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EPA AND NANOTECHNOLOGY: OVERSIGHT *for* THE 21st CENTURY

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Foreword

Nanotechnology, the science of manufacturing material at the tiny scale, creates new possibilities to make dramatic improvements to our lives. Yet, the uncertain impacts to health, the environment, and society that may arise with this emerging technology demand our urgent attention. If we want to ensure that the benefits of nanotechnology far exceed any risks, we need an oversight system that assures safety while providing transparency for both businesses and the public.

Over the past two years, nanotechnology has moved dramatically from the lab into the marketplace. Today, there are more than 450 manufacturer-identified nanotechnology-enabled products in the commercial market and "over 600 raw materials, intermediate components and industrial equipment items" used by nano manufacturers (U.S. EPA 2007) and many more are sure to follow, given the large investments in research, development, and commercialization. These products open a wide array of questions concerning the risk of nanomaterials to workers, consumers, and the environment and provide new challenges to regulatory agencies. If we expect to see an effective regulatory system for nanotechnology, the Environmental Protection Agency (EPA) and other players must come together today and take the necessary steps to evaluate different approaches and move forward with a plan of action.

The author of this report, J. Clarence (Terry) Davies, has thought through and analyzed many of the nanotechnology regulatory issues and challenges facing the EPA, as well as other parties such as the Congress. In a prior report, Dr. Davies argued that better and more aggressive oversight and new resources are needed to manage the potential adverse effects of nanotechnology and to promote its continued development (Davies 2006). In this report, he points out weaknesses within the system, and offers solutions. Following a comprehensive review of EPA's experience regulating nano-based substances and products, Dr. Davies evaluates various environmental management and policy tools and proposes a number of innovative regulatory and non-regulatory approaches.

The intention of this report is to stimulate a broad dialogue about a next-generation oversight system that will work with nanotechnologies and the technologies that follow. The report contains a number of action items for government, industry, and other stakeholders in both the near and long term. Finally, it challenges EPA to rethink its role, resources, and capabilities and provides a starting point for a discussion about environmental protection in the 21st century.

—David Rejeski
Director, Project on Emerging Nanotechnologies

Author's Preface

This paper focuses on the need for an oversight system for nanotechnology that will identify any potential adverse health or environmental effects of the technology and prevent them from occurring. It analyzes the steps that must be taken to create such a system, particularly emphasizing the role of the U.S. Environmental Protection Agency (EPA).

I have discussed broad possible approaches to nano oversight, not just approaches within EPA's current legislative authority. New approaches are needed, and I have tried to stimulate ideas for what the new approaches might be. Also, I have discussed broad areas in which, in my opinion, EPA needs to change. Nano requires specific changes within the agency, but my hope is that nano will be a catalyst that will revitalize all of the agency's functions.

I am grateful to the Project on Emerging Nanotechnologies for its generous support and encouragement, and also to Resources for the Future for its continuing support. Dave Rejeski, Julia Moore, and Andrew Maynard of the Wilson Center were tremendously helpful in all aspects of producing this report. Deanna Lekas and Evan Michelson provided very useful research support, and Deanna ably and diligently shepherded the report through every stage of its creation. Four outside reviewers—Dan Fiorino, Monroe Newman, Barry Rabe, and Rena Steinzor—gave me excellent comments within an unreasonably short deadline. I am very much in their debt. As usual, for better or worse, responsibility for everything in the report, other than the conditions that exist in the real world, belongs solely to the author.

—J. Clarence (Terry) Davies

Executive Summary

Nanotechnology has enormous potential to improve everyone's life. For the potential to be realized, the new technology must be subject to an adequate oversight system, a system designed to identify and prevent any adverse effects of nano on health or the environment. It has been estimated that, by 2014, 15% of all goods manufactured globally will involve nanotechnology. The accelerating pace of nano discoveries and new products means that time is running short for the establishment of an oversight system. Action is needed now.

This paper identifies many of the actions that should be taken. It focuses in particular on the U.S. Environmental Protection Agency (EPA), which will be a key agency in any oversight effort because of its numerous regulatory authorities and its mission to protect the environment and human health.

A review of existing EPA authorities reveals a large number of weaknesses. In particular, the Toxic Substances Control Act (TSCA), which is the only law potentially capable of providing general oversight for nanotechnology, is extremely deficient in many respects and needs to be amended. But moving beyond TSCA, virtually every authority that EPA has at its disposal has weaknesses in terms of nanotechnology oversight.

The nanotechnology revolution provides an opportunity to institute new kinds of regulation, to create an oversight system for nano that will be more effective but less intrusive than existing forms of regulation and that will require fewer resources from both the public and private sectors. The report discusses a variety of tools that will need to be combined in a nano oversight system—information tools, voluntary efforts, economic tools, and liability. It also discusses the role of state and local governments, and public participation. It outlines nine different examples of the ways the tools could be used. The optimal mix needs to be determined by a dialogue among the affected parties, including manufacturers, non-governmental organizations, EPA, and consumers.

Nanotechnology can also be a catalyst for the revitalization of EPA, an opportunity to bring the agency into the 21st century. The major areas that require strengthening are science, program integration, personnel, international activities, and program evaluation. Inadequate resources, both money and trained people, is a problem for EPA as it is for all federal regulatory agencies.

The report concludes with an action agenda that contains more than 25 actions that need to be taken to improve the oversight of nanotechnologies (see Table ES.1). EPA, Congress, the president, the National Nanotechnology Initiative, and the nanotechnology industry each have steps they should take. A number of the steps are aimed at increasing both the amount and the focus of research on nano's health and environmental effects. More research is urgently needed, but the gaps in knowledge should not be used as an excuse to delay work on an oversight system. There will always be gaps in knowledge. An oversight system will help fill the gaps.

The most important next steps are, first, to equip TSCA to deal with nano by changing both the law and the current TSCA regulations, and, second, to get started on the new reg-

ulatory approach by convening a dialogue of stakeholders to formulate the outlines of a next-generation oversight system appropriate for 21st-century technologies. With new nanoproducts being commercialized each week, we need a system now for considering whether the products pose a risk. This report provides an agenda for creating that system and for ensuring that society is prepared as nanotechnology advances.

