of environmental problems and their solutions has become central to thinking about the evolution of policy responses over the years. From the first generation of mostly point source pollution caused by large industrial facilities, the environmental problem has become more a matter of smaller, more dispersed sources; patterns of land use and development; degradation of the global commons; and the effects of new, rapidly evolving technologies. As the causes and consequences of environmental problems have become dynamic, fluid and complex, more flexible and diverse sets of policy responses have been developed to deal with them. Government and others are struggling to adapt to a newer set of what often are termed second and third generations of environmental problems that go beyond industrial pollution.[1]

Nanotechnologies – a highly diverse range of technologies arising from the field of nanotechnology – and the environmental and health risks that may be associated with them are one such third-generation problem. Nanotechnologies present complex and distinctive challenges to the public and private institutions responsible for managing environmental and health risks in society. In this sense, they are characteristic of many new environmental issues. Risks that may be associated with them are difficult to assess. They represent a rapidly growing economic sector and constantly evolve with changes in technology, markets and products. They do not appear to fit neatly into any set of legal frameworks that have been developed in the past or exist today. In addition, more so than some of the earlier generations of environmental issues, nanotechnologies in themselves offer potentially huge environmental and health benefits, along with the possibility of new and novel risks. In many respects, the issues associated with nanotechnology are more typical of the future of environmental problem-solving than those of large manufacturing sources and high-volume commodity chemicals that determined the design and application of environmental statutes in the past four decades.

As with many environmental policy issues, there is something of a policy lag in developing an oversight framework for nanomaterials and products. Government and others are struggling to keep up with the development of the industry. The Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars has been working to reduce this lag by helping business, government and the public anticipate and manage the health and environmental effects of nanotechnology.

Of previous PEN reports on the policy aspects of nanotechnology, six are most directly relevant to this report. Four reports by Terry Davies assess and offer proposals about how to manage health and environmental effects, with emphasis on legal authorities, agency capabilities and options for statutory and institutional change (Davies 2006, 2007, 2008 and 2009). With respect to existing authorities, Davies concludes that although they provide a starting point, the current laws are not well suited to the needs of nanotechnology oversight. Ideally, a new law designed specifically for this purpose, administered by stronger and more integrated government institutions, would be enacted. Another report, by Mark Greenwood, focuses specifically on designing a product-oversight system around the themes of risk criteria, information needs and risk management measures (Greenwood 2007). Suellen Keiner's report examines

the alternatives available for state and local governments in regulating nanotechnology (Keiner 2008).

This report begins with a brief overview of the nanotechnology industry, its distinctive features as an environmental issue and existing legal authorities and regulatory tools. Following that is discussion of voluntary initiatives in environmental policy, including an assessment of their general strengths and weaknesses and the conditions in which they are likely to be effective. The final sections suggest options, principles and models for using voluntary initiatives for nanotechnology oversight, either as a precursor to or combined with regulation. The thesis of this report is that well-designed and credible voluntary initiatives should be incorporated into a broader strategy for managing the possible health and environmental effects of nanotechnology.

An effective oversight and governance system will combine many strategies, tools and relationships. Linda Breggin and Leslie Carothers make this point well:

> A multi-pronged approach is likely to be the most effective way to address environmental, health, and safety concerns, given the complexity and likely pervasiveness of the technology, the uncertainty regarding the potential hazards, and the multimedia nature of the problems that could arise. A multi-pronged approach could include elements of regulatory and voluntary programs under existing environmental statutes; corporate stewardship; tort liability; federal, state, and local legislation; voluntary standards; disclosure; liability insurance; and international measures. Developing the optimal mix of these tools is a significant aspect of the governance challenge (Breggin and Carothers 2006, p. 310).[2]

NANOTECHNOLOGY AS AN ENVIRONMENTAL ISSUE

The term "nanotechnology" is less a description of a technology than "a generic term for a large number of applications and products" which are engineered at an unimaginably small scale and demonstrate special properties as a result" (Swiss Re 2004). It thus describes an order of magnitude rather than a specific discipline. These "unimaginably small" particles occur at the molecular and atomic scales and are measured in nanometers. A nanometer is one-billionth of a meter; in practical terms it is one seven-thousandth of the width of a red blood cell or one eighty-thousandth of the width of a human hair. "Nanoscale" generally refers to the manipulation of materials of 100 nanometers or less on any dimension. The Environmental Protection Agency (EPA) defines nanotechnology as "the creation and use of structures, devices, and systems that have novel properties and functions because of their small size" and as "the ability to control or manipulate matter on a small scale" (USEPA Nanotechnology White Paper 2007, p. 5), while the U.S. National Nanotechnology Initiative describes nanotechnology as "the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications" (NNI 2010). The common feature of nanotechnology organizations is "the tiny dimensions in which they operate" (Royal Society 2004, p. 2).

A "nanomaterial" may be described as a "material having one or more external dimensions in the nanoscale or which is nano-

structured" (British Standards Institution, 2007, p. 2) – essentially a material that is made up of nanometer-scale particles or otherwise includes nanometer-scale structures.[3] Although nanomaterials come in many forms, for purposes of this report the specific qualities of nanomaterials are less important than their general characteristics. The same characteristics that make them valuable in a wide range of practical applications have also led to concerns about their health and environmental effects. Nanomaterials have the same chemical composition as their larger counterparts, but they may exhibit a larger surface area for any given mass, are often more chemically reactive and may penetrate cells more easily than bulk materials do. A material that is inert in larger form may be reactive at the nanoscale. As EPA has noted, nanoparticles and products containing them may also affect aquatic and terrestrial ecosystems differently than do products made up of larger particles of the same material.

Nanoscale materials and products present distinctive characteristics that should influence the choice of policy strategies. In the policy literature, such issues often are described as "wicked" policy problems.[4] Such problems exhibit multiple dimensions, are constantly changing and evolving, are rarely solved entirely and at best managed, present high levels of uncertainty and have no single, obvious solution. In this sense, the effects of nanotechnology are similar to such issues as climate change, biodiversity loss and ecosystem loss in terms of complexity, dynamism and the level of technical and scientific uncertainty they pose. Such issues require creative and innovative responses.

At the same time, the products of nanotechnology present issues that are typical of chemical regulation and risk management. The data and testing cannot keep pace with the growth in materials and products. Exposures are difficult to predict. Regulation often lags a few steps behind the evolution of the industry itself. Oversight of nanotechnology-based products also differs in key respects from more conventional chemicals regulation, however. One difference is that nanomaterials have different properties that could pose distinctive risks, as discussed above. A second is that the evolution of the various industrial sectors that could use nanoscale processes and produce products with nanoscale components is large and is probably more difficult to predict than it has been historically for other chemicals. Confronting the challenges of nanotechnology oversight means addressing both the information issues of chemicals regulation and the dynamic and complex aspects of a cutting-edge technology.

This report is based on the premise that strategies for responding to policy issues need to be based on an analysis of the characteristics of the issues themselves. Among the distinctive characteristics of nanotechnology as a policy issue are the following six:

1. Nanotechnology is a rapidly growing, global industry with tremendous economic potential.

Some recent estimates provide an indication of that growth and potential. In 2006, an estimated $11.8 billion was invested in nanotechnology research and development. That investment had grown to more than $18 billion by 2008. Lux Research estimates that nanotechnology will impact more than over $2.5 trillion worth of manufactured goods by 2015 (Lux Research 2009), although many of these goods may contain only minute amounts of intentionally engineered nanomaterials.

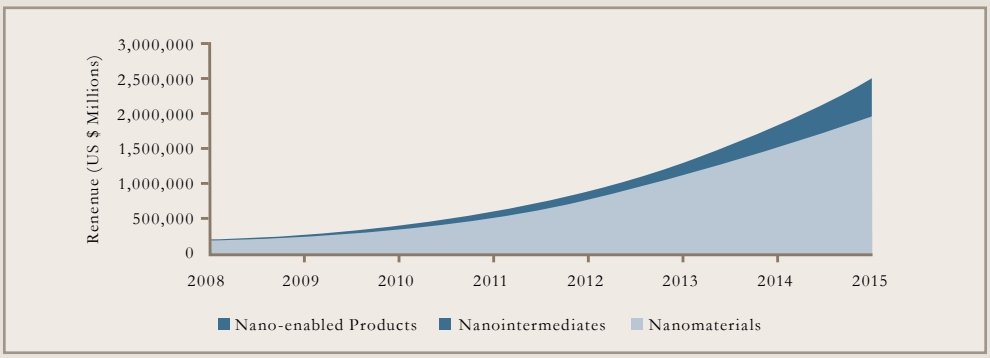
In addition to the United States, countries that lead in corporate funding include

Japan, Germany, South Korea and the United Kingdom. In the United States, the states with the most organizations (i.e., firms, universities, and government labs) in nanotechnology are California, Massachusetts, New York and Texas, although all 50 states and the District of Columbia contain at least one such organization (PEN Putting Nanotechnology on the Map, 2009). In 2014, Lux Research predicts, 50% of electronics and information technology applications and 16% of manufactured goods in health care and the life sciences will include nanomaterials. By 2014, the value of products with nanomaterials will increase to some 15% of the total value of manufactured goods (Lux Research 2007). Nanotechnology is also an industry in which small firms are important: an estimated two-thirds of nanomaterials are being developed by small and medium-size firms, often with the goal of marketing applications to larger firms for use in their products. The International Risk Governance Council has observed that "nanotechnology applications "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." (Renn and Roco, 2006, p. 2).

2. Nanotechnology products, applications and materials are constantly evolving.

The industry itself became possible after developments in microscopy that began to bear fruit in the 1980s. The capacity to manipulate materials at the molecular and atomic scales created a potential for new classes of products with distinctive properties. Early applications relied on passive nanostructures, which do not change form or function. Newer applications involve active nanostructures, which do change form or function, leading to such applications as targeted drug-delivery systems. Even now, nanotechnology is shifting from passive materials to active nanoscale devices (Subramanian et al. 2010), leading to advanced generations of applications. At some point, David Rejeski has noted, "We will be dealing with multifunctional machines operating at the interface of classical and quantum physics, and, eventually, the convergence of nanotechnology, biotechnology, information technology, and cognitive science" (Rejeski 2006, p. 5). Similarly, EPA has observed that this integration of later- generation nanotechnologies "with information, biological, and cognitive technologies will lead to products which can now only be imagined" (USEPA Nanotechnology White Paper, 2007). As

FIGURE 1: PROJECTION OF REVENUES FROM NANOTECH-ENABLED PRODUCTS (LUX RESEARCH 2009)



technology and applications change, it will be necessary to adapt systems for governance and oversight and to continually reassess benefits and risks of products.

3. There is the potential for large health and environmental benefits.

With many past environmental issues, the challenge was to weigh economic benefits against the potential health and environmental risks. Nanomaterials may be different because of the extent to which the technology itself offers direct health and environmental value. Among the health applications, for example, are more efficient drug- and vaccine- delivery systems, high-contrast imaging agents for medical diagnosis, new cancer therapies capable of targeting specific cells and detectors for biohazards. Beneficial environmental applications include means of improving energy efficiency, reducing solvent use and waste products, de-salinizing water, cleaning up hazardous waste and detecting and monitoring contaminants. In addition to these direct environmental benefits, nanotechnology may transform manufacturing processes generally and become a tool for pollution prevention.[5] The challenge for an oversight system is to responsibly balance these benefits against potential risks in the face of uncertainty, leading to the next point.

4. There is a great deal of uncertainty regarding the health and environmental risks of nanotechnology.

As is the case with any new technology, many of the health and environmental effects of nanotechnology are unknown. The most common nanomaterials found in products are silver, carbon, titanium, silicon/silica and zinc. Even for chemicals whose effects in bulk form are well characterized, however, the particular properties of nanoscale materials make them different qualitatively. One source of differences is that nanoscale materials exhibit a very large surface area per unit of mass, making some of them particularly reactive. Another is that many nanoscale materials have different optical, magnetic or electrical properties than their conventional counterparts. Among the physical characteristics raising questions are their capacity to integrate into biological systems, change cell metabolism and evade biological defense mechanisms in the body. Although research is limited, there are indications of potential health risks in existing studies. Environmental effects are defined by the characteristics of nanomaterials—their permeability, dispersability, persistence, adsorption and potential for being transformed into or interacting with other contaminants, among others.[6] Little is known at this stage about the effects on aquatic and terrestrial ecosystems when nanomaterials are released into the environment.

5. Environmental and health risks will vary by product.

The range of products using nanomaterials means that the exposure element of risk is critical, as it is for other chemicals issues. PEN now lists more than 1,000 nanotechnology-based consumer products in its online inventory, an increase of 379% since the inventory was first released in 2006 (PEN Nanotechnology Consumer Products Inventory, 2009). The largest product category is health and fitness (605 products), followed by home/garden (152), food and beverage (98), automotive (68) and electronics/computers (57). Illustrative applications of nanotechnology include such products as cosmetics, cordless power tools, waterless car wash, toothbrushes, recreational-boat

hulls, guitar strings, golf clubs, tennis rackets, computer chips, plastic wrap, tea and building insulation. Having nanomaterials in semiconductor chips and golf clubs clearly involves very different health risks than does using them in cosmetics, beverages, food and drug delivery. This is why it makes sense initially to focus on products, rather than materials, in any oversight system, as well as to have methods of assessing health and environmental risks through a product's life cycle.