TABLE ES.1. PROPOSED ACTIONS

	Proposed Agenda Items for the Next 1 to 2 Years
Research	1. NNI revise its research plan for nano health and environmental effects.
	2. Congress amend the National Nanotechnology for the Twenty-First Century Act to require NNI to issue a research plan for health and environmental effects every three years.
	3. EPA and/or NIEHS initiate discussions with nano companies about creation of a joint government-industry nano effects research institute.
	4. Congress increase funding for strategically targeted research on health and environmental effects of nano to at least $50 million annually.
Regulation	5. Industry, environmental groups, and other stakeholders begin a dialogue.
	6. EPA launch its nano voluntary program.
	7. EPA formulate changes to TSCA to deal with nano.
	8. EPA promulgate a significant new use rule under TSCA that covers all nanomaterials.
	9. EPA formulate and implement an internal coordination plan for nano.
	10. EPA work with FDA, OSHA, CPSC, and USDA to create an interagency nano regulatory coordinating group.
	11. Congress request that the GAO conduct a study of what other nations are doing with respect to nano regulation and oversight.
	12. NNI establish and publish evaluation metrics.
	13. NNI commission a study on the economics of nano.
	14. NNI commission a study of the pros and cons of labeling nanomaterials and nanoproducts.
	15. Congress establish a temporary committee in each house to consider options for a regulatory mechanism for nano.
Other	16. The president and Congress convene an EPA Modernization Commission.
	17. Congress commission GAO to study what resources federal agencies are currently devoting to nano health and safety, both research and regulation, and then conduct a hearing to consider whether these resources are adequate.
	18. NNI, with funding primarily from NSF, increase its public education and participation efforts.
	19. EPA re-establish a policy office with responsibilities for coordinating agency programs, evaluating programs and measuring progress toward agency goals.
	20. Congress hold hearings to amend the Federal Advisory Committee Act to facilitate public participation.
	Proposed Agenda Items for the Next 2 to 5 Years
Research	21. Congress amend the National Nanotechnology Act to facilitate NNI funding the priorities it identifies.
	22. The Nanotechnology Effects Institute begin operation; Congress provide separate funding for the Institute in the EPA or NIEHS budget.
Regulation	23. Congress amend TSCA to remove the constraints that make rulemaking nearly impossible, to change the criterion for judicial review to the "arbitrary and capricious" standard, to require manufacturers to produce enough data, and to authorize EPA to share confidential business information with states and foreign governments, provided the data are adequately protected.
	24. The White House consider the recommendations of the EPA Modernization Commission for implementation.
	25. Trade associations establish industry codes of conduct related to nano.
	26. EPA, working with the State Department and other relevant agencies, fully support the OECD mechanisms for exchange of nano research results.

Note: For further detail on these agenda items, see Chapter V. For acronyms used, see list at end of report. Row shading corresponds with lead organization for each action item.
Key: NNI = ■ Congress = ■ EPA = □ White House = ■ Nano industry = ■

About the Author

J. Clarence (Terry) Davies

Dr. Davies, a senior advisor to the Project on Emerging Nanotechnologies and a senior fellow at Resources for the Future, is one of the foremost authorities on environmental research and policy. He helped pioneer the related fields of risk assessment, risk management, and risk communication, and his work has advanced our understanding of cross-media pollution, the tendency of pollutants to move across boundaries, from air to water to land, revealing shortcomings in the legal and regulatory framework.

Dr. Davies served during the administration of the first President Bush as Assistant Administrator for Policy, Planning and Evaluation at the U.S. Environmental Protection Agency (EPA). Earlier, he was the first examiner for environmental programs at the Bureau of the Budget (now the Office of Management and Budget). In 1970, as a consultant to the President's Advisory Council on Executive Organization, he co-authored the plan that created EPA. Dr. Davies also was Executive Vice President of The Conservation Foundation, a non-profit think tank on environmental policy; Executive Director of the National Commission on the Environment; and a senior staff member at the Council on Environmental Quality, where among other activities, he wrote the original version of what became the Toxic Substances Control Act. He has served on a number of committees of the National Research Council, chaired the Council's Committee on Decision Making for Regulating Chemicals in the Environment, chaired the EPA Administrator's Advisory Committee on Toxic Substances, and served on EPA's Science Advisory Board. In 2000, he was elected a Fellow of the American Association for the Advancement of Science (AAAS) for his contributions to the use of science and analysis in environmental policy.

Dr. Davies is the author of *The Politics of Pollution*, *Neighborhood Groups and Urban Renewal*, *Pollution Control in the United States*, and several other books and monographs addressing environmental policy issues. He authored the report, *Managing the Effects of Nanotechnology*, released in January 2006 by the Project on Emerging Nanotechnologies. A political scientist by training, Dr. Davies received his B.A. in American government from Dartmouth College, and his Ph.D. in American government from Columbia University. He taught at Princeton University and Bowdoin College, and has helped mentor a generation of environmental policy researchers.

I. Setting an Agenda

Nanotechnology has enormous potential to improve life. In a few decades, almost every aspect of our existence, from the clothes we wear to the food we eat, from the cars we drive to the buildings we live in, is likely to be changed for the better by nano. However, if the potential for good is to be realized, society must also face nano's potential for harm. This paper is intended to provide some guidance about how to prevent harm from occurring, thereby allowing nano's positive potential to become a reality.

This paper focuses on the U.S. Environmental Protection Agency (EPA) and its role in dealing with the potential adverse effects of nano. EPA administers more laws that are relevant to nano than does any other agency. The federal law that potentially could have the broadest coverage of nanomaterials is the Toxic Substances Control Act, administered by EPA. EPA is doing more research on nano than is any other regulatory agency. It will inevitably be a central player in the unfolding drama of nano's development.

Other federal agencies and many other organizations are involved with nano. The Food and Drug Administration (FDA) and the Occupational Safety and Health Administration are the two other federal agencies most involved in regulating nano, and they also will be major players in any oversight system that develops. The Woodrow Wilson International Center for Scholars already has published a paper on nano and FDA (Taylor 2006).

Definition of Nanotechnology

The definition of nanotechnology is both controversial and consequential. It is controversial because there is, as yet, no consensus about how to define it and because how it is defined has important implications for how it is managed and marketed. Several international organizations that deal with standards are working on nano definitions, and their work may result in greater agreement.

All the nano definitions based on the physics and chemistry of the technology relate to size. Everyone agrees that nano is the technology of the very small—the manipulation of things at the level of individual atoms and molecules. The U.S. National Nanotechnology Initiative (NNI), the interagency effort to coordinate federal funding for nano research and development, defines nanotechnology as "the understanding and control of matter at dimensions of roughly 1 to 100 nanometers" (**www.nano.gov**, accessed 9/18/06). A nanometer is a billionth of a meter. A human hair is 60,000–120,000 nanometers wide. A red blood cell is 2,000–5,000 nanometers wide (*ibid*.). Things at the nanoscale can be seen only with techniques such as super-magnifying scanning tunnel microscopes, which were first used in the mid-1980s (**www.nano.gov/html/facts/home_facts.html**).

In the context of legislation and regulation, the sources and types of nano are important. Different sources and uses will be regulated under different laws and in different ways. From this perspective, we can describe five categories of nano materials, processes, and products:

1. There are nanoparticles that come from **natural processes** or that exist in nature. Sea spray contains nano-size particles, and

many natural combustion processes give off similarly small particles. Most viruses are nano-size. Particles in this category are generally not considered to be part of nanotechnology because they are not made intentionally, but they help inform our understanding of the products of nanotechnology, and how they might affect health and the environment.