6. Legal mechanisms currently exist but are not designed specifically for this issue.

Among the existing laws for regulating nanotechnology risks, the most likely initial mechanisms that could be, and in many cases are being, used include the Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide and Rodenticide Act (administered by EPA); the Federal Food, Drug, and Cosmetic Act, administered by the Food and Drug Administration (FDA) and EPA; the Occupational Safety and Health Act, under the Occupational Safety and Health Administration (OSHA); and the Consumer Product Safety Act, administered by the Consumer Product Safety Commission. None of these acts was designed with the characteristics of nanotechnology in mind. In the other aspects of nanotechnology regulation (e.g., air and water dispersion, soil contamination), the Clean Air Act, Clean Water Act, Resource Conservation and Superfund laws offer potential regulatory control points for managing other environmental exposures. Again, however, the fit between these laws and nanotechnology is problematic.[7] Even where authorities exist, agencies face the constraints of limited information and resources and the challenges of adapting an old regulatory framework to a rapidly changing technology.

These characteristics should influence decisions about how to manage potential risks. Information will clearly be the lifeblood of any risk management strategy. High levels of uncertainty and the dynamism of the nanotechnology industry put a premium on having information at all stages of the materials life cycle. The challenge with nano is that information on uses, exposures and risks is limited; what information does exist becomes outdated. The novel characteristics of nanomaterials mean that existing laws may need to be modified or replaced. The variety of applications and products suggests, as Terry Davies advised in earlier PEN reports, that a product focus may be preferable to a process or materials focus (Davies, 2009, p. 22). The point for now is that these characteristics should be reflected in the strategies and tools that are devised to deal with nanotechnology issues.

Nanotechnology oversight involves so many issues that it is difficult to capture even the relatively narrow topic of voluntary initiatives within one report. This analysis approaches the topic from the perspective of environmental policy. Lessons could be drawn from the perspectives of health and worker safety policies as well. In particular, exposures to nanomaterials in occupational settings involve one of the more likely potential areas of risk as the industry grows. OSHA's Voluntary Protection Programs (VPP), for example, could provide useful experience for developing voluntary initiatives to reduce worker risks, as a precursor or complement to regulatory action.[8] The aim here is to draw upon the experience and literature in environmental policy to chart a path for using voluntary initiatives in nanotechnology oversight more generally.

VOLUNTARY INITIATIVES IN ENVIRONMENTAL POLICY

The first generation of environmental problems was met in the United States and most other countries largely through a regulatory strategy. In this strategy, government develops standards for achieving society's environmental goals, applies those standards to categories of pollution sources, establishes mechanisms for overseeing conformance with those standards and then applies punitive sanctions in cases of non-conformance.

Regulation has been the core strategy underlying such major environmental laws as the Clean Air Act, Clean Water Act, Safe Drinking Water Act and others. As a strategy, regulation relies heavily on having information on best available technologies that may be applied to sources, being able to identify and control the behavior of the sources of pollution and having the oversight capacity to maintain credible systems for compliance. In addition to laws based on controlling releases to the environment, environmental laws have relied on a regulatory strategy to assess and control the risks of chemicals and related products, through the Federal Insecticide, Fungicide, and Rodenticide Act and the TSCA. In product-based regulation, agencies assess the risks of chemicals or products, limit or ban their manufacture and use and attach conditions to their use, such as warning labels and application restrictions.

In the late 1970s and 1980s, agencies began to expand their use of policy tools beyond conventional regulation to incorporate market- and information-based strategies. Emission trading was adopted in several air quality programs in the 1980s, and sulfur dioxide allowance trading was a key element of the 1990 Clean Air Act Amendments. Market approaches have been applied in many other programs as well. Since the 1980s, government also has drawn increasingly on information as a strategy. Environmental and health agencies began to use risk communication more systematically as a way of informing people about risks. They also began to require public disclosure of information through such mechanisms as the Toxics Release Inventory (TRI) and amendments to the Safe Drinking Water Act. This served to inform the public at the level of a right-to-know about risks they could be exposed to, and there is evidence that disclosure led some firms to reduce chemical releases to avoid negative publicity and harm to their reputations.

By the 1990s, this diversification in policy tools expanded to include a greater use of voluntary initiatives of many kinds. This trend was not limited to government; the business community and environmental groups also relied more on partnerships, challenge programs, information exchanges and other such tools.[9] The lessons of those efforts and their relevance to managing the health and environmental effects of nanotechnology are the subject of this report. In this discussion, a "voluntary initiative" *is any collective effort to improve environmental performance or manage environmental problems in ways that are not required by law.* Use of the term "collective effort" is meant to exclude initiatives on the part of one business or other organization but to include joint efforts by more than one business firm or agency or by a combination of government agencies, business firms and non-government organizations (NGOs). Most voluntary initiatives fall into one of three categories: government-

sponsored programs that involve business participation; collective efforts by business firms, such as a trade association; and partnerships among firms or groups of them and NGOs. Recent history offers examples of all three.[10]

At a definitional level, the term "voluntary" is problematic. It applies to actions that are not required by law and for which non-participants are not subject to legal sanctions. There are two ways, however, in which an organization's participation in such initiatives is not entirely voluntary. First, if there exists a regulatory backstop or default, and non-participation or non-performance could subject someone to regulatory action, the decision of whether or not to participate may be seen as less than entirely voluntary. Second, once an organization becomes part of an initiative, it may be compelled to meet specific obligations (e.g., achieving a performance goal, passing a third-party audit, providing data) as a condition of continued participation. Indeed, experience with voluntary initiatives suggests that they may be more effective when these conditions—a regulatory default and/or having specific obligations—are present. The term "voluntary" thus is used here to distinguish these initiatives from conventional regulatory programs that prescribe enforceable legal obligations that are backed by sanctions. Entirely voluntary initiatives are, the evidence suggests, those that are least likely to achieve policy goals.

Imperfect as it is, the concept of a voluntary initiative will be used in this report to define a diverse class of policy tools that may be distinguished from regulation. It is fair to say that the decision of whether or not to participate in these initiatives is more optional or discretionary than a decision to submit to regulatory authority, where an organization has little or no discretion.[11] For many reasons, however, an organization will perceive pressure to participate, in the form of regulatory threats, customer demands, competitive pressures or access to information or resources offering business advantage. If an initiative is purely voluntary, there may be little reason to participate.

Voluntary initiatives as a policy tool inspire a range of reactions. To promoters, they offer a flexible, results-oriented, collaborative, relatively quick way of responding to problems and getting results. To critics, they are unreliable, use precious resources, involve too little accountability and distract attention from compliance. Both sides may be right; there is such a wide range and variety of voluntary initiatives that it is difficult to generalize about them. It is even fair to say that regulatory programs have more in common than non-regulatory ones, because the latter may take so many different forms.

Well-designed voluntary initiatives may contribute to achieving environmental goals in several ways. However, they may be especially well suited to nanotechnology at its current stage of development for several reasons: the industry and technology are changing rapidly; there is limited information on health and environmental risks; existing legal authorities may be poorly suited to the challenges of regulating nanomaterials; public and NGO perceptions are still forming; it is a global industry and should be addressed as one; and acting quickly and collaboratively to manage the possible risks responsibly is in the interests of the industry as well as of others, including investors, insurers, firms, government and the public. Voluntary initiatives are not the final word for nanotechnology, nor are they by any means the only word. But they could be effective as part of an overall strategy. The key questions are as follows: What role could they play, given the characteristics

of the issue? How should they be designed to be effective? and How could they be used to complement regulation?

Before considering how the concept of voluntary initiatives has been and could be applied to nanotechnology, it is important to examine the forms that voluntary initiatives may take, how they are applied in environmental policy, their strengths and weaknesses and what the evidence suggests about the links between their design and effectiveness.

One way of distinguishing among the many applications of voluntary initiatives is in terms of who sponsors and participates in them. As mentioned above, there are three principal types. In the first type, government agencies sponsor an initiative (usually termed a voluntary "program") and invite others to participate. In some initiatives, such as the 33/50 or Climate Leader programs discussed later, agencies challenge companies and other organizations to achieve an environmental goal or result. Others, like the High Production Volume (HPV) chemicals program, challenge companies and organizations to fill gaps in information by voluntarily submitting the needed data. Some of these programs take the form of a "green club," in which organizations are recognized officially by government for meeting certain criteria and qualify for benefits that accrue only to members of the program (i.e., the club).[12] Other government-sponsored initiatives focus on providing information or resources to participants: they offer technical assistance, create networks, encourage innovative technologies, disseminate best practices and encourage pollution prevention.

In a second type of voluntary initiative, groups of business firms organize to achieve some set of environmental goals or to improve their environmental practices and performance. These initiatives also may take the form of green clubs, in this case sponsored by business rather than government. The best examples of a business-sponsored green club are Responsible Care (the chemical industry) and the Sustainable Forestry Initiative (the forest-products industry). In these two cases, as with many others, a trade association sponsors the voluntary initiative as a means of improving the collective performance of firms. The purposes of such initiatives may be to enhance the industry's reputation, forestall regulatory action, disseminate best practices or improve the performance of weaker firms.

A third type of voluntary initiatives is one in which business firms and NGOs create partnerships. The purposes and design characteristics of these initiatives, like those of the other two types, vary considerably. Some are designed to make information available, others to achieve a specific environmental result or to develop and apply a new technology or product.

The next section presents and evaluates each of these three types—government programs, collective business initiatives and business-NGO partnerships—as a means of evaluating the possible contributions the different types of voluntary initiatives could make to nanotechnology oversight.

GOVERNMENT-SPONSORED PROGRAMS

For the past 20 years, EPA has turned to voluntary programs as a means of expanding its policy capacities and responding to new issues. In some ways, this trend reflected a recognition of the limits in regulation. Regulation requires that agencies have statutory authority, involves complex and time-consuming procedures, limits flexibility of agencies and firms and is implemented in the context of what often are adversarial and distrustful relationships. Voluntary initiatives

were seen as a more flexible, adaptive, collaborative and faster way of problem-solving than a purely regulatory strategy.

Three points should be kept in mind in thinking about EPA voluntary programs. First, despite all the attention given to them, they remain a very small fraction of EPA's overall efforts. One study estimated that the kinds of programs discussed here account for about 1.6% of EPA's resources, a number that is consistent with the author's experience and other estimates (Morgenstern and Pizer 2007, p. 2). Second, EPA voluntary programs vary tremendously in their goals, design, obligations and benefits, a point that will be clear in what follows. Third, the specific motivations for creating these programs vary. Several were created as part of the Clinton administration's Climate Acton Plan in the 1990s. Others aimed to promote pollution prevention when regulatory tools were unavailable or unlikely to be effective. Still others were designed in response to issues that were important but over which EPA had no regulatory authority, such as energy, water and materials use.[13] These initiatives generally emerged from specific goals and circumstances, rather than as a grand, EPA-wide strategy, so one should be wary of any attempts to generalize about their origins and intentions.

The use of voluntary programs by the EPA is generally seen to have begun with the 33/50 program in 1991. Early rounds of reporting under the TRI had revealed that releases of many chemicals were not covered by existing regulations. Instead of seeking legal authority to control these releases, EPA challenged industry to reduce them voluntarily. EPA Administrator William Reilly invited firms reporting information on 17 chemicals in the TRI to commit to a 33% reduction in releases by 1992 and a 50% reduction by 1995. In exchange, EPA would recognize firms for their participation and achievement. Although participation was voluntary, EPA implied that failing to achieve results could lead to new regulation.[14]

The 33/50 experience was followed in the 1990s with several programs. Most were created under President Bill Clinton's Climate Action Plan as a way to encourage cuts in greenhouse gases until mandatory reduction measures were adopted. Begun in 1994, WasteWise invited firms to commit to reduced generation of solid wastes. ClimateWise (later renamed Climate Leaders) encouraged firms to commit to and report on reductions in greenhouse gases. In what would become the largest voluntary program yet, Energy Star encouraged computer firms, and later manufacturers of other products, to adopt more energy-efficient designs in exchange for being able to use the Energy Star label and receive other recognition. As a further inducement, the federal government later gave preference to Energy Star products in making purchasing decisions. In 2000, Administrator Carol Browner launched EPA's National Environmental Performance Track (Performance Track), designed for organizations that would commit to achieving measurable results beyond legal compliance on a range of environmental indicators. The issue of water use and efficiency was addressed more recently in WaterSense, which encourages the use of water-efficient products and practices, partly through labeling.