2. There are nanoparticles that are incidental **by-products** of human activity. Welding, for example, gives off nano-size particles. Exhaust from diesel and gasoline-fueled vehicles contains nano-size particles. As with nanoparticles from natural processes, these are not considered to be products of nanotechnology, although the particles may have the same health and environmental effects.

3. There are **nano manufacturing processes** that are often, but not necessarily, used for making nanomaterials. New types of microscopes and new ways of handling minute amounts of materials have made it possible to put things together atom by atom. These techniques are used for making filters, sensors, electronic and computer components, and many other products. In theory, they could be used to build anything.

4. There are particular types of **nanomaterials** that have been developed in recent years to take advantage of the unique properties of nano. They can be made from a variety of substances (e.g., carbon, titanium, gold). Nanomaterials include things such as nanotubes, quantum dots, and nanocrystals.

5. A fifth category is **nanoproducts**, products that contain nanomaterials. Commercialization of nano has proceeded rapidly. In early 2007, the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars found almost 400 manufacturer-identified nanoproducts on the market, including clothing, golf clubs, and milkshakes. Sixty-seven of these products are cosmetics, the largest single category, and another 18 are sunscreen preparations(**www.nanotechproject.org/consumer**, accessed 2/7/07). The consulting firm EmTech Research estimated in 2005 that in addition to the consumer products there are more than 600 nano raw materials, intermediate components, and industrial equipment items that are used by manufacturers (U.S. EPA 2007, p. 4). No figure is available for non-consumer nanoproducts on the market, such as medical devices, ceramics, and industrial filters. The number is certainly in the hundreds, and probably over a thousand. Nano-based catalysts have become an integral part of oil refining. And many of the lights in athletic stadiums are based on nanotechnology.

Each of these categories poses different challenges and questions. Natural nanoproducts can generally be disregarded in the context of regulation. Some of the human activities that produce nano by-products are already regulated, although the regulations do not focus specifically on nano-size particles. For example, automobile emissions are regulated under the Clean Air Act.

Nano manufacturing processes are likely to be regulated under EPA media programs (see Chapter II). Nanomaterials and nanoproducts, the major focus of this report, would be primarily regulated by EPA product programs, such as the Toxic Substances Control Act, but could also be covered by some media programs, for example, when products are discarded.

Nano Promise and Red Flags

We are just at the threshold of seeing the ways in which nano can be useful. Every major area of human activity is likely to be deeply affected by the new technology. Carbon nanotubes are around 100 times as strong as steel but weigh only about one-tenth as much. Nano windows that never need washing are on the market now, as are nano batteries and solar panels that are much more efficient than pre-nano ones. Nano will enable us to make filters that filter almost anything (thus, for example, drastically reducing the cost and energy consumption of desalinating water), sensors that sense almost anything (greatly improving airport security), and photon computer chips that will revolutionize what computers can do. Nano drugs will vastly increase the range and effectiveness of medical interventions, and nano foods will be more nutritious, tastier, and less subject to spoilage. The list could go on and on. Not all of these applications will be realized, and hyperbole is tempting when describing powerful new technologies, but the vast promise of nano is clear.

Lux Research, the authoritative commercial source of nano information, estimates that, worldwide, nano was incorporated in $30 billion of manufactured goods in 2005, which more than doubled the amount in the previous year. It estimates that by 2014 the figure will be $2.6 trillion, a more-than-85-fold increase (Lux Research 2006, p. iii).

The potential of nano to contribute positively to society is hard to exaggerate, but this potential could be undermined if society neglects dealing with potential health and environmental problems that might be caused by nano. The studies done to date show "a number of red flags that indicate some engineered nanomaterials present a new or unusual health hazard" (Maynard 2006b, p. 7; also see Maynard 2006c). Some of these potential hazards are discussed below.

Laboratory animals experienced respiratory problems following high exposure to nanotubes (Warheit at al. 2004; Lam et al. 2004). Nanoparticles when inhaled can enter the bloodstream and may also circumvent the blood-brain barrier, thus affecting the central nervous system (Oberdörster et al. 2004; Elder et al. 2006), and dermal exposure may cause inflammation in the lymph system (Oberdörster et al. 2005). Skin exposure to nanoscale titanium dioxide in sunscreens could damage DNA and harm already damaged skin (Dunford et al. 1997). Mice exposed by ingestion to nanoscale copper particles suffered "heavy injuries" to the kidney, liver, and spleen (Chen et al. 2006). Nano zinc powders produced more renal damage and anemia than exposure to microscale zinc powders (Wang et al. 2006). There is a lot of uncertainty about the importance of these findings, but the more studies that are done, the more red flags get hoisted.

Very few studies have looked at potential environmental damage from nanomaterials. Oberdörster (2004) did suggest that large-mouth bass exposed to uncoated fullerenes (a type of nanomaterial) experienced inflammation, perhaps resulting from nanoparticles being transported to the brain. The widespread use of nano bactericides such as silver has raised a variety of questions about how nanoparticles will affect the environment (Kinney 2006).

A very important point that emerges from the studies of nano is that the human and environmental toxicity of nanomaterials seems dependent on a variety of different characteristics of the material. Even before getting to what tests to perform, there are major difficulties in knowing what charac-

teristics should be used to describe the material being tested. As Maynard (2006b, p. 7) states, "Unlike many conventional materials, the relevant characteristics of engineered nanomaterials may be non-obvious and non-trivial to quantify. In constructing a framework for nanomaterials toxicity testing, Oberdörster et al. . . . recommend sixteen physicochemical parameters that should be evaluated in toxicity tests—a far cry from the two or three usually measured. These range from surface area and surface chemistry to particle size distribution and particle charge. Engineered nanomaterials are notoriously difficult to characterize—even two materials that are notionally the same may have subtle but significant differences that determine their behavior."

This aspect of nano greatly complicates the task of determining which materials can or will cause problems. It requires more testing of each kind of material but, most important, it suggests that tests should be performed on almost every individual product because small changes in product characteristics can have large implications for toxicity.

Other possible complexities emerge from the relatively small number of tests that have been done on nano effects. One area that has major ramifications for the existing regulatory structure involves the number of nanoparticles to which a person or the environment is exposed. All current regulations have as an unstated premise that the larger the dose, the greater the risk. The opposite may be true for some types of nanomaterials under some conditions. They may have a tendency to clump together, and the more they clump, the less likely it may be that they will penetrate skin or cause other kinds of exposure or toxicity. To the extent that this is true, it would mean that if someone were exposed to a nanomaterial, he or she would be better off being exposed to a larger amount of the material, the opposite of the premise of current standards.

There have been no known cases of people or the environment being harmed by nanomaterials. In Germany, a score of people suffered respiratory problems after using a new product called "Nano Magic," but on investigation it seems that the product did not actually contain any nanomaterials (vonBubnoff 2006). However, there is ample evidence from laboratory tests on nano and from past experience with other materials that the potential adverse effects of nano must be investigated and that an adequate system for both identifying and managing such effects must be put in place. This should be done with some urgency because the new technology is being commercialized and put to use at a very rapid pace.