Such programs as 33/50 and Climate Leaders are examples of what may be termed "challenge" programs, in which agencies encourage organizations (including government and non-profits, like universities and hospitals) to commit to and achieve environmental results that exceed legal requirements. They also illustrate the concept of green

clubs, which aim to differentiate one set of organizations from others on the basis of their environmental performance or characteristics. By committing to follow certain practices, meet defined goals or achieve other results beyond legal minimums, members of green clubs qualify for such benefits as recognition, access to information or other resources, lower regulatory transaction costs or the opportunity to be part of a network. The goal is to encourage behavior that offers environmental or other benefits to society outside of the regulatory framework. EPA's most comprehensive such green club, the National Environmental Performance Track, had grown to some 550 members before it was canceled early in 2009. However, programs such as Climate Leaders, state leadership efforts (e.g., Virginia's Environmental Excellence Program) and Responsible Care also apply the concept.[15]

Other programs are designed for different purposes, such as providing information and technical assistance; encouraging product innovation; finding alternative ways to achieve results; and negotiating agreements that give firms more flexibility in compliance when they achieve better environmental outcomes. These programs come in many forms. Most relevant to nanotechnology, aside from the *Nanoscale Materials Stewardship Program* discussed below, are programs focused on improving the environmental attributes of materials and products or on collecting information on chemicals. In *Design for the Environment*, EPA partners with industry to develop environmentally preferable technologies. It focuses on sectors that "combine the potential for chemical risk reduction and improvements in energy efficiency with a strong motivation to make lasting, positive changes" (USEPA Design for the Environment). *The Green Suppliers Network* provides information and other resources, including technical reviews, to help firms leverage their supply chains for environmental and economic gains. Two other initiatives, *Green Chemistry and Green Engineering*, encourage the development of less harmful chemicals and improved pollution prevention within the engineering profession.

Three other EPA programs focus on screening new chemicals or collecting data needed to evaluate chemical risks. Most directly linked to regulation is the *Sustainable Futures Initiative*, which complements new chemical reviews under Section 5 of TSCA. Manufacturers of new chemicals must submit information to EPA for a Pre-Manufacture Notification (PMN), a screening process for predicting whether adverse effects are likely to occur. EPA then has the option of allowing the manufacturer to proceed, attaching conditions to marketing of the chemical or requiring additional testing or information. If EPA does not act within a 90-day period, the manufacturer may proceed. Sustainable Futures allows manufacturers to qualify for an expedited PMN review if they complete a training program and conduct a screening analysis of the new chemical using an approved EPA methodology. For manufacturers, this provides a means of evaluating a chemical under EPA's own criteria before developing it further and submitting for a PMN review. For EPA, this transfers some of the burden of chemical screening to the company and builds pollution prevention into the development process. As of July 2009, however, EPA had not applied the Sustainable Futures process to any nanoscale materials, given the uncertainty about their effects and the still-early stage of development of the industry.[16]

Two programs were designed to collect health and environmental effects data on chemicals of concern. The HPV Challenge

Program invited firms to provide data on chemicals produced or imported in amounts of a million pounds or more annually. EPA created the HPV in cooperation with the Environmental Defense Fund (EDF), American Chemistry Council and American Petroleum Institute in 1998, based on concerns about gaps in publicly available information on the toxicity of high production volume chemicals. Individually or as part of consortia, firms were asked to provide screening-level hazard data on chemicals as a basis for EPA and others to set priorities for additional testing or action. From EPA's perspective, the HPV "has created attention by exceeding all expectations" (USEPA Status and Future of the High Production Volume Challenge Program 2004, p. 5). Industry "sponsors" provided data on more than 2,200 chemicals (1,371 directly and 851 through an international counterpart to the HPV); 59% of the data submitted from some 6,800 studies were not publicly available at the program's start. The HPV appears to have made information available that otherwise would not have been public. Chemicals without sponsors (orphans) could be the subject of required testing under TSCA. The data collection phase of the HPV ended in 2005.

Another data initiative is the Voluntary Children's Chemicals Evaluation Program (VCCEP), which began in December 2000. Its purpose is to "ensure that adequate data be made publicly available to assess the special impact that industrial chemicals have on children" (USEPA VCCEP). EPA invited companies to report information on toxicity, exposure and data needs for 23 chemicals of concern. Thirty-five companies and 10 consortia responded with information on 20 chemicals. The program was designed to obtain information in three tiers, each involving additional testing and assessment. Sponsors of chemicals may commit to one tier at a time. A noteworthy aspect of the VCCEP is the "peer consultation" process; it provides a forum for experts to discuss the assessments and data needs. It is managed by an independent third party, Toxicology Excellence for Risk Assessment (TERA), under a cooperative agreement with EPA. TERA's role is to "ensure that it is a rigorous, science-based process for reviewing VCCEP assessments that stakeholders recognize as impartial and of significant technical merit and value" (USEPA VCCEP).

An initiative that does not fit neatly into these categories is the Environmental Results Program (ERP), designed to improve compliance and performance in business sectors made up of small firms. Small organizations have always posed a challenge for regulators; they typically lack the resources and expertise available to large companies to understand and maintain compliance. Given their numbers and relative lack of visibility, small firms also are difficult to monitor. Created by the Massachusetts Department of Environmental Protection (DEP) in 2003, the ERP applied tools of self-certification and tailored assistance to three sectors made up of small firms: printing, dry cleaning and photo processing. Working with trade associations, the DEP compiled a registry of firms, conducted outreach and education and provided workbooks and other materials to inform firms of their legal obligations and how to meet them. Each firm had to document annually that it was in compliance. DEP inspected a sample of facilities but focused as much as possible on enabling firms to perform well, rather than on catching and punishing violators.

The ERP is a model for how agencies may work cooperatively with business to improve compliance and environmental performance. A National Academy of Public

Administration study found that the ERP not only expanded the reach of the DEP but also provided a means for small firms to learn what to do and how to do it and reduced the incentives to ignore environmental standards (USEPA "environment.gov" 2000, pp. 34-39).[17] These positive results have led 15 other states to adopt the ERP model. Given the many small firms in nanotechnology, the ERP model is considered in the conclusion as a potential model for nanotechnology.

INITIATIVES SPONSORED AND MANAGED BY BUSINESS

Another type of voluntary initiative includes those that are organized, sponsored and managed by business. Although government and NGOs may play an advisory or other limited role, these "unilateral" initiatives are led and controlled by business, through trade associations, other established organizations or on a more ad hoc basis. For purposes of this discussion, the focus is collective initiatives by business groups rather than action by individual firms, even though both may involve similar activities, such as developing environmental management systems or supply chain initiatives.

A major example of a collective industry initiative is the chemical sector's Responsible Care program. In the United States, the Chemical Manufacturers' Association (now the American Chemistry Council) adopted Responsible Care based on a model developed by its counterpart in Canada. Like similar initiatives, it was created because of concerns about public perceptions of the industry, especially after the Bhopal catastrophe in 1984. For the first several years, Responsible Care consisted of 10 guiding principles, six codes of practice (such as product stewardship, pollution prevention and community awareness), and more than 100 management practices grouped under the codes. In response to calls for more transparency and performance information, Responsible Care was revised in 2002 to require third-party auditing at the site and corporate level as well as company-level reporting on specified environmental indicators. The program was re-aligned to make it consistent with the expansion of environmental management systems that had been occurring over the previous decade. The new version, known as the Responsible Care Management System (RCMS), combined many substantive provisions of the existing program with the elements of an environmental management system as set out in the International Standards Organization's 14001 series. Participation in Responsible Care, including certification by independent, accredited auditors, is a condition of membership in the American Chemistry Council.

The revisions in Responsible Care were stimulated in part by studies finding that members were not improving at a faster rate than non-members, at least on the basis of changes in TRI releases (King and Lenox 2000, pp. 698-716; Gunningham 1995, pp. 57-109). Relying on this one measure, however, ignores the broad range of behaviors that Responsible Care aims to improve, such as pollution prevention, accident prevention and community outreach. Central to the program's effectiveness was the network of resources, relationships and pressures that backed them up. They created a learning system of norms and practices and a useful model for nanotechnology.

Another example of an industry code comes from the forest-products sector. The Sustainable Forestry Initiative (SFI) was created in 1994 by the American Forest and Paper Association as a trade association initiative to improve environmental practices

in forest management and build public confidence in the forest-products industry.[18] The assumption was that achieving the first goal would lead to the second. In practice, the second goal has been difficult to achieve, especially when the SFI is compared to the Forest Stewardship Council (discussed below under NGO-business partnerships). At the heart of the SFI is its forestry management standard. The 2005—2009 version of the SFI Standard comprises nine principles, 13 objectives, 34 performance measures and 102 indicators. It also includes chain of custody provisions for tracking and linking certified products to certified forest lands (the reliability of this chain of custody had been questioned in a 2001 report [Meridian Institute 2001]), labels for informing customers of certified products and third party-certification to verify compliance with the program.

Environmental Management Systems (EMS) also illustrate the use of a voluntary initiative sponsored by industry, although not specific to a trade association or industry sector. An EMS defines largely internal protocols for managing environmental, health and safety aspects of organizations. It may be described as "a formal set of policies and procedures that define how an organization will manage its potential impacts on the natural environment and on the health and welfare of the people who depend on it" (Andrews 2001, p. 32). Organizations with an EMS adopt a written environmental policy; identify aspects of their activities, products and services that affect the environment; set objectives and targets for improved performance; assign responsibility for implementing the EMS, such as training; and evaluate and refine the system to continually improve it and the results it helps them obtain. The decision of whether to adopt an EMS lies with an organization; there is no legal requirement for doing so. It may not be entirely voluntary, however, because many major firms have made adoption and third-party certification of an EMS a condition for their suppliers. Government agencies also have encouraged EMS adoption and required them as a condition in some enforcement actions.

Although several EMS models have been developed in the past 15 years, the most influential is that of the International Standards Organization, known as ISO 14001. Developed at the initiative of business and others after the 1992 Earth Summit and issued in 1996, ISO 14001 defines a model and process for third-party certification. The model has been used not only by private firms (facility and corporate) but also by government agencies and non-profits, such as hospitals and universities. Many organizations use the model but do not seek formal certification. Surveys of EMS adopters have found that they are a useful way of organizing environmental activities (including legal compliance); searching for opportunities for improvement, including cost savings; and demonstrating to customers and others a more systematic approach to environmental management. Studies of the effects of EMS adoption have found evidence of improved compliance and overall environmental performance, although it is difficult to isolate the effects of the EMS from other factors.[19] Research suggests that an EMS is most effective when top managers are committed to the system and it is integrated with other business activities.

Supply chain management is a third type of business initiative. Most such efforts are led by firms seeking to improve the reliability of and confidence in their suppliers. In a trend that mirrors in many respects the role of regulatory enforcement agencies, such firms as Wal-Mart, Hewlett-Packard, Johnson & Johnson and Ford prescribe standards

for suppliers; meeting these standards is a condition for doing business with the firm. Wal-Mart's supplier standards aim to reduce packaging, encourage use of recycled and non-toxic materials and improve energy and water efficiency, among others. Hewlett-Packard issued a Social and Environmental Responsibility Supplier Code of Conduct in 2003 that addressed a range of management and operational practices and expanded it to include its indirect supply base in 2009. Supply chain management illustrates the limits of the term "voluntary" in business settings. For suppliers of Wal-Mart and other firms, following prescribed practices is not optional; it is an economic necessity. In this sense, big firms with supply chain leverage may have clout comparable to that of government regulators. Although like EMS, many supply chain initiatives are carried out by single firms, they suggest an approach that could be applied to nanotechnology by groups of firms or in cooperation with NGOs and government.

BUSINESS-NGO PARTNERSHIPS

A third type of voluntary initiative is one in which business firms or organizations partner with NGOs to achieve an environmental goal or improve performance. Some of these, such as the EDF's corporate partnerships, are formed with companies for a specific purpose and then end. Others, such as the Forest Stewardship Council and Marine Stewardship Council, are long-standing entities with substantial business and NGO involvement. Still others exist to promote a specific policy goal, such as the U.S. Climate Action Partnership's (USCAP's) call for mandatory greenhouse gas limits. These partnerships may offer a powerful mechanism for environmental progress; they combine the credibility and expertise of NGOs with the resources, knowledge and economic power of major business firms.

Among national environmental groups, the EDF has incorporated partnerships most substantially into its strategy. EDF pioneered its approach in a partnership with McDonald's to develop more environmentally friendly packaging in the early 1990s. It later partnered with Federal Express to develop a new generation of eco-efficient delivery vehicles, including a hybrid electric truck; with Wal-Mart to reduce environmental impacts through supply chain management; with Wegmans to offer eco-friendly seafood; and with KKR (a financial rating firm) to develop metrics and analytical tools for evaluating environmental performance (Environmental Defense Fund "Corporate Partnerships"). Most significant for this report, EDF and DuPont have jointly developed the *Nano Risk Framework* discussed below. Although partnerships are central to EDF's strategy, other NGOs also work with business. For example, the National Resources Defense Council (NRDC) worked with Dow Chemical some years ago on the Michigan Source Reduction Initiative to jointly identify and implement pollution-prevention options at Dow facilities. Many other NGOs (e.g., the Wildlife Habitat Council and CERES) work collaboratively with business firms and organizations.

Another model for business-NGO collaboration is the USCAP, which calls for mandatory, national limits on greenhouse gases through a cap and trade program. It includes major firms (such as Ford, DuPont, Johnson & Johnson and BP America) as well as the EDF, NRDC and World Resources Institute. The USCAP has called for a more than 40% reduction in greenhouse gases from 2005 levels by 2030 and 80% by 2050. In addition to mandatory cuts through cap and trade, it is pushing for other steps to support a transi-

tion to a clean energy economy (United States Climate Action Partnership). Another climate partnership is Business for Innovative Climate and Energy Policy, whose goal is to work with business and Congress "to pass meaningful energy and climate change legislation that is consistent with our core principles" and will reduce emissions 80% below 1990 levels by 2050. Convened by Ceres, it includes such firms as Levi-Strauss, Nike, Starbucks, eBay and Seventh Generation among its membership (Ceres).

An interesting model for an initiative based on business-NGO collaboration is the Forest Stewardship Council (FSC). Formed in 1993 in the aftermath of the Rio Earth Summit, the FSC reflected concerns about the inadequacy of existing mechanisms for protecting forests and related resources. The FSC describes itself as "an international body which accredits certification organizations in order to guarantee the authenticity of their claims" (Forest Stewardship Council). Its goal is "to promote environmentally responsible, socially beneficial, and economically viable management of the world's forests …" The core standards of the FSC are set out in a "Principles and Criteria" document. Among the nine principles are those relating to legal compliance, indigenous peoples' rights, efficient management of forest benefits and protecting biodiversity and ecological resources. Nearly 50 more-specific criteria give additional substance to these standards. While the often-competing SFI is an industry initiative with some external participation, the FSC was from the start a multi-stakeholder effort with engagement from the three "chambers" (as they are termed in FSC governance) of environmental, social and economic interests. The FSC is strongly supported by Greenpeace and other groups that have been critical of the SFI (Sierra Club 2009).

A similar model is the Marine Stewardship Council (MSC). The catalysts for the MSC were the World Wildlife Fund and Unilever, which were concerned with the effects of unsustainable fishing and saw a need for an international certification for seafood and fisheries. Initial standards were adopted in 1997, and the MSC became operational in 1999. Based in London, MSC has offices in several countries. Comprising three principles and 23 criteria, the Sustainable Fishing Standard defines what a fishery must do to become sustainable and be certified. Independent, accredited certifiers assess the fishery against the standards. Certification allows the fishery to use the MSC's eco-label on its products and increase its appeal to consumers. The MSC is governed by a board of directors, which is advised by a technical advisory board and a stakeholder council. The council had certified 60 fisheries through 2008. In its purpose, method and general approach, the MSC is similar to the FSC, only with a focus on fisheries rather than forest sustainability.

EVALUATING VOLUNTARY INITIATIVES

Although voluntary initiatives are a relative newcomer to the environmental policy toolbox, several assessments of their design and effectiveness have been conducted. Indeed, although they draw an extremely small fraction of agency resources compared to regulatory programs, voluntary initiatives often have drawn a great deal of interest from researchers. This research is by no means conclusive in telling us what works and why, but it does offer lessons on designing voluntary initiatives and their likely effectiveness.[20]

Having said this, it is important to consider the difficulties in evaluating these initiatives. They vary greatly in goals, designs, obligations, benefits and the context in which they are implemented. Governments sponsor or are directly involved in some of these initiatives; others involve a unilateral action by business or partnerships with NGOs. Some require regular reports, third-party verification or training and certification. Others are minimal in their obligations and transparency. Not meeting either performance or procedural obligations will disqualify participants from some programs, while other programs do not monitor for such activities or do not sanction participants for non-performance. At least regulatory programs share common features—binding technology or performance standards, oversight through reporting and inspections, legal penalties for non-compliance and so on. Voluntary initiatives as a class do not share such features. For this reason, the results of one study or a few studies should be interpreted carefully.

Aside from the sheer variety, there are many challenges in evaluating any program or initiative.[21] From a research perspective, it is not easy to separate the effects of voluntary initiative from other variables that influence behavior in any setting. Even without regulation, many factors influence a firm's carbon dioxide emissions, for example. These include changes in the availability or prices of alternative fuels, NGO or investor scrutiny, expectations about future regulation, changes in products or customer demand, changes in production levels and so on. Isolating the effects of a voluntary initiative, whether sponsored by government or another entity—is a daunting challenge.

A second challenge is defining and measuring the dependent variable: What is it that we expect to change, and how can we measure it for research purposes? A comprehensive program such as Responsible Care is designed to improve a range of behaviors within an organization, including product stewardship, community engagement, air and water releases, pollution prevention and chemical safety. Yet evaluations of Responsible Care have focused on TRI releases, an important but narrow indicator of environmental performance, because that is where data exist. It is difficult to evaluate an organization's performance on the other factors because of a lack of data for evaluating changes over time or comparing one organization with another. Even when an initiative focuses on one specific result, such as water use, other factors, such as changes in product mix, production levels or maintenance schedules, make comparisons over time (with respect to a baseline) or across organizations a challenge.

A major issue in defining and measuring the effects of an initiative is what may be termed the "soft" or "social" benefits it may be designed to achieve. A considerable body of social science research suggests that some relationships and governance structures are more suited to effective environmental

problem-solving than others. This research has concluded, for example, that more consensus-based policy systems are better at integrating multiple goals for environmental policy success; that environmental innovation is more likely in an atmosphere of trust, dialogue and communication; and even that voluntary initiatives are more likely to succeed in the context of collaborative and predictable relationships.[22] Whether consciously or not, many voluntary initiatives have been designed with these considerations in mind. A stated goal in many is to improve communication, information-sharing, trust among actors and the capacity in general for jointly solving problems. Such results are difficult to measure in any systematic way. Nonetheless, given the uncertainty and rapidly evolving nature of the industry, and broad agreement in the nanotechnology community on the value of dialogue and information sharing, they are relevant to developing an effective oversight and governance system.

The goal here is not to summarize the extensive and growing literature on voluntary initiatives but to draw key conclusions regarding when these initiatives are more or less effective. This will serve as a rough guide to evaluating their effects in addressing the health and environmental effects of nanotechnology. Existing research and experience suggest that voluntary initiatives are more likely to be effective under these conditions:

1. There are defined consequences if participation and results do not reach the desired levels.

One lesson from assessments of voluntary initiatives is that the less they are perceived as being purely voluntary, the more likely they are to be effective. The targets of an initiative must perceive that participation and goal attainment will lead to a better outcome for them than will an alternative. One such alternative is a regulatory backstop or default that will be adopted if a voluntary approach fails.[23] For example, in the ERPs being implemented in many states, a strategy of information and assistance is backed up by the threat of enforcement for recalcitrant firms.[24] Having regulation and enforcement as the default should voluntary efforts fail may induce more and better participation than not having such a regulatory backstop.

2. Participation and achievements yield business or other organizational benefits.

In place of or in combination with sticks (negative consequences) are carrots (positive consequences). Business firms and others engage in voluntary efforts for many reasons. They tend to value recognition, because it may carry weight with customers, investors, employees, insurers and others. Recognition may translate into business value in the form of higher market share, lower insurance premiums, access to capital, employee recruitment and retention and better (that is, less adversarial) relationships with regulators. To encourage participation in voluntary initiatives, agencies also may offer other benefits, such as access to information, streamlined permitting or lower regulatory transaction costs. As the director of EDF's Corporate Partnership Programs has put it, "In order to be 'sustainable' in every sense of the word, environmental innovation must also fundamentally fit with a companies' overall strategy to generate business value." (Ruta 2009)

3. The sponsoring organization is clearly committed to the initiative and communicates its goals and value.

The design of the initiative is important, but the way in which it is presented and communicated also matters. Participation is more likely if the agency or other sponsoring organization supports it clearly from the top, conducts effective outreach to the target audience, promotes its value to other constituencies and provides adequate resources for its implementation. Participants in an initiative should also have the sense that the agency can deliver on its commitments. Lacking a clear statutory foundation or authority to force participation or performance, voluntary initiatives rely heavily on the perceived credibility of both the sponsoring organization and the participants. The irony of voluntary initiatives is that they are aiming to build trust at the same time that they are requiring a degree of trust if they are to be successful.

4. Public credibility is enhanced with mechanisms for monitoring performance, minimizing free-riding and applying sanctions (e.g., removal) for not meeting obligations.

In their study of green clubs, Matthew Potoski and Aseem Prakash distinguish "weak sword" from "strong sword" programs (Potoski and Prakash 2009, chapter 1). Programs with reliable reporting systems, third-party oversight (such as independent auditing) and sanctions for not meeting participant obligations constitute strong sword programs, are more credible and are more likely to achieve their desired goals. Organizations are less likely to be able to free-ride by claiming the benefits of participation without producing value. This not only makes the program more credible but also increase the overall results achieved and maintains the program's value for the participants. The degree of rigor and accountability in a program's design affects its likely success. The relevance of these points to nanotechnology is clear from surveys suggesting that public trust is higher when there is transparency and third-party verification. Table 1 presents an overview of the initiatives discussed here, including nanotechnology initiatives discussed in the next section.

With these general lessons in mind, the next section turns to the more significant efforts that have been made to use voluntary initiatives in nanotechnology oversight. The final section of the report proposes criteria for voluntary initiatives based on these lessons and the characteristics of the nanotechnology issue. It also recommends options for using voluntary initiatives as part of a larger governance system for nanotechnology.

> *"A second challenge is defining and measuring the dependent variable: What is it that we expect to change, and how can we measure it for research purposes?"*

TABLE 1. TYPES AND EXAMPLES OF VOLUNTARY INITIATIVES

Type of Initiative	Examples
Government-Sponsored Programs	
Green Clubs and Challenge Programs (EPA Programs)	• 33/50 • Climate Leaders • Performance Track • State Excellence Programs
Data Collection Programs	• High Production Volume Chemicals • Voluntary Children's Chemicals Evaluation Program
Information Sharing/Assistance	• *Nanoscale Materials Stewardship Program* • Design for the Environment • Environmental Results Program
Collective Business Initiatives	• Responsible Care • Sustainable Forestry Initiative • ISO 14001
Business-NGO Partnerships	• Forest Stewardship Council • Marine Stewardship Council • *Nano Risk Framework* • *Responsible Nano Code*

VOLUNTARY NANOTECHNOLOGY INITIATIVES THAT HAVE BEEN DEVELOPED SO FAR

A review of early experience with nanotechnology reveals efforts that involve all three types of initiatives—government-sponsored programs, business initiatives and NGO-business partnerships. These efforts illustrate the variations such initiatives may take and the strategic interests of different actors in finding ways to manage potential health and environmental risks. It is worth considering these strategic interests. If they do not align, and there are few incentives to collaborate, prospects for including voluntary initiatives in an effective governance system are low. If the strategic interests of different actors do align and overlap, the prospects for using voluntary initiatives in some form improve.

The actors involved in identifying, evaluating and managing nanotechnology effects include, from the private sector, the industry itself (with its many components), investors and insurers. These actors have a direct financial stake in the industry's development. For businesses and their investors, the principal goal is to create conditions that support the industry's evolution in ways that maximize its economic potential. Factors that could detract from this goal include a highly publicized event or series of events that highlight the health or environmental risks of nanomaterials or products;[25] unreasonable, restrictive or costly government regulation (at least from a business perspective) that would constrain the industry's growth; and negative media coverage of nanotechnology and its products. Although insurers share these interests, they have a particular concern with potential liabilities from nanoscale materials or products containing them. It is no surprise that, as they have done with climate change, major insurers have sponsored thoughtful assessments of the nanotechnology sector and its potential risks. [26]

Another set of actors does not share a direct financial interest in the industry but does have a stake in its safe and responsible development. The clear benefits that will accrue from nanotechnology lead many outside of the industry to want it to proceed. Within the NGO community, opinions are split. The EDF has pushed for more research funding on the effects of nanotechnology and a more active regulatory role for government, but it also has endorsed collaborative efforts to build a governance system, most directly in working jointly with DuPont on the *Nano Risk Framework*.[27] Another group of NGOs, consisting of those that rejected outright the *Nano Risk Framework*, are far more skeptical of any growth of the industry until risks have been evaluated and a stronger government oversight system is in place. One NGO, the ETC Group, has called for a moratorium on nanotechnology research and new commercial products "until these materials are shown to be safe" (ETC Group 2007).[28] Given their opposition to any kind of non-legally binding efforts to manage nanotechnology risks, these groups are not likely to have any strategic interests in the topic of this report. For other NGOs, however, voluntary initiatives could be viewed as part of an effective governance system. EDF has demonstrated commitment to this by collaborating with DuPont, as is discussed below.

The goal of EPA, FDA, OSHA and other regulatory agencies is to protect the public from the health, environmental and safety risks of a new and evolving technology. For nanoscale materials in particular, agencies have a critical need for information that enables them to identify and evaluate potential risks and decide

what protective action to take. Much of the focus by agencies thus far has been on how to obtain information needed to make risk management decisions. Chemicals regulation is an information-intensive activity; agencies need an array of chemical-specific data to set priorities for testing or action. If voluntary programs can help agencies gain the information needed to make sound decisions, a voluntary effort could align with their strategic interests.

Aside from limited information, agencies face two main constraints: limits in their legal authority and in resources. Analyses in previous PEN reports concluded that EPA, FDA and OSHA have statutory authority to exercise oversight over the industry, but that it is certainly less than ideal. The TSCA grants data collection authority to EPA but is relatively weak in enabling it to act to reduce risks.[29] Industry and environmentalists agree that TSCA requires an overall "modernization." The Federal Food, Drug, and Cosmetic Act covers some applications but offers limited authority over cosmetics and dietary supplements, both of which are emerging as major uses for nanoscale materials. OSHA's authority is limited to occupational settings and has its own set of limitations. In addition, given the broad scope of nanoscale materials and their applications, federal statutory authority is highly fragmented. As for resources, it is fair to say that regulators always are struggling with constraints, especially on emerging issues where the regulatory infrastructure is lagging. Each of these constraints—information, authority, resources—will affect the interest of regulators in using voluntary initiatives. If voluntary initiatives can help in offsetting agency limitations in these areas, they offer a possible basis for agency action and for improving nanotechnology oversight.