Setting an Agenda

This report is primarily an agenda-setting document. It describes and analyzes what has to be considered in constructing an oversight system for the identification and prevention of any adverse effects from nano. It outlines what has to be considered in reinvigorating EPA and equipping it to deal with nano. It concludes by providing an agenda of action items for nano over the next few years.

The broad public policy options for nano oversight provide the context for the agenda. To simplify, there are three options: (1) do nothing in regard to nano oversight; (2) just do research on applications and risk; or (3) begin to formulate and implement a regulatory system for nano while continuing to do research.

The do-nothing option is a prescription for trouble. It leaves the public open to potential adverse effects from nanoproducts

because the current system is not equipped to deal with risks from nanomaterials. It leaves industry open to a potential backlash from a public that feels unprotected and from insurers and investors unable to measure their risk. It fuels the Katrina syndrome, i.e., the perception that the government is incapable of dealing with any significant challenge.

The research-only option is the primary current policy. Research on the effects of nano is absolutely necessary, and the government should be supporting more of it. But research without a system to manage the effects of nano invites the same trouble as the do-nothing option. Furthermore, a nano regulatory system may be necessary to get the scientific information needed for intelligent oversight (see Chapter II).

We need to start considering regulatory options, the third alternative. Many approaches are possible, and the dangers of regulation should be borne in mind. Nano is still very much an evolving technology, and a cumbersome or overly intrusive regulatory system could prevent nano from reaching its full potential. The new technology calls for new regulatory approaches, and this report is intended to help answer that call.

Chapter II describes the current situation with respect to nano and EPA. It describes relevant EPA laws and programs and analyzes their adequacy—in terms of legal authority, resources, and political will.

Chapter III analyzes the tools available to manage any adverse effects of nano. These tools include modification of existing laws and regulations, generation and use of information, voluntary efforts, economic and liability tools, state and local government efforts, and formulation of new kinds of oversight. Public participation must be a part of any of these efforts. The chapter concludes with some criteria for choosing tools but also points out that a dialogue among the interested parties is the only way in which a viable nano regulatory program can be formulated.

Chapter IV deals with EPA and ways in which it might be rejuvenated. I emphasize the role of science, the need for integration, the need to attract good people, the international context, and the importance of evaluation.

Chapter V is a list of action items for the next few years. Most of them are discussed in the earlier chapters, but the list is supplemented by additional suggestions. The chapter gives a time frame for the recommendations and assigns specific responsibility for initiating action on each item.

Although the report is premised on the need to do more to identify, manage, and prevent any nano adverse effects, it does not advocate a specific overall proposal. It is a compilation of things to consider, experiences to ponder, and steps that can be taken to advance toward an intelligent oversight approach. It is a beginning, not an end.

Nano has vast potential. That potential is being realized at a fast pace, but it is probably not without its dangers. What is being done with respect to anticipating, identifying, and managing the effects of nano on health and the environment? In the next chapter, I describe the current situation, focusing particularly on EPA.

II. The Current Situation

There is now a great deal of activity with respect to nano. Most of it is focused on discovering and developing new knowledge, some is on basic science, but much of it is focused on practical applications that will be commercially profitable. Some research is being done on the health effects of nano, and there is a small amount of regulatory activity arising from the operations of programs (pesticides, fuel additives, etc.) that were created before nano was on anyone's agenda.

I will look first at how the science and regulation are related, a knotty problem. I then turn to the existing EPA laws and programs: what they are, how they apply to nano, and how adequate they are for dealing with potential nano problems.

Science and Regulation

Almost everyone agrees that we do not know enough about the health and environmental effects of nanotechnology. But enough for what purpose? Will we ever know enough? What can or should be done based on the knowledge we have now?

The relationship between science and regulation is complex. Science can be distorted to bolster arguments for a particular regulatory outcome (Wagner and Steinzor 2006). Regulatory outcomes can be skewed by poor science (Powell 1999). Good science can be encouraged or discouraged by regulation.

A fundamental dilemma with respect to nano is that the existing science is clearly inadequate to manage the potential adverse effects of the technology. We do not know much about what adverse effects to look for, and there is no consensus on the type of data necessary to determine adverse effects. We do not know enough to identify the materials and products that are safe and that do not require regulatory scrutiny and management.

Some groups have concluded that because the science is inadequate there should be a moratorium on marketing nanoproducts, or even a moratorium on nano research (see Davies 2006, p. 22). This is one way to interpret the "precautionary principle" (see Durant in Durant et al. 2004). There are, however, many other interpretations, and the most helpful ones inevitably involve striking a balance between the harm that could be done by proceeding with an innovation and the harm that could be done by not proceeding. In my view, and the view of most others, based on what is currently known, the balance argues against any kind of general moratorium. Testing can be done on individual nano materials and products, and judgments on limiting production or marketing should be based on the results of these tests.

The traditional toxicological approach of exposing mice or rats to the substance in question may work as well for testing nanomaterials as for conventional materials (see ILSI 2005). What we do not know are the key variables that determine toxicity, what kinds of toxic effects are most likely to occur from what kinds of nanomaterials, and how traditional toxicological principles, such as dose-response relationships, apply to nano.

Much of the missing scientific knowledge cuts across different nanomaterials and nanoproducts. A lot of this knowledge will have to be generated by government funding and will be done by university and govern-

ment laboratories. However, if the science is to be adequate, there will need to be testing of specific materials and products. The scope of what effects and what materials are of concern cannot be determined in the abstract—it will require specifics based on testing of individual samples.

The manufacturers of nano materials and products can be relied on to do some testing out of self-interest. No company wants to injure its workers or have its consumers die from use of a product. Thus, most companies will test their products for acute toxic effects—those effects that are obvious and that happen within a short time of being exposed.

Long-term chronic health effects and environmental effects are a different story. For effects such as cancer, which can take 20 years to manifest itself, or genetic damage, which may not show up until the next generation, or environmental effects, which may not become apparent for decades, there is very little incentive for companies to do testing. Testing for such effects is often expensive, and it is only rarely possible to tie a specific product to an adverse effect. The few exceptions are when a material results in a unique type of effect (e.g., asbestos and mesothelioma) or when scientific serendipity connects an identifiable material to an identifiable effect (e.g., chlorofluorocarbons and depletion of stratospheric ozone).

It is hard to see what will motivate manufacturers to carry out chronic and environmental testing if regulation does not require it. A study by the Swiss Federal Institute of Technology surveyed 32 Swiss and German manufacturers of nanoproducts. Only two of them had investigated the effects of absorption of nanoparticles by living organisms. Three-quarters admitted they had not carried out risk assessments on their products (**nanotechwire.com/news**, 3/22/06). Wendy Wagner (2004) has persuasively described the reasons why it may not be in the rational interest of manufacturers to do health and environmental testing.

The dilemma is that the science needed to prescribe intelligent testing requirements is lacking, but that without requirements the needed science will not be forthcoming. It is a classic catch-22.