In sum, there is a basis for assuming a collective interest in voluntary initiatives among several of the various actors in nanotechnology. Their strategic interests align in several ways; this alignment suggests a potential for using voluntary initiatives. Further evidence of this conclusion comes from efforts made thus far to use voluntary initiatives.

This section examines three of the more prominent voluntary initiatives as case studies: the *Nano Risk Framework*, developed collaboratively by the EDF and DuPont; the *Responsible Nano Code*, sponsored by stakeholders from the United Kingdom; and the EPA's *Nanoscale Materials Stewardship Program.* These are three of many voluntary initiatives that have been launched in the past five years. Among them, for example, are the *Voluntary Reporting Scheme for Engineered Nanoscale Materials*, launched by government in the United Kingdom in 2006; *Assured Nano*, a safety, health and environment accreditation scheme announced in Europe in 2009; a code of conduct and certification program for consumer products containing applications of nanotechnology, initiated by the Swiss Retailer's Organization in 2008; and the European Commission's voluntary guidelines (*Commission Recommendations on a Code of Conduct for Responsible Nanosciences and Nanotechnology Research*), which were issued in 2008. These have been the subject of some analysis, but they should receive more in the context of the issues discussed in this report as a basis for expanding our understanding of the role of voluntary initiatives (Bowman and Hodge 2008, pp. 145-164).[30]

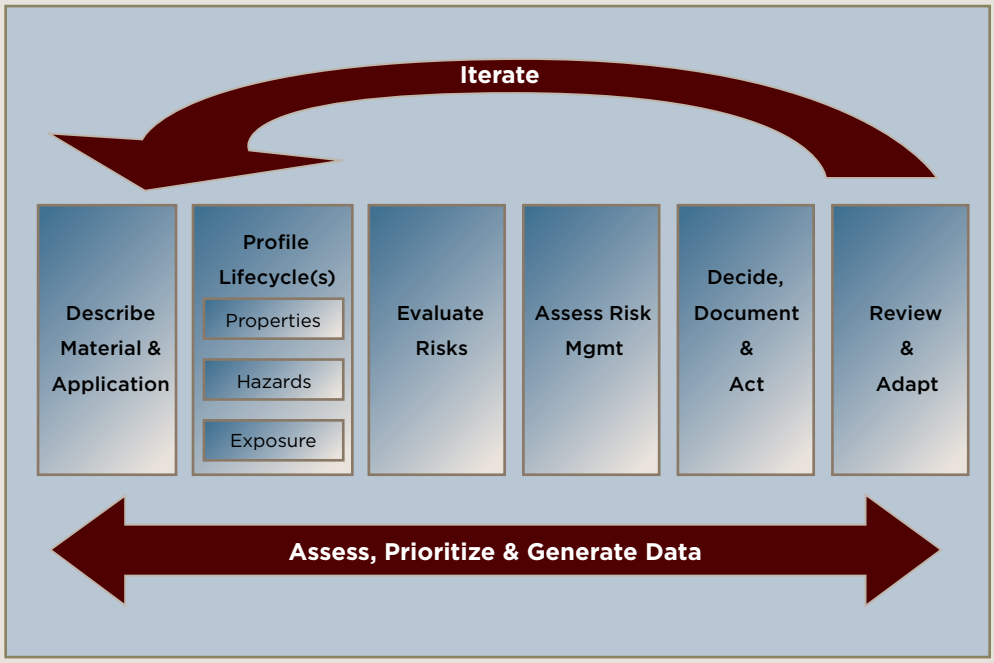
THE NANO RISK FRAMEWORK

The most comprehensive voluntary nanotechnology initiative undertaken so far, at least from the perspective of developing a risk management framework, is the *Nano Risk Framework*. Led jointly by the EDF and DuPont, it was begun in 2005 and released in

June 2007, after many rounds of workshops and public review. The goal was "to define a systematic and disciplined process for identifying, managing and reducing potential health, environmental and safety risks of engineered nanomaterials across all stages of a product's life cycle—its full life from initial sourcing through manufacture, use, disposal or recycling and ultimate fate" (Environmental Defense–DuPont 2007, p. 12).[31] The sponsors aimed for a "comprehensive, practical, and flexible" framework—one that recognized the limits in data and would be usable for organizations working with and developing applications for nanoscale materials. It is voluntary, because the decision of whether to use all or part of it is at a company's discretion; there is no third party, from government or elsewhere, requiring its use. The intended audience was large, however, with the objective of developing a framework "that will be accepted, endorsed, and adopted by a wide range of stakeholders …" [32]

The framework defines a six-step process for identifying, characterizing and communicating information about potential risks of nanomaterials and products. Figure 2 provides an overview of these steps. Although the framework itself is fairly detailed, it is worth presenting a brief overview to gain an idea of its scope and content. The process begins with a description of the material and application, followed by a profile of the material's properties, hazards and exposures throughout its life cycle. This covers "all the processes and activities that occur from initial extraction of the material (or its precursors) from the earth to the point at which any of the material's residuals return to the environment" (p. 27). The model also includes the processes by which materials return to the life cycle when they are recycled, remanufactured or reused. The results of the three elements of a life cycle profile (properties, hazards and exposures) are

FIGURE 2. NANO RISK FRAMEWORK
(ENVIRONMENTAL DEFENSE - DUPONT 2007)



integrated in Step 3, which is to characterize and evaluate risks from a material or application. Step 4 consists of an analysis of the options for managing risks and recommending appropriate actions. The final two steps are (5) deciding what action to take (including not developing and producing the material) and (6) reviewing and adapting evaluations, decisions and actions taken under the framework.

Several aspects of the framework are worth noting as a voluntary initiative. First, having a national environmental organization and major chemical company as co-leads made the process for developing it and the framework itself more credible. In addition, the development process was consultative, with industry and NGO workshops, involvement by various organizations and opportunities for expert and public comment. The framework, support documents and comments have been available on www.nonoriskframework.org website.

Second, the framework adopts a pragmatic approach to the limits in data. If test data on health and environmental effects are unavailable, the framework recommends using reasonable *worst-case default values and bridging information* for filling in the data gaps, at least as a temporary measure. Worst-case default values draw upon existing assessments of analogous materials to establish a worst-case outcome for the nanomaterial being evaluated. Similarly, when better information exists for other materials regarding a risk endpoint, the information may be used to inform simpler and shorter tests for the nanomaterial. Both may be especially appropriate at the early stages of developing a nanoscale material to guide later testing and risk management actions.

A third aspect worth noting is the framework's use of a materials life cycle model. Nanoscale materials may cause health, environmental and safety risks at many stages of their life cycle. The standard concepts of product life cycle or product stewardship do not capture those potential risks. By viewing materials from the sourcing stage through manufacturing, use and beyond, the *Nano Risk Framework* provides a comprehensive model to guide data collection, risk assessment and management by government or through other third-party oversight. It offers a foundation for a broader business-NGO effort with more substantial participation (perhaps in the form of a green club) or in the form of an expanded, more comprehensive regulatory approach than exists now.

The framework has its critics. The most vocal critics focused less on the content than on industry being actively involved in developing it and on the possibility that voluntary efforts could displace regulation. One reporter wrote, in referring to the framework, that a "recent attempt to forge a partnership between environmental advocates and nanotech-business advocates has bred fears that the appearance of industry self-regulation could trump government oversight" (Chen 2007). The criticisms came from a coalition that included the International Center for Technology Assessment, Greenpeace, Friends of the Earth and United Steelworkers. In a July 2007 press release, these groups called for a strong, highly precautionary, government oversight system for nanotechnology. It should include, the release stated, a burden of proof on industry to prove safety, the completion of a full life cycle analysis before products are commercially available and product labeling, among other measures (International Center for Technology Assessment, 2009).[33]

The more general view is that the *Nano Risk Framework* offers a useful starting tool for managing the effects of a new and evolving technology. There even is concern that it may be too demanding and ambitious for organizations that lack the resources of major companies

like DuPont. Although generally supportive, Jo Anne Shatkin and Michael Davis argue that the framework is too demanding in calling for an evaluation of risks at each stage in the life cycle, for all products, across the supply chain. A more workable approach could be to rely on screening assessments based on likely exposures. For these and other reasons, they call for a more iterative and adaptable approach than is set out in the framework (Shatkin and Davis 2008, p. 118). These are differences in approach, however, that underscore the value of having a comprehensive risk management tool to augment or prepare for regulation, or to use until (and if) a regulatory framework emerges. The same authors note that EDF and DuPont "used their collective extensive resources to define for them what information is needed to make sound decisions for managing nanotechnology risks in the absence of regulation" (p. 119). It is difficult to see the framework as anything other than a serious, comprehensive, collaborative contribution to nanotechnology oversight.

Since release of the framework in June 2007, EDF and DuPont have held workshops, given presentations and held training sessions to encourage its use. DuPont also conducted and made public three case studies that evaluate and demonstrate how to use it. EDF also has been working with the ISO on incorporating the framework as an ISO standard and has encouraged insurers to use its adoption as a factor in decisions about insurance coverage. Beyond these efforts, however, there has been limited sustained activity to institutionalize the framework or to discuss and refine it for application in different settings. Doing so would be one of the tasks of the Nano Policy Forum proposed in the recommendations.

THE RESPONSIBLE NANO CODE

Another approach to developing an oversight framework is the *Responsible Nano Code*. This initiative began with efforts of a consultancy (Acona and later Responsible Futures) and a socially responsible investment firm (Insight Investment) to apply the concepts of corporate responsibility to the nano issue; it later drew the interest of the Royal Society and the Nanotechnology Industries Association (NIA), among others.

The collaborative effort to develop a code began in November 2006, when a group of industry, scientific, government, labor and NGO stakeholders met to explore the uncertainties associated with nanotechnology and to consider approaches to responsible governance. This initial workshop was guided by a briefing paper setting out the characteristics of the nanotechnology issue as well as the need for and conditions that could support responsible oversight.[34] This group agreed unanimously on the value of a voluntary code. It further agreed that any such code should be *principles*- rather than *standards*-based and that it would be developed in consultation with a wide range of business, government, consumer and NGO stakeholders. Four organizations—the Royal Society, Insight Investment, the NIA and the Nanotechnology Knowledge Transfer Network (from the Department of Trade and Industry in the United Kingdom)—were recognized as founding partners and agreed to sponsor the effort to develop a code. The working group first met in June 2007. It disseminated a "Consultation Draft of the Code" in September; after further consultations it adopted the elements of the code in May 2008.

The code is organized as a three-level hierarchy. At the first, highest level is a set of

seven principles that address broad issues of governance. The principles range from those related to stakeholder involvement, transparency and disclosure to worker and public health, safety and environmental risks (see Table 2). The second level is "Examples of Good Practice" developed for each principle. For Principle Four, "Public Health, Safety and Environmental Risks," for example, one of the good practices is for an organization to disclose publicly "how it identifies, assesses, manages, and mitigates any public health, safety and environmental risks identified as relating to its products." Table 3 presents an example of

TABLE 2: THE SEVEN PRINCIPLES OF THE RESPONSIBLE NANO CODE

PRINCIPLE ONE – BOARD ACCOUNTABILITY
Each organisation shall ensure that accountability for guiding and managing its involvement with nanotechnologies resides with the Board or is delegated to an appropriate senior executive or committee.
PRINCIPLE TWO – STAKEHOLDER INVOLVEMENT
Each organisation shall identify its nanotechnology stakeholders, proactively engage with them and be responsive to their views.
PRINCIPLE THREE – WORKER HEALTH & SAFETY
Each organisation shall ensure high standards of occupational health and safety for its workers handling nano-materials and nano-enabled products. It shall also consider occupational health and safety issues for workers at other stages of the product lifecycle.
PRINCIPLE FOUR – PUBLIC HEALTH, SAFETY & ENVIRONMENTAL RISKS
Each organisation shall carry out thorough risk assessments and minimise any potential public health, safety or environmental risks relating to its products using nanotechnologies. It shall also consider the public health, safety and environmental risks throughout the product lifecycle.
PRINCIPLE FIVE – WIDER SOCIAL, ENVIRONMENTAL, HEALTH AND ETHICAL IMPLICATION AND IMPACTS
Each organisation shall consider and contribute to addressing the wider social, environmental, health and ethical implications and impacts of their involvement with nanotechnologies.
PRINCIPLE SIX – ENGAGING WITH BUSINESS PARTNERS
Each organisation shall engage proactively, openly and co-operatively with business partners to encourage and stimulate their adoption of the Code.
PRINCIPLE SEVEN – TRANSPARENCY AND DISCLOSURE
Each organisation shall be open and transparent about its involvement with and management of nanotechnologies and report regularly and clearly on how it implements the Responsible Nano Code.

Source: www.responsiblenanocode.org

best practices. Also planned is a third level "Benchmarking Framework" for assessing the extent to which organizations are using the code. The target audience is "organizations involved in the research, development, manufacturing, retailing, disposal and recycling of products using nanotechnologies …" The plan was to complete the benchmarking framework by the end of 2008 and begin to apply it in 2009, although as of early 2010 that schedule is on hold because of funding issues.

The organizations behind the code are careful to emphasize what it is not meant to be as well as what it is. It is not intended, for example, to supplant or delay regulation, but to provide guidance on best practices "during the transitional period in which the appropriate national and international regulatory frameworks are being evaluated and, if necessary, developed, and to complement any existing regulation" (*Responsible Nano Code 2008*). Nor is it intended to provide auditable standards or detailed operational guidance. Rather, the aim is "to establish a consensus of good practice in the research, production, retail, and disposal of products using nanotechnologies and to provide guidance on what organizations can do to demonstrate responsible governance of this dynamic area of technology" (*Responsible Nano Code 2008*).

One question worth considering is the fit between the *Nano Risk Framework* and the *Responsible Nano Code*. Both illustrate the concept of "governance outside of government." In both, interested and motivated stakeholders organized to design a governance system that others could use at their option. In the first, an influential and highly visible NGO and a global chemical company jointly took the lead. This was a powerful combination, backed by solid economic and technical resources. Responsible Nano aimed to create a more general and far less detailed set of principles and practices. At this point, Responsible Nano is an unfinished product. More work is needed for it to fulfill it original purposes. Until then, it is difficult to evaluate it as the basis for a larger governance system. However, the status of the organizations that have been involved, the breadth of the consultative process and the substance of the materials developed so far provide an excellent strategic guide for taking the next steps in nanotechnology governance and oversight and for constructively engaging a range of stakeholders.

THE EPA NANOSCALE MATERIALS STEWARDSHIP PROGRAM

In January 2008, EPA introduced its own voluntary initiative in the form of the *Nanoscale Materials Stewardship Program* (NMSP). The link to future regulation was explicit. The program was developed, EPA stated, "to help provide a firmer scientific foundation for regulatory decisions by encouraging submissions and development of information for nanoscale materials" (*USEPA Nanoscale Materials Stewardship Program* 2009, p. 3). EPA aimed "to complement and support its regulatory activities on nanoscale materials" under TSCA (p. 6). More specifically, the NSMP was designed to collect existing data from manufacturers, importers, processors and users of nanoscale materials and to "identify and encourage use of risk management practices in developing and commercializing nanoscale materials" (USEPA NMSP). The focus was information—what existed, its value and accessibility and what gaps to fill before making regulatory decisions.

The process for developing the NMSP began with a public meeting in June 2005 and ended in January 2008 with the announcement of the final design and format. The proposal for a voluntary program initially was supported by the National Pollution Prevention and Toxics

TABLE 3: AN EXAMPLE OF NANO CODE BEST PRACTICES: ENVIRONMENTAL RISKS

PRINCIPLE FOUR BEST PRACTICES – PUBLIC HEALTH, SAFETY & ENVIRONMENTAL RISKS

Each organisation shall carry out thorough risk assessments and minimise any potential public health, safety or environmental risks relating to its products using nanotechnologies, it shall also consider the public health, safety and environmental risks throughout the product lifecycle.

Examples of how the organisation can implement the Code may include:

1. Putting processes in place to identify, evaluate and minimize any risks to the general public, users or the environment from the development, manufacture, distribution, use, disposal or recycling of nano-materials or nano-enabled products. In particular, demonstrate clearly that there is no default assumption that the risks associated with nanotechnology are the same as those involved with existing materials at a larger scale.

2. Highlighting to other appropriate organisations in the supply chain any risks that they might need to address.

3. Disclosing publicly the standards and protocols it has used to assess product safety and the actions it has taken in the absence of appropriate standards, protocols, or relevant legislation.

4. Disclosing how it identifies, assesses, manages and mitigates any public health, safety and environmental risks identified as relating to its products.

5. Marketing products only after ensuring that the safety of the nanotechnology enabled elements of the products have been substantiated.

6. Sharing information on risk assessment and mitigation methodologies, and assessment results, with government agencies, regulators and other organisations in order to enhance global understanding and the development of appropriate risk assessment methodologies.

7. Contributing constructively to the development of appropriate regulations and standards in all markets. Proactively support government and independent research initiatives to bridge information or research gaps when [they] hinder the responsible development of nanotechnologies.

source: www.responsiblenanocode.org

Advisory Committee, an external advisory group, which also suggested the elements of the program and criteria for evaluating it. On the basis of the group's advice, EPA proceeded with a concept paper, a public meeting, two rounds of scientific peer consultation, a response to public comments and then the final program.

The NMSP has two components. The Basic Program called for existing information on nanoscale materials (physical and chemical properties; hazard, exposure and use data; risk management plans). The scope for this component was thus on what was currently available. The In-Depth Program asked for a commitment to work with EPA and develop test data for selected nanoscale materials. The In-Depth Program thus involved a more substantial commitment to plan for and develop new test data rather than only submit what already existed. By the initial, six-month deadline established for the Basic Program, EPA had received submissions from 16 companies and trade associations on 91 different nanoscale materials, based on 47 different chemicals. EPA continued to accept data, however, and by the end of 2008, it had received information from 29 companies and trade associations on 123 materials, based on 58 different chemicals.

Given the greater commitment required from industry, participation in the In-Depth Program was much more limited. As of December 2008, four companies had offered to develop test data on materials that included carbon nanotubes and a carbon nanoparticle. The limited response to the in-depth component was disappointing and likely attributable to (1) the lack of economic incentives for investing in the testing plans and (2) the uncertainty about precisely what committing to the testing plan would entail.

In an Interim Report on the NMSP, EPA concluded, "Thus far, the program has considerably increased the Agency's understanding of the types of nanoscale materials in commerce" (USEPA 2009, p. 9). EPA did receive information that previously had not been available. However, submissions largely covered physical and chemical properties, actual or projected commercial use, manufacturing processes and risk management practices. Information on toxicity, exposure and fate were limited. In addition, only a fraction of nanoscale materials were covered in the submissions, based on comparisons of reported materials with the best available information on nanomaterials in commercial production.[35] Although the NMSP provided a relatively quick, first brush with data, either incentives (positive and negative) or a mandatory approach will probably be needed to collect data for making regulatory decisions. EPA has recognized and announced its intention to develop a rule under Section 8(a) of TSCA that will collect the needed data. EPA will issue a final report on the NMSP in 2010.

Evaluations of the NMSP will be influenced by interpretations of its objectives. If one assumes that the objective was to obtain information needed to make regulatory decisions, the NMSP had limited success.[36] If, in contrast, it is seen as preparation for mandatory data collection, then it may have had value in improving the quality of regulatory actions. It also is possible that had the NMSP been designed differently, it would have achieved a better response. Even with a mandatory reporting scheme, agencies could augment regulation with a voluntary program that expands on the range of available data and serves as a pre-test for further regulatory action. All of these options should be considered, and they are part of the recommendations made in the conclusion of this report.

OTHER VOLUNTARY INITIATIVES

Other, smaller-scale initiatives also may be relevant to using voluntary action. The EMS concept has so far drawn limited attention from nanotechnology firms beyond established chemical companies. However, a few years ago Nanofilm (a small coatings company in northern Ohio), collaborating with EPA's Performance Track and the Wilson Center's PEN, developed an EMS focused on its products and operations as a possible template for other small firms. Its experience is described in Box 1. Another model is the GoodNanoGuide, a collaborative effort sponsored by the International Council on Nanotechnology at Rice University. It provides an interactive forum for exchanging information and best practices in the workplace. There also has been interesting work, mostly in Wisconsin, to adapt the concept of the "science café" (café scientifique as currently being practiced in the United Kingdom) to nano issues. Nano cafés engage citizens and scientists in coffee shops and other settings to promote understanding and discussion of nanotechnology and its social implications.[37]

BOX 1: NANOFILM DEVELOPS AN ENVIRONMENTAL MANAGEMENT SYSTEM

In the fall of 2008, Nanofilm, a small-scale coatings company in Ohio, developed one of the first Environmental Management Systems (EMS) in the nanotechnology industry. The company developed the EMS in collaboration with the U.S. Environmental Protection Agency's Performance Track Program and the Project on Emerging Nanotechnologies at the Woodrow Wilson Center. The goal of the collaboration was to enable Nanofilm to be the first nanotechnology company to qualify for Performance Track and provide a model for others.

The Performance Track Program encouraged facilities with strong environmental records to go above and beyond their legal requirements. Organizations that applied and were accepted became eligible for a number of benefits, including national recognition, networking opportunities and priority for a Green Supplier Network Review.

PERFORMANCE TRACK HAD FOUR CRITERIA IN ORDER TO QUALIFY FOR MEMBERSHIP:

- A strong compliance record;
- A working EMS that was independently assessed, if not formally certified;
- A commitment to community outreach; and
- Setting and reporting on two to four goals for environmental improvement beyond legal requirements and reporting annually on progress.

Nanofilm's goals were to improve its recycling practices and reduce landfill wastes. The firm credits the EMS with helping it think more innovatively about its environmental impacts and those of its products.

EPA canceled the Performance Track Program in May 2009. Despite this, Nanofilm still implements the EMS, which can serve as a guide for other nanotechnology companies that wish to improve their environmental performance and risk management practices.

CONCLUSIONS FROM EXISTING VOLUNTARY NANOTECHNOLOGY INITIATIVES

One goal of this report is to document and draw lessons from existing initiatives. Four such conclusions are appropriate at this stage. First, there now exists a community of technical, legal, management and policy experts who have been engaged in identifying and finding solutions to the challenges of nanotechnology oversight. This community provides likely participants for future dialogue and problem-solving. The EPA/NMSP and the EDF-DuPont framework engaged a variety of stakeholders and experts. To the extent that the strategic interests of stakeholders overlap, as suggested above, there may be an opportunity to engage this community in discussions about collective action through a variety of regulatory, voluntary and information-based initiatives.

Second, the voluntary initiatives that have been undertaken so far recognize the distinctive characteristics of nanotechnology and tailor their efforts to them. An advantage of voluntary initiatives is their flexibility and adaptability, and the opportunity they offer to try different approaches before locking into a broader or new regulatory scheme. Although people involved in nanotechnology issues often make comparisons to debates over biotechnology from a decade or so ago, they also stress what is different about nanotechnology and the limits of generalizing from that previous experience. The dynamism, rapid growth and health and environmental benefits of nanotechnology distinguish it from many earlier environmental issues, and these characteristics need to be recognized in a search for solutions. Indeed, nanotechnology is more typical of the future of environmental problem-solving than of the past, and there is more need for innovation and flexibility than with more conventional pollution and chemicals issues.

Third, although there is some overlap in coverage and participation among the initiatives, they appear largely to have proceeded in parallel rather than to be coordinated. This has probably been an advantage to this point, but the time may be right for a more coordinated, comprehensive initiative conducted in parallel with any regulatory actions.

Fourth, the participants in these efforts accept that the likely role of voluntary initiatives is (1) to inform and prepare the ground for regulation or (2) to complement existing and future regulatory capacities rather than to supplant them. This was explicit in the *Nano Risk Framework* and the NMSP. The former states that it "is not intended to be a substitute for government regulation or continuing public discourse …" (Environmental Defense – DuPont 2007, p. 21). One of the main purposes of the NMSP is "to help provide a firmer scientific foundation for regulatory decisions by encouraging submission and development of information for nanoscale materials" (USEPA NMSP 2009, p. 3). Both avoid either-or debates about voluntary versus regulatory action and recognize that one complements the other in an effective oversight system.

ISSUES AND RECOMMENDATIONS IN USING VOLUNTARY INITIATIVES

An advantage of voluntary initiatives is their flexibility. They do not necessarily require legislative action, although they could. They may be sponsored by government, business, NGOs, trade associations or a combination thereof. They can focus on any one of the many stages in the materials life cycle, all of

them or only a few. They may be implemented at local, regional, national or international scales. Efforts at these different scales may be combined at some point to expand coverage, or they may evolve over time.

The obvious weakness of voluntary initiatives is that they do not necessarily make anyone do anything. The element of legal coercion is missing, an omission that causes worry not only among NGOs but also among some business firms.[38] This does not mean that a voluntary program cannot be effective; however, it does underscore the importance of evaluating the purposes of such initiatives; their fit with existing authority and resources and the level of participation that is needed and likely; and the role of the initiative within a larger strategy. If there is a compelling issue that must be addressed, agencies have the needed authority and resources and a sufficiently high level of voluntary participation cannot be achieved, the case for regulation is strong. If, as is often true of emerging problems, legal authority is insufficient and there are incentives (positive or negative) that will induce high levels of participation, voluntary initiatives could play a central role.

A problem in past use of voluntary initiatives is that their links with regulatory programs and strategies were unclear or, at best, tenuous. This report suggests three possible models for how voluntary and regulatory strategies may be related to each other. In one model, they are used as a precursor to or preparation for regulation. EPA's *Nanoscale Materials Stewardship Program* appears to fit into this category. A second model is to create and operate a voluntary effort that is completely independent of regulation. The EDF-DuPont *Nano Risk Framework* illustrates this type, although it could at some time evolve into the first and be used as a combination or trial run for regulation. The third model is to create an initiative that explicitly, and from the start, complements existing regulation. It appears that none of the initiatives undertaken so far fits this model, but it will be considered in the final recommendations to this report.

One of the telling criticisms of voluntary programs is that they may provide an excuse not to regulate. This has been a concern in the NMSP. Similarly, several activists rejected the EDF-DuPont framework, arguing that it would undermine the case for regulation. This is why voluntary initiatives should be viewed as one component in a larger oversight system; they should be evaluated in the context of a broader set of regulatory, economic, educational and other strategies for managing potential risks.