The dilemma is similar to that faced by the Toxic Substances Control Act (TSCA) new chemicals program. Because of weaknesses in the Act, the only data that EPA gets on most new chemicals is their chemical structure, i.e., their molecular composition. However, the agency is required to review each new chemical and, presumably, to do some kind of assessment of whether or not it poses a risk to health or the environment. Faced with the need to determine the chemical's biological and environmental activity, but with only the chemical's structure to work from, the agency has come to rely on what it calls "structure-activity relationship," or SAR. SAR involves comparing the molecular structure of the new chemical with the molecular structure of existing chemicals whose health and environmental effects are known. From this comparison, EPA infers the potential effects of the new chemical.

There is not a lot of empirical basis for SAR, and the one major empirical examination of its validity found that it was moderately accurate for some effects but not at all accurate for others (U.S. EPA 1993). For example, it was correct only 57% of the time when predicting systemic toxicity (*ibid*. p. 49). Furthermore, it consistently tended to underestimate health effects (*ibid*. p. 50). However, SAR has allowed both EPA and the chemical industry to defend the TSCA program and to claim that it adequately protects the public.

In theory, it might be possible for EPA to deal with the nano dilemma by using SAR, since TSCA is the Act on which the agency is primarily relying for managing nano. However, in addition to the inherent limitations of SAR, it is even more limited with respect to nanomaterials because evidence indicates that the biological activity and effects of nano are in part dependent on characteristics other than chemical structure, such as size, physical form, and surface area (Maynard 2006b).

Another way out of the dilemma, and in my view a more scientifically defensible approach, would be to focus on exposure. If people are not exposed to a material and it does not get into the environment, then there is no need to worry about its health or environmental effects. Rather than ask manufacturers to test for effects, the government could ask for evidence that there will not be exposure to the material. Such evidence would have to include an analysis of the entire life cycle of the material, but such analysis would still be less expensive and difficult than testing for effects.

The exposure approach will not work for all materials because there will be some, such as cosmetics or food additives, that inevitably involve exposure, and others where exposure will occur because the material will get into the environment after it has been discarded. Also, in many, perhaps most, cases, regulations will have to be promulgated to ensure that the workers at the manufacturing plant will not be exposed.

Research by government, universities, and industry may provide the scientific basis for determining the safety of some major nano materials and products. International cooperation will be important because the magnitude of the scientific task will be more manageable if it is shared by several countries. Nevertheless, it is likely that some form of regulatory incentive will be necessary to get test data from manufacturers. In Chapter III, I discuss some of the ways in which this might be done. Many of these ways involve EPA's current programs.

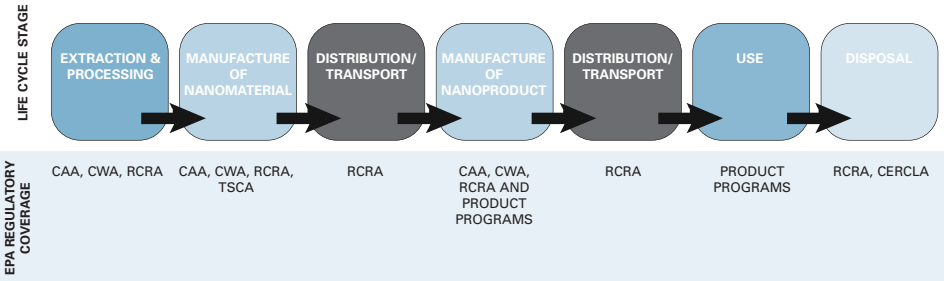
EPA Product Programs and Media Programs

EPA, like most federal agencies, is an amalgam of different programs, each with its own legal basis, mission, history, and culture. How many EPA programs exist is a number that varies with definitions. Estimates range from 8 or 10 to 90 or 100.

A basic distinction among EPA programs is between product programs and media programs. The media programs are the ones most familiar to the public—clean air, clean water, hazardous-waste disposal. They regulate some segment of the environment and deal primarily with wastes. The product programs—pesticide registration, toxic substances control—as the term implies regulate some kind of engineered or manufactured product. The distinction is not always sharp. For example, regulation of drinking water, which EPA shares with the Food and Drug Administration (FDA regulates bottled water), has characteristics of both a product and a media program.

The product-media distinction is important for managing nano because the two types of programs address different parts of the nano life cycle and the problems posed by nano for product programs differ from those posed for media programs. Figure 2.1 shows a simplified version of the nano life cycle and the EPA programs that relate to each stage (also see Wardak et al. 2006, Lekas 2005). Among the many questions that need to be raised are where in the life cycle the most serious health and environmental problems would be likely to arise, and where interdic-

FIGURE 2.1. NANO LIFE CYCLE AND CORRESPONDING EPA REGULATORY COVERAGE



Note: Product Programs in this context refer to FIFRA, TSCA, and CAA §211.
CAA = Clean Air Act; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CWA = Clean Water Act; FIFRA = Federal Insecticide, Fungicide, and Rodenticide Act; RCRA = Resource, Conservation and Recovery Act; TSCA = Toxic Substances Control Act.

tion to prevent adverse effects would likely be most effective in protecting health and the environment and least disruptive to innovation and commercialization.

We do not yet know enough about the potential adverse effects of nano to know where the most serious problems are likely to occur. We do not even know for certain that there are potential problems, although it would be extraordinary and unprecedented if there were not, given a technology as broad and powerful as nano.

Because of the nature of nanomaterials—their small size and high value—it is likely to be more effective to regulate them under the EPA product programs than under the media programs. At present there are no good ways to monitor nanomaterials in ambient air or water, and this in itself makes it impossible to regulate them under the Clean Air Act (CAA) or Clean Water Act (CWA). However, even if economical and accurate ways of measuring nanomaterials in air and water are developed (and it is possible that sensors using nano devices will solve the monitoring problem), it will still be more practical and efficient to require product designs and handling requirements that prevent dangerous nanomaterials from getting into the ambient environment. Developing and requiring technologies to remove nanomaterials from ambient environments is likely to be difficult, expensive, and less effective than regulating nanoproducts.

A product-based oversight system demands more government resources than a media-based system. Also, as Mark Greenwood (2007, p. 20) has noted, "the information requirements for nanoscale materials are likely to be more extensive than those currently expected for conventional forms of the same materials," making a product focus even more expensive. However, a product focus is essential for adequate nano oversight.

Disposal and recycling are stages of the product life cycle where it may be difficult to take preventive steps by regulating products. Nanoproducts can be designed to prevent the nanomaterial from getting into the environment (e.g., by requiring it to be chemically and physically combined with other materials), but when the product is discarded the design protections may cease to be effective. Nanomaterials used in automobile bodies,

for example, are chemically bound to other materials and thus are not likely to be released to the environment. However, when the auto's useful life is ended it may be shredded or burned or subject to other processes that might release the nanomaterials. We need to know more before we can tell whether or not this is a serious problem.