A goal of this report is to draw lessons from the experience with voluntary initiatives and apply them to nanotechnology. Before proceeding to recommendations, it is worth considering some final points on the three types of initiatives discussed above and their possible applications to nanotechnology oversight.

Agency initiatives may be justified on several grounds: to prepare for or enhance regulation; to achieve results beyond what is likely through regulation on its own; or to build the social capital that will enhance collective capacities for future problem-solving.

The NMSP could be justified on the first ground, and possibly on the others as well. EPA's position is that however disappointing the results of the voluntary data collection itself, the NMSP provided data and experience that will inform future efforts for mandatory reporting under TSCA. It seems clear that EPA has a better idea of what information is out there, of its quality and of how best to structure information requirements under its regulatory authority. If the next step in building the information base for nanoscale

materials is better designed and more successful because of this effort, it will not be difficult to justify the time delay in issuing mandatory requirements, especially given the still-limited information base on nanoscale materials.

One role government could play beyond a purely regulatory one is to work with industry and other interested parties to build a capacity for risk management. The ERP offers a model for such an effort. Especially given the large number of small firms in the nanotechnology business, a state-level, ERP-type pilot project could have merit. Like ERP model as applied to conventional business sectors dominated by small firms, this kind of program could help identify organizations, disseminate information on regulations and best practices, improve risk management capacities and expand the level of information available to regulators and the public. To be sure, the typical small nanotechnology organization differs in many ways from the local photo shop or printer, but it still may lack experience with the regulatory system and the need for best practices in protecting worker and product safety. Still, the ERP model could be adapted to the circumstances and needs of the nanotechnology sector.

The typical criticism of *unilateral business-led environmental initiatives* is that they are the fox guarding the henhouse and cannot be relied upon to attain the desired results. Related criticisms have been that they lack transparency and do not necessarily change performance from a "business as usual" scenario. Although these may be valid criticisms in the context of specific initiatives, they are not necessarily valid for all initiatives in all settings. The objective of the initiative also must be taken into account.

Unilateral business initiatives are less than ideal for purposes of building public credibility and confidence in an industry, activity or products. Although transparency, third-party audits and public reporting may provide more public assurances than would otherwise be the case, business-sponsored green clubs always will be subject to the suspicion that the industry is making its own rules and overseeing its own behavior. The efforts of the chemical industry's Responsible Care program to increase measurement and accountability are laudable and have increased confidence among some stakeholders. Still, the core perception of it as "self-regulation" limits the acceptance it will achieve outside of the industry and a small number of knowledgeable observers.

What unilateral programs like Responsible Care can achieve, however, are higher standards of care and performance within the industry. Dynamic and complex issues such as nano (i.e., "wicked" problems) require adaptive, collaborative learning systems if they are to be managed effectively. Regulation imposes a set of constraints; although often essential, these constraints do not necessarily create the conditions suited to learning, adaptation and effective management within the organizations that develop, apply and commercialize nanoscale materials and products (Fiorino 2009, pp. 63-86). Industry codes need not be seen as a substitute for regulation, nor need they be taken prima facie as a sign of industry responsibility. They should be evaluated fairly and critically on their merits. Their more important function may be to create, within groupings of firms, systems of learning, lesson-sharing, best practices and expectations of collective responsibility. Given the characteristics of nanotechnology, industry codes and associated green clubs offer a useful complement to regulation.

As for *business-NGO partnerships*, their

strengths are credibility, balance and transparency. They offer useful models that could be applied to nanotechnology. One model comes in the form of the FSC and MSC. They are distinguished by their (1) collaborative foundation that includes both NGO and business interests; (2) emphasis on technical expertise and advice; and (3) reliance on information and, more specifically, certification as a strategy for influencing behavior. Given the early stage in the evolution of nanotechnology and uncertainty about health and environmental effects, it is too soon to create a well-formed certification scheme such as those for forest practices and fisheries. It may not be too soon, however, to build upon the efforts now under way to prepare longer-term for future "governance without government" that builds upon the *Nano Risk Framework* and *Responsible Nano Code* as well as the FSC and MSC.

In the meantime, it should be possible to expand both the discussions about and uses of the *Nano Risk Framework* as a basis for business-NGO collaboration. Some such efforts, including incorporating the framework into ISO's certification system, already are under way. Missing is a forum for ongoing consultation and assistance in assessing the framework's value for different business settings and creating the capacity for using it. The following recommendations include the development of such a forum.

In previous PEN reports, Terry Davies focused largely on regulatory issues, but he also offered proposals for non-regulatory or voluntary action. The following are consistent with his recommendations but expand on them and add others to reflect this report's focus on voluntary initiatives. All of these recommendations assume that there will be appropriate legislative authority and associated regulatory action needed to complement voluntary efforts. Credible and effective use of voluntary initiatives cannot proceed in the long term without the necessary regulatory action being taken. Given the concerns about workplace exposures, appropriate action by OSHA should be a priority, although EPA and FDA should clarify their regulatory plans for nanotechnology as well.

Terry Davies' 2007 report provides a thorough discussion of policy tools available for dealing with nanotechnology. The section of that report on voluntary efforts distinguishes industry-initiated from government-initiated tools. In the first, he briefly reviews industry codes, environmental management systems and third-party initiatives in environmental policy. In the second, he discusses some of the strengths and weaknesses of voluntary approaches and the start-up of the NSMP. He also suggests a possible hybrid of voluntary and regulatory programs, a concept that has merit as a way to complement regulation or to prepare for it later. In the 2008 PEN report, Davies' proposals for voluntary efforts include using the DuPont-EDF *Nano Risk Framework* to analyze risks and issuing a handbook for small nanotech businesses. The following endorses and builds upon both. This list is organized according to who should take the lead; most involve some form of government, business and NGO collaboration.

A. REGARDING EPA AND OTHER FEDERAL AGENCIES

1. EPA and other federal regulatory agencies should collaborate on a multi-year strategy for nanotechnology that sets out regulatory options and agendas as a basis for considering the role of other kinds of initiatives, including voluntary ones. The development of regulatory and voluntary initiatives should proceed in parallel so that doing the latter is not seen simply as an excuse for not proceeding with the former. Each should be part of an overall oversight system; neither should be considered in isolation from the other.
2. Federal agencies (principally EPA and OSHA) should begin to work with key trade associations associated with nanoscale materials and products to establish the initial elements of an ERP focused on nanotechnology. Its purpose would be to create a basis for identifying and working with nano-related organizations and developing appropriate resource materials aimed specifically at small firms. It could begin with a pilot effort on a state scale, perhaps in Massachusetts, which has experience with ERP and is home to many nanotechnology organizations. This effort could start with the ERP model and adapt it to the particular circumstances of the nanotechnology sector.
3. EPA should proceed with mandatory reporting under TSCA for nanoscale materials, as it intends, but should specifically consider how well-designed voluntary efforts could augment information collection and inform future regulatory initiatives. Firms that commit to extra testing/reporting or piloting alternative formats for future regulation could be recognized within the regulatory system later, perhaps through expedited reviews or other incentives. Voluntary reporting also could be an option for small businesses, for which EPA currently lacks authority to require reporting under TSCA 8(a).
4. EPA should commission evaluations of the NMSP, HPV Challenge, VCCEP and Sustainable Futures to assess their strengths and weaknesses, barriers to greater participation and other lessons for use in designing future voluntary, chemicals-related initiatives. These chemicals programs have drawn less interest from researchers than have other voluntary initiatives and warrant more study. A broad evaluation of voluntary nanotechnology initiatives would provide further information on their role and how to design and implement them. These evaluations could be included as part of any revisions in the TSCA.

B. REGARDING FURTHER NGO AND BUSINESS COLLABORATION

1. The strong foundation of the *Nano Risk Framework* should be evaluated and further refined as the basis for establishing a working voluntary oversight system available for broader adoption. The framework could be further institutionalized through incorporation by the ISO (as is now under way) and other venues, such as the Organization for Economic Development, trade associations or new a entity established jointly by stakeholders. The broader framework provided by the *Responsible Nano Code* could be part of this evaluation.
2. NGOs, business, government and others should establish a Nano

Policy Forum for discussing nano oversight issues and developing needed tools. This body should be tasked with considering the long-term value and development of a multi-stakeholder Nano Stewardship Council modeled generally on other collaborative mechanisms. The forum could be funded in equal amounts by government, foundation and business resources or be the subject of a specific congressional appropriation. It would provide an ongoing, neutral forum for discussions on nanotechnology policy issues and options and a clearinghouse for information.

3. A subset of these groups engaged in nanotechnology issues should develop options and recommendations for voluntary labeling of nanomaterials and products. This is likely to work best as a concept-development step, given the many uncertainties about how a labeling program could work at this early stage. This is a case where a voluntary initiative could be a basis for evaluating the need for and design of a possible regulatory initiative.

C. REGARDING FIRMS AND BUSINESS ORGANIZATIONS

1. The *Nano Risk Framework* suggests the potential for an industry sector program modeled after Responsible Care and the Sustainable Forestry Initiative. This is likely to be a longer-term prospect, given the state of the industry, the many small organizations, limited information about health and environmental risks and uncertainty about the next steps in the evolution of the regulatory framework. Given the evolving nature of the industry, a business code could prepare for and complement regulatory action by government.
2. Business groups should consider the merits of and potential audience for an EMS tailored to the specific features of the nanotechnology business. This could be part of an industry code or focus more specifically on making an EMS template and guidelines available. The work on the Nanofilm EMS could provide a template for any such efforts. International efforts such as Assured Nano also could provide a basis for such a system.

D. REGARDING OTHER STAKEHOLDERS

1. The socially responsible investment community should add participation in voluntary nano-related initiatives as a factor in ranking companies. Credible commitment to testing and data collection, labeling, the *Nano Risk Framework* and other evidence of corporate responsibility may provide evidence of lower investment risk and competitive advantage that may draw investors' interest and motivate nanotechnology organizations to adopt risk management protocols.
2. Insurers should consider incentives for encouraging firms to commit to and credibly participate in voluntary nano-related initiatives such as those listed earlier. These incentives could include lower premiums, better terms of coverage and eligibility for different kinds of coverage. Action by the investment and insurance sectors recognizes that many factors beyond regulatory compliance may strengthen risk assessment and management in the nanotechnology sector.

FINAL OBSERVATIONS: VOLUNTARY INITIATIVES AND NANOTECHNOLOGY OVERSIGHT

Broad agreement exists on the value of voluntary initiatives as part of an overall oversight strategy. EPA's Nanotechnology White Paper recommends "research into approaches that encourage environmental stewardship through the complete life cycle of nanomaterials and products" (USEPA 2007, p. 179). It calls for research on "nanotechnology sectors, supply chains, analytical and design tools and application in order to inform pollution prevention approaches" (p. 180). David Rejeski and Andrew Maynard of the Wilson Center assert that "new government and industry partnerships are needed to ensure access to relevant and trusted data on nanomaterial risks" (Maynard and Rejeski 2009, p. 174). In urging a multi-pronged approach, Linda Breggin and Leslie Carothers include regulatory and voluntary programs, corporate stewardship, and voluntary standards (p. 73). The Nano Business Alliance calls for voluntary programs that "engage industry" and help to focus agency efforts. In setting up the *Nano Risk Framework,* Fred Krupp of the EDF and Chad Holliday of DuPont urged adoption of "the right mix of voluntary corporate leadership, coordinated research, and informed regulation" and collaborative efforts to "set interim standards for nanotechnology … while regulations are under development" (Krupp and Holliday 2005). Jo Anne Shatkin argues that given the time lag for putting regulations in place, "it is imperative to be managing risks, and voluntary approaches are an important step toward that management" (Shatkin 2008, p. 119).

Of course, there are some things that voluntary initiatives cannot do. They cannot bring funding on health and environmental effects research to some $100 million annually, as several experts have urged. They cannot manage the problem of industry laggards who do not share the goal of responsibly developing the technology or managing its potential risks. Voluntary initiatives cannot resolve the policy choices related to burdens of proof, risk-benefit balancing and levels of acceptable risk, among others, that political institutions legitimately must make. They may, however, form part of a portfolio of tools and strategies that will allow for a more dynamic, flexible and effective governance and oversight system for the industry, its materials and its products. They deserve consideration as part of a balanced portfolio of policy tools for responding to the rapidly evolving and complex policy challenges of nanotechnology oversight.