Many federal government programs dealing with specific nanoproducts are in agencies other than EPA. For example, food additives and packaging, drugs and medical devices, and cosmetics are all regulated by the FDA (see Taylor 2006). EPA has three product-regulation programs: TSCA, which regulates chemicals; the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which regulates pesticides; and section 211 of the CAA, which regulates automobile fuel additives. The agency has placed primary reliance for dealing with nano on TSCA.

TSCA is a product program in that it deals with manufactured materials, not wastes, and it is not limited to any particular part of the environment. Its new chemicals authority applies to chemicals before they are manufactured. This is different from most product statutes, which apply to products before they are marketed. The pre-manufacturing coverage of TSCA allows occupational exposures to be covered (and encouraged organized labor to support passage of the legislation), but it has proved cumbersome and ineffective. EPA has to review a large number of chemicals that are never commercialized, and the agency generally has not been able to use TSCA to protect workers.

The pre-market application of most product statutes has raised questions about whether there should be greater authority to monitor and take action after the product has been marketed (see Taylor 2006). The EPA product programs do give authority for post-market actions. Section 8 of TSCA gives broad authority to EPA to require chemical manufacturers and distributors to maintain records on such things as health and environmental effects, levels of exposure, and methods of disposal. Section 8(e) states, "Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the [EPA] Administrator of such information. . . . " The registration of pesticides regulated under FIFRA expires after five years, thus providing an opportunity to review any new data. Also, the EPA Administrator is authorized to suspend or cancel a registration at any time if she believes that the product is causing adverse effects, and she may conditionally register a pesticide for a period of time "sufficient for generation and submission of required data" (FIFRA sec. 136). The section of the CAA regulating fuel additives (sec. 211) allows EPA to prohibit the sale of a fuel additive at any time if its costs exceed its benefits and, in this connection, to obtain data from motor vehicle engine manufacturers (sec. 211(c)(3)(A)).

Legal Authority of EPA Programs to Cover Nano

The following five elements need to be considered in evaluating whether EPA's programs are up to the task of managing any adverse effects of nano:

1. Is there legal authority to cover nano?

2. Is the legal authority adequate to collect the information and take the steps necessary to prevent adverse effects from occurring?

3. Is the available technical and scientific information sufficient to implement the legal authorities?

4. Are there sufficient resources to implement the legal authorities?

5. Is there the political will to address nano effects?

I will discuss each of these elements in turn. There have been two reviews of EPA's laws to determine whether they are broad enough to cover nano. Both efforts have generally concluded that EPA's statutory authorities can cover nano.

In May 2005, the Environmental Law Institute (ELI) and the Project on Emerging Nanotechnologies (PEN) convened a two-day meeting of 40 noted scientists, lawyers, and policymakers to discuss "Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up to the Job?"[1] The meeting did not seek consensus conclusions, but the views of most participants were reflected in ELI's comments on EPA's draft nano white paper: "Because there are no nanotechnology-specific laws and regulations, and the enactment of new nanotechnology legislation related to environmental, health, and safety is unlikely, at least in the near term, it will be necessary to use existing legal authorities and adapt current programs to regulate nanotechnologies" (ELI 2006).

In 2006, the American Bar Association's (ABA's) Section of Environment, Energy, and Resources issued a series of papers reviewing the legal authority of various EPA programs to deal with nano. Six of the seven papers contain a detailed analysis of a particular EPA law. The seventh deals with innovative regulatory approaches (ABA 2006d). The general conclusions are remarkably similar: the CAA "contains sufficient authority" to adequately address nano (ABA 2006a); under the CWA, "EPA likely has the authority to regulate nanoparticles" (ABA 2006c); under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), "the existing statutory framework is readily adaptable to nanomaterials" (ABA 2006b); the Resource Conservation and Recovery Act (RCRA) "has expansive authority . . . to regulate discarded wastes that might include nanoscale materials" (ABA 2006f); "EPA has considerable authority under FIFRA to prohibit, condition, or allow the manufacture and use of nanopesticides" (ABA 2006e); and "nanomaterials can be 'chemical substances' that can be regulated under TSCA" (ABA 2006g).

That a particular law covers nano does not mean that it covers it adequately, a question I will discuss in the next section. It also does not mean that major changes in regulation and interpretations will not be necessary to apply the law to nano. For example, the ABA report on the CAA points out that "currently, all CAA standards are based upon mass limitations whether mass concentrations, such as nanograms per cubic meter, or mass limitations, such as tons per year. It does not appear as though nanoparticulate can be effectively regulated in terms of mass . . . nanoparticles must be measured in terms of number, rather than mass" (ABA 2006a). In other words, the basic standard-setting metric used in the CAA does not work for nano.

The major debate about legal coverage of nano has centered on the question of whether

1. A summary of the meeting is available at **www.elistore.org/reports**.

nanomaterials are "new chemicals" as defined by TSCA. The debate is important because it is somewhat easier for EPA to regulate new chemicals than existing ones. TSCA (sec. 3(2)) defines a chemical as "any organic or inorganic substance of a particular molecular identity." A new chemical is one that is not listed on EPA's inventory of existing chemicals (sec. 3(9)). Almost all the raw materials of which nanomaterials are composed (e.g., gold, carbon, titanium) are on the existing chemicals inventory. The molecular identity of the nanomaterial is, in most cases, the same as that of the raw material, and thus it would seem that most nanomaterials are not "new chemicals," even though they may have different biological and ecological effects than the substance in bulk form.[2] As discussed below in the section on EPA experience regulating nano, of the 15 nanomaterials reviewed in 2005 under TSCA, EPA found that 14 were not new chemicals.

Although most nanomaterials probably do not meet the TSCA definition of a new chemical, TSCA provides an alternative way to oversee nanomaterials. It allows EPA to designate specific new uses of existing chemicals and to treat such new uses almost the same way as new chemicals are treated. In designating new uses, the EPA administrator must consider the projected volume of production of the substance, changes in degree or patterns of human and environmental exposure, and the anticipated manner and methods of manufacturing, processing, distributing, and disposing of the substance (TSCA sec. 5(a)(2)).

Most, if not all, nanomaterials could be designated under the significant new use provisions, although designation has to be done by promulgating a rule. If the law requires the agency to issue a separate rule for each individual nanomaterial, the new use provision would not be very helpful because there are so many different nanomaterials. It is an open question whether EPA could designate all nanomaterials or selected classes of nanomaterials by issuing one single rule. EPA probably can designate broad categories of nanomaterials. Section 26(c) of TSCA allows EPA to regulate "categories" of chemicals as if they were individual chemicals. To date, EPA has shown no inclination to use the significant new use provisions to deal with nano.

Most of the discussions of TSCA (and the other EPA authorities) implicitly assume that the focus of nano regulation would be on nanomaterials. However, as noted in my discussion of adverse effects, if the concern is risk to health or the environment (and that *is* the concern), it may be necessary to focus on individual products rather than on generic materials. The risks posed by carbon nanotubes in golf clubs may be very different from the risks that might be posed by carbon nanotubes in dental amalgam. Worse still, the risks posed by one brand of nano golf club may be different from the risks posed by another brand because, for example, the two brands mix the nanomaterial with different other substances. For single-walled carbon nanotubes (and there are other types of nanotubes), there are 20 different structural types, and their lengths can vary from 5 to 300 nanometers. Four different processes exist for manufacturing them, five methods for purifying them, and ten surface coatings are typically applied. So, there are up to 50,000 different versions of single-walled carbon nanotubes (Schmidt 2007, p. 18), and each version may have different chemical, physical, and biological properties.

2. An excellent discussion of this can be found in the ABA paper on TSCA (ABA 2006g).

The need to focus on individual products is a potentially complicating factor of immense proportions. EPA has the legal authority to regulate individual products. Specific provisions of TSCA authorize regulation of "articles," a term that is not defined in the Act but presumably can mean individual products. However, even if the need to deal with individual products can be legally encompassed by the existing laws, it can likely never be managed by the resources available to EPA. A combination of better scientific understanding and legal ingenuity will be required to deal with this problem.

Adequacy of EPA Programs to Deal with Nano

Having the legal authority to cover nano is not the same as providing adequate protection for the public. As noted above, the program needs sufficient authority and technical capability to perform certain necessary functions. It must also have the resources and political will to implement those functions. This section deals with the legal and technical capability of EPA programs. The following two sections deal with resources and political will.

To provide adequate nano oversight, an EPA program must be able to do the following: get the information necessary to determine whether a material or product is safe; promulgate restrictions on the product or, in the case of media programs, establish standards for the pollutant; and monitor and enforce the restrictions. Table 2.1 shows the degree of legal adequacy of EPA's product programs for these functions.

As the table shows, **TSCA** is particularly deficient in a number of the functions. The Act makes it difficult to get information on a new chemical beyond elementary information on its chemical properties. To require any information beyond that which the manufacturer chooses to submit, EPA must show either that the chemical may pose an unrea-

TABLE 2.1. LEGAL ADEQUACY OF EPA PRODUCT PROGRAMS FOR NANOTECHNOLOGY OVERSIGHT

Function	TSCA	FIFRA	Fuel Additives
Requiring toxicity and use data	Weak	Strong	Strong
Placing burden to prove safety on manufacturer	None	Strong	Strong
Reviewing safety prior to marketing	Moderate	Strong	Strong
Requiring needed monitoring	Moderate	Moderate	Moderate
Requiring timely adverse event reporting	Strong	Moderate	Weak
Prohibiting initial marketing	Weak	Strong	Strong
Limiting uses or conditions of use	Weak	Strong	Weak
Requiring product withdrawal from market	Weak	Strong	Moderate

Note: TSCA = Toxic Substances Control Act; FIFRA = Federal Insecticide, Fungicide, and Rodenticide Act; Fuel Additives refer to section 211 of the Clean Air Act (CAA).

sonable risk or that it will be produced in substantial quantities and will result in significant human or environmental exposure. Neither of these criteria is easy to meet—risk because the data are unavailable, and substantial quantities because only rarely are new chemicals initially produced in large volumes. With respect to nano, neither the meaning nor the relevance of "substantial quantities" is clear.

TSCA is equally deficient with respect to promulgating restrictions. The Act contains a number of very difficult, perhaps impossible, requirements that must be met before a chemical can be regulated. For example, EPA must show that the proposed regulation is less burdensome than any alternative and that the risk could not be sufficiently reduced under some other law. All the requirements must be "supported by substantial evidence in the rulemaking record," an extraordinarily high legal hurdle. The courts have already established that the combination of the difficult requirements and the high legal hurdle make it practically impossible to regulate existing chemicals under TSCA (*Corrosion Proof Fittings v. EPA* (947 F. 2d 1201)).

Another important problem with TSCA is its treatment of confidential business information. Manufacturers have tended to label much of the information they submit to EPA as trade secrets, thus preventing it from being made public. The Act (sec. 14(a)) even prohibits EPA from sharing such information with states or with other nations, regardless of how well the data would be protected. At least with respect to regulation, it might be possible to get the courts to allow EPA somewhat more leeway under TSCA. However, the Act desperately needs to be amended, both to deal with nano and to adequately address all types of chemicals.

EPA has announced a voluntary program for getting risk information about nanomaterials from industry, but has not yet put it into effect (see 70FR24574, 5/10/05). The program is intended to help the agency to know what data are necessary for determining the risk of nanomaterials and which materials should be the focus of its efforts. There should be an interplay between modifying the regulations (such as promulgating a significant new use rule for nano) and the voluntary effort. A sequential approach will leave nano unregulated for far too long and will also be less productive than if the two efforts proceed in tandem.

FIFRA, which regulates pesticides, is much more stringent than TSCA and clearly places the burden of proof for establishing safety on the manufacturer. This makes sense because pesticides have the unique combination of being poisonous and being deliberately released into the environment.

FIFRA, unlike TSCA, has the legal authority to deal adequately with nano, although it is handicapped by the same lack of scientific information about nano as all other programs. A major problem for the pesticide program is how to deal with anti-bacterial nanoproducts that are incorporated in things that are not normally thought of as pesticides, such as the washing machines that release silver ions with each load for the purpose of killing bacteria (Kinney 2006). FIFRA clearly defines a pesticide as anything intended to destroy or repel a pest (sec. 136(u)(1)), and it explicitly defines "pest" to include bacteria and viruses (sec. 136 (t)(2)). Nevertheless, there is something surreal about asking whether washing machines or food-storage containers are pesticides, and it is a type of problem not envisioned by the drafters of the statute.

EPA needs to craft a category of nanopesticides and decide how to regulate them. This can probably be done without any new law

and perhaps even under existing regulations. It will require close coordination with other EPA programs because the major environmental impacts of such pesticides are likely to fall within the jurisdiction of environmental laws other than FIFRA. For example, in the washing machine case, the major potential impact is in water and on wastewater treatment plants.

For a variety of reasons the legal issue of whether nano versions of already-registered pesticides require new registration is not a major problem. In contrast to TSCA, it is clear that in almost every case a nanopesticide will be considered "new" and will have to go through the FIFRA registration process (ABA 2006e). However, EPA probably will need to make some changes in the data it requires to be submitted for registration, and perhaps it will need to modify or add to other regulations to deal with nanopesticides (*ibid.)*.

Both the **CWA** and the **CAA** suffer from a fundamental problem in dealing with nano: there are no good methods for monitoring nanoparticles in air or water. The monitoring problem is double-edged. First, to collect and analyze samples, there is a need for machines or devices that are both affordable and easily usable in the setting of a factory or a water monitoring station. Second, the scientific basis for knowing what to monitor is not yet available. The second problem may prove more difficult than the first. Monitoring the number or weight of nanoparticles will not help much if their surface area, shape, electrical conductivity or other characteristics are the primary determinants of their toxicity.