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ACRONYMS

DEP	Department of Environmental Protection (Massachusetts)
EMS	Environmental Management Systems
EDF	Environmental Defense Fund
EPA	Environmental Protection Agency
ERP	Environmental Results Program
FDA	Food and Drug Administration
FSC	Forestry Stewardship Council
HPV	High Production Volume
ISO	International Standards Organization
MSC	Marine Stewardship Council
NGO	Non-government organization
NIA	Nanotechnology Industries Association
NMSP	Nanoscale Materials Stewardship Program
NRDC	National Resources Defense Council
OSHA	Occupational Safety and Health Administration
PEN	Project for Emerging Nanotechnologies
RCMS	Responsible Care Management System
SFI	Sustainable Forestry Initiative
TERA	Toxicology Excellence for Risk Assessment
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
USCAP	U.S. Climate Action Partnership
VCCEP	Voluntary Children's Chemicals Evaluation Program
VPP	Voluntary Protection Programs

ENDNOTES

[1]On changes in environmental problems and the need to adapt strategies, tools and relationships, see National Academy of Public Administration, *Setting Priorities, Getting Results: A New Direction for the Environmental Protection Agency* (Washington, DC: NAPA, 1995); *environment.gov: Transforming Environmental Protection in the 21st Century* (Washington, DC: NAPA, 2000); President's Council for Sustainable Development, *Sustainable America: A New Consensus for Prosperity, Opportunity, and a Healthy Environment for the Future* (Washington, DC: PCSD, 1996); and U.S. Environmental Protection Agency, National Advisory Committee on Environmental Policy and Technology (NACEPT), *Outlook for EPA* (Washington, DC: NACEPT, March 2009). Available at www.epa.gov/ocem/nacept/reports. For an academic perspective, see Daniel J. Fiorino, *The New Environmental Regulation* (Cambridge, MA: MIT Press, 2006) and Robert F. Durant, Daniel J. Fiorino, and Rosemary O'Leary, *Environmental Governance Reconsidered: Challenges, Choices, and Opportunities* (Cambridge, MA: MIT Press, 2004).

[2]This point is made generally for environmental problems in the essays in Daniel A. Mazmanian and Michael E. Kraft, eds., *Toward Sustainable Communities: Transition and Transformations in Environmental Policy*, 2nd. ed. (Cambridge, MA: MIT Press, 2009).

[3]Nanometer-scale particles—or nanoparticles—are a particular class of nanomaterials that raise questions over potential health and environmental impact because of their size and their often-unusual behavior. Not all nanomaterials are nanoparticles, just as not all nanotechnologies involve nanomaterials.

[4]On the concept of wicked problems, see Horst W.J. Rittell and Melvin M. Weber, "Dilemmas in a General Theory of Planning," *Policy Sciences*, 4 (1973), pp. 155-169.

[5]On the environmental benefits of nanotechnology, see Karen F. Schmidt, *Green Nanotechnology: It's Easier Than You Think* (Washington, DC: Project on Emerging Nanotechnologies, 2007).

[6]For a discussion of environmental effects, see the U.S. Environmental Protection Agency's *Nanotechnology White Paper* (EPA: Science Policy Council, February 2007), pp. 32-43; and Jo Anne Shatkin, *Nanotechnology: Health and Environmental Risks* (Boca Raton, FL: CRC Press, 2008).

[7]For detailed discussions of statutory authorities, see Davies, *Managing the Effects of Nanotechnology*, 2006, pp. 11-17, and Breggin and Carothers, Breggin, Linda K., Robert Falkner, Nico Jaspers, John Pendergrass and Read Porter. *Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation*. London: Chatham House, 2009. A comparative analysis of U.S. and the European Union with respect to legal issues may be found in Linda Breggin, Robert Falkner, Nico Jaspers, John Pendergrass and Read Porter, *Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation* (London: Chatham House, 2009).

[8]For information on OSHA's Voluntary Protection Programs, see www.osha.gov/vpp.

[9]On voluntary programs generally, see Jan Mazurek, *The Use of Voluntary Agreements in the United States: An Initial Survey* (Paris: Organization for Economic Cooperation and Development, 1998); Keith Brouhle, Charles Griffiths and Ann Wolverton, "The Use of Voluntary Approaches for Environmental Policymaking in the U.S." in Edoardo Croci, ed., *The Handbook of Voluntary Environmental Agreements: Design, Implementation, and Evaluation Issues* (New York: Springer-Verlag, 2005), pp. 107-134; Theo de Bruijn and Vicki Norberg-Bohm, *Industrial Transformation: Environmental Policy Innovations in the United States and Europe* (Cambridge, MA: MIT Press, 2005); Magali Delmas and Ann Terlak, "Voluntary Agreements for the Environment: Institutional Constraints and Potential for Innovation," in Kurt Deketelaere and Eric Orts, eds. *Environmental Contracts: Approaches to Regulatory Innovation in the United States and Europe* (Cambridge, MA: MIT Press, 2000), pp. 203-228; Richard D. Morgenstern and William A. Pizer, eds. *Reality Check: The Nature and Performance of Voluntary Environmental Programs in the United States, Europe, and Japan* (Washington, DC: Resources for the Future, 2007); Dinah H. Koehler, "The Effectiveness of Voluntary Environmental Programs—A Policy at the Crossroads?" *Policy Studies Journal*, 35 (2007), pp. 689-722; and Peter deLeon and Jorge E. Rivera, eds., *Voluntary Environmental Programs: A Policy Perspective* (Lexington, MA: Lexington Books, 2009).

[10]Also discussed in Fiorino, *The New Environmental Regulation* (Cambridge, MA: MIT Press, 2006), pp. 129-155.

[11]Regulated facilities at times do have discretion regarding regulatory coverage. One example is when a facility sets out to lower its air emissions to fall below the 250-ton minimum that would make them a regulated source under the Clean Air Act. Another is when a facility decides not to store hazardous wastes on-site for more than 90 days, thus avoiding the need for a permit under the Resource Conservation and Recovery Act. In such cases, regulation is having the desired effect without being applied to a facility.

[12]On the concept of green clubs, see Matthew Potoski and Aseem Prakash, eds., *Voluntary Programs: A Club Theory Perspective* (Cambridge, MA: MIT Press, 2009).

[13]Information on all existing EPA voluntary programs is available at www.epa.gov/partners.

[14]For a recent assessment of 33/50, see Madhu Khanna, "The U.S. 33/50 Voluntary Program: Its Design and Effectiveness," in Richard D. Morgenstern and William A. Pizer, eds. *Reality Check: The Nature and Performance of Voluntary Environmental Programs in the United States, Europe, and Japan* (Washington, DC: Resources for the Future, 2007), pp. 15-42. The author of previous studies on 33/50, Khanna concludes that "the program did contribute to a faster decline of program chemicals as compared to other TRI chemicals" (p. 28). Khannu also makes a case for the "social" benefits of the program, such as increased communication among firms on reduction strategies, employee engagement and increased awareness of waste generation and disposal costs that cold be avoided (p. 31).

[15]Discussed in Daniel J. Fiorino, "Green Clubs: A New Tool for Government?" in Potoski and Prakash, *Voluntary Programs: A Club Theory Perspective* (Cambridge, MA: MIT Press, 2009), pp. 209-229.

[16]A core regulatory issue under TSCA is whether or not nanoscale materials with the same chemical composition as "existing" chemicals must undergo a Section 5 Pre-Manufacture Review. EPA has determined that such materials are existing chemical substances on the basis of their molecular composition. The Environmental Defense Fund and others argue that the different properties of nanoscale materials may pose different risks and that they should be considered to be "new" chemical substances, thus requiring a TSCA Section 5 review.

[17]For current status, see www.epa.gov/erp.

[18]Available at www.sfiprogram.org.

[19]On EMS effects, see Matthew Potoski and Aseem Prakash, "Green Clubs and Voluntary Governance: ISO 14001 and Firms' Regulatory Compliance," *American Journal of Political Science* 49 (2005), pp. 235-248; Potoski and Prakash, "Covenant with Weak Swords: ISO 14001 and Firms' Environmental Performance," *Journal of Policy Analysis and Management,* 24 (2005), pp. 745-769; Wilma Rose Q. Anton, George Deltas and Madhu Khanna, "Incentives for Environmental Self-Regulation and Implications for Environmental Performance," *Journal of Environmental Economics and Management*, 48 (2000), pp. 632-654; and Toshi H. Arimura, Akira Hibiki and Hajman Katayama, "Is a Voluntary Approach an Effective Environmental Policy Instrument? A Case for Environmental Management Systems," *Journal of Environmental Economics and Management*, 55 (2008), pp. 281-295.

[20]Useful sources on evaluating voluntary initiatives include National Research Council, *New Tools for Environmental Protection: Education, Information, and Voluntary Measures* (Washington, DC: National Academy Press, 2002), pp. 213-334; Richard D. Morgenstern and William A. Pizer,, eds. *Reality Check: The Nature and Performance of Voluntary Environmental Programs in the United States, Europe, and Japan* (Washington, DC: Resources for the Future, 2007); and Edoardo Croci, ed., *Handbook of Environmental Voluntary Agreements: Design, Implementation, and Evaluation Issues* (New York: Springer, 2005). An excellent resource on third-party certification is Potoski and Prakash, *Voluntary Programs: A Club Theory Perspective* (2009), which includes analyses of several such systems.

[21]For a discussion, see Kathryn Harrison, "Challenges in Evaluating Voluntary Environmental Programs," in National Research Council, *New Tools for Environmental Protection*, pp. 263-282.

[22]Examples are Lyle Scruggs, *Sustaining Abundance: Environmental Performance in Industrial Democracies* (Cambridge, UK: Cambridge University Press, 2003), on the advantages of consensus-based systems that are better able to integrate competing goals; David Wallace, *Environmental Policy and Industrial Innovation: Strategies in Europe, the USA, and Japan* (London: Earthscan, 1995), on the effects of trust and dialogue on innovation; and Magali Delmas and Ann Terlak, "Regulatory Commitment to Negotiated Agreements: Evidence from the United States, Germany, the Netherlands, and France," *Journal of Comparative Policy Analysis: Research and Practice*, 4 (2002), pp. 5-29, on the institutional and cultural context in which voluntary initiatives are most likely to succeed.

[23]On the value of a regulatory stick, see David E. Grimeand, "Convergence or Divergence in the Use of Negotiated Environmental Agreements in U.S. and European Environmental Policy: An Overview," in Norman J. Vig and Michael G. Faure, eds., *Green Giants: Environmental Policies of the United States and European Union* (Cambridge, MA: MIT Press, 2001), pp. 159-181; Morgenstern and Pizer, *Reality Check: The Nature and Performance of Voluntary Environmental Programs in the United States, Europe, and Japan* (New York: Resources for the Future, 2007), Chapter I; and M. de Clerq and R. Brache, "On the Assessment of Environmental Voluntary Agreements in Europe: Lessons to Be Learned From a Comparative Case Study Analysis," in Edoardo Croci, ed., *Handbook of Voluntary Environmental Agreements Design, Implementation and Evaluation Issues* (New York: Springer, 2005), pp. 239-260.

[24]Similarly, in the Dutch covenant system, firms that decide not to participate in the sector covenants are subject

to the regulatory standards and sanctions that normally would apply to them. See Delmas and Terlak, "Voluntary Agreements for the Environment," 2002, p. 357.

[25]One incident occurred in China in 2009, when seven women suffered lung damage and two died after working for several months in a factory that used nanoparticles in paint. Their deaths apparently were from exposure to the nanoparticles. "Experts said the findings are the first clear evidence that nanoparticles can be hazardous to health and should be taken seriously." See www.telegraph.co.uk.com (August 19, 2009).

[26]Excellent examples are Swiss Re, Nanotechnology: Small Matter, Many Unknowns (April 2004; available at www.swissre.com) and Lloyd's Emerging Risks Team, Nanotechnology Recent Developments, Risks and Opportunities (2007; available at www.lloyds.com).

[27]For a statement of EDF's views, see John Balbus, Richard Denison, Karen Florini, and Scott Walsh, "Getting Nanotechnology Right the First Time," *Issues in Science and Technology* (2005), pp. 65-71.

[28]This group also is advocating that all food, feed, beverage, products and sunscreens containing nanomaterials be taken off the shelf.

[29]Many of the limitations in TSCA with respect to nanomaterials also apply more generally to bulk chemical substances. A "modernized" TSCA would benefit chemicals policy generally.

[30]The authors reach many of the same conclusions as this report regarding the need for credibility and transparency for voluntary codes, particularly those that are industry sponsored..

[31]Materials on the Framework are available at www.nanoriskframework.com.

[32]From the "Partnership Agreement and Project Description" (August 30, 2005), available on the website in note 31.

[33]One quote from the release is that "voluntary initiatives are not sufficient." This is a point on which all stakeholders would probably agree. It is not clear what role these groups would consider for voluntary initiatives combined with a regulatory oversight system.

[34]The initial briefing paper setting out the issues and approach was issued as Hilary Sutcliffe and Simon Hodgson, An Uncertain Business: The Technical, Social, and Commercial Challenges Presented by Nanotechnology (Acona, October 2006). Available at www.responsiblefutures.com. The Royal Society's influential 2004 report was important in stimulating the effort to develop a code. See The Royal Society and The Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (July 2004). Available at www.nanotec.org.ok. (accessed August 10, 2009).

[35]According to the Interim Report, it appears that some two-thirds of the chemical substances and 90% of the different nanoscale materials that are commercially available were not reported in the Basic Program.

[36]The Department for Environment, Food, and Rural Affairs (Defra) in the United Kingdom also adopted a voluntary program for nano-related reporting. It ran from 2006 to 2008. See the UK Voluntary Reporting Scheme for Engineered Nanoscale Materials (September 2006), available at www.defra.gov.uk. The industry response in this case also was less than enthusiastic.

[37]An excellent resource is the Nanotechnology Citizen Engagement Organization (www.nanoceo.net). It provides accessible resources and promotes citizen engagement and participation, including nano cafés.

[38]Business firms that have adopted risk management and transparency policies and made commitments to a voluntary initiative would be concerned about free-riders who claim credit for a voluntary program but do not meet their obligations or act responsibly. Free-riders may gain a short-term competitive advantage or engage in behavior that brings down the reputation of other participants in the voluntary initiative.

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