Another fundamental problem for both Acts is the paucity of control methods. As the ABA (2006c, p. 4) paper on the CWA states, "Very little is known about the availability of technology to control nanoparticles in wastewater streams." The ABA (2006a, p. 15) paper on the CAA concludes that "it is clear that air pollution control technologies exist upon which EPA can rely in implementing specific air emission standards," but most of these technologies have not been tried on nanoparticles in realistic settings.

At this point in time, so little is known about how to monitor and control nanoparticles in water that it is not useful to talk about changes in the CWA that might be needed to deal with nano. The one possibility for action under the Act is that writers of water pollution control permits might specify some kind of "best management practices" for individual facilities (e.g., handle nanomaterials only in airtight enclosures) as a non-quantitative way of dealing with nano (ABA 2006c, p. 11). There is a lot of flexibility in the CWA permitting system (Davies 2001), so this could probably be done without changes in the Act.

Under the CAA, EPA regulates fine particulates as a criteria air pollutant. Although the particulates currently regulated are generally larger than nano-size (they can be up to 2,500 nanometers), in theory nanoparticles could be regulated as part of this category (ABA 2006a, p.12). This would have the advantage of fitting nanoparticles into the overall current approach to air pollution control. However, the fit might not be comfortable because of the differences, with respect to monitoring and controls, between nanoparticles and the fine particles currently regulated. Also, EPA would have to establish that the nanoparticles being regulated pose a risk to human health, a difficult task because of the dearth of scientific information and the very wide variety of nanoparticles.

The same problem of proving risk would apply to an alternative approach, adding nanoparticles to the list of hazardous air pol-

lutants. If nanoparticles were officially declared to be hazardous air pollutants, EPA could prescribe control requirements for categories of sources emitting nanoparticles. Here again, however, the fit might not be comfortable. Hazardous air pollutants (like criteria pollutants) are regulated based on mass (*ibid.* p.17), a generally inappropriate basis for regulating nanoparticles.

The CAA's fuel-additives provisions are intermediate between TSCA and FIFRA. They give the agency ample authority to obtain safety information from the manufacturer, but they limit the agency's actions to approving or disapproving the additive. As discussed below, a nano fuel additive is currently being evaluated by EPA under the fuel additive provisions of the CAA. It is likely that there will be additional nano additives that come under these provisions.

EPA authorities under **RCRA** and **CERCLA** are broad enough to cover nanomaterials, as noted above. Application of both acts is handicapped by the lack of monitoring and control techniques for nano. To the extent that nanomaterials are different from larger materials in terms of toxic action or transport in the environment, procedures under RCRA and CERCLA "may inappropriately over- or under-predict environmental risks" (ABA 2006f, p. 10). Major adjustments will be necessary in the RCRA requirements for hazardous-waste generators because the requirements vary based on the amount of hazardous waste they generate (often measured in tens or hundreds of tons), and "amount" may not be a useful criterion for nanomaterials.

For both RCRA and CERCLA, the ABA conclusion about CERCLA (ABA 2006b, p. 13) is applicable: "The current state of knowledge concerning the environmental and health effects of nanomaterials poses practical difficulties. . . It is probably correct to say that most of the scientific and technical predicates for applying the statute to nanomaterials do not yet exist."

Resources to Deal with Nano

Resources are a major constraint for all federal regulatory agencies. For most of the agencies, e.g., the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), and the Consumer Product Safety Commission (CPSC), it is clear that there is insufficient money and people to take on additional tasks, such as regulating nano, without sacrificing some other essential task (see Taylor 2006; Davies 2006). With EPA, the resource constraints are severe but less clear-cut.

EPA's budget is by far the largest of any of the regulatory agencies (Eisner 2006, p. 32). A significant proportion of the budget (varying from year to year) goes for grants to state environmental agencies, to researchers, and for construction. The fiscal year (FY) 2008 budget requests $7.2 billion in budget authority for EPA. This is an approximately 10% reduction from three years earlier, not adjusting for inflation. Adjusting for inflation, the EPA budget is less now than it was in 1973 (see Eisner 2006, p. 33). The agency's responsibilities have continued to expand as the economy has grown and as new authorities and programs have been added to its portfolio. The gap between resources and responsibilities has widened considerably over the past 25 years.

The actual width of the gap is hard to measure. Where numerical workload measures are available, for example, issuing air and water permits, EPA is not able to keep up with the workload (see Davies 2001). However, the balkanized, fragmented nature of the agency (often reinforced by congressional allegiances to particular programs)

makes it hard to shift resources from one program to another, so it is often unclear whether the problem is a lack of resources or a failure to change priorities. The perception within the agency is that resources are inadequate and that important and needed activities remain undone because the resources are not available to do them.

Funding for nano in EPA is concentrated in the Office of Research and Development (ORD) and the Office of Pollution Prevention and Toxics (OPPT). According to the NNI, EPA's nano budget was $7 million in FY 2005. This dropped to $5 million in FY 2006, but increased to $9 million in FY 2007. The FY 2008 budget requests $10 million (National Nanotechnology Initiative 2006, p. 35; 2008 figure from **www.ostp.gov** accessed 2/3/07).

The major part of the EPA money (about 80%) is for ORD. According to NNI, EPA spent $4 million for nano risk research in FY 2006. For all government agencies in FY 2006, the NNI estimates nano risk-related expenditures to be $38.5 million. PEN estimates that total nano risk expenditures in calendar year 2005 were only $30.6 million and that highly relevant risk research amounted to only $10.8 million. There is broad agreement outside of the government that federal expenditures on nano risks should be significantly increased (see Nordan 2006).

Research funding for nano is, at least in theory, coordinated by the NNI. However, the nature of NNI's coordinating function is not altogether clear. It has no authority to transfer money from one agency to another, and it is difficult to know how much influence it has had on the allocation of funds within any of the participating agencies. It can be argued that NNI is less a coordinating mechanism than a fund-raising device that raises the visibility of nano research and development (R&D) to Congress and the public.

The National Research Council (NRC) (2006) has conducted two reviews of the NNI. The 2006 review concluded that "NNI is successfully coordinating nanoscale R&D efforts and interests across the federal government; catalyzing cooperative research and technology development across a spectrum of disciplines . . . and opening a host of new opportunities for scientific discoveries at the nanoscale . . . " (NRC 2006, summary p. 3). It found that NNI is "greater than the sum of its parts" and "is successfully establishing R&D programs with wider impact than could have been expected from separate agency funding without coordination"(*ibid*. p. 4). It credits NNI with influencing agency budgets and programs, citing "the FY 2005 refocusing of the Environmental Protection Agency's nanotechnology resources on studies of the toxicity of nanomaterials" (*ibid*. p. 3). The NRC also recommended that research on the environmental, health, and safety effects of nanotechnology should be expanded (*ibid*. p. 8).

NNI currently lacks any metrics or indicators by which to evaluate its accomplishments. The broad scope of NNI's mission makes metrics difficult, but there are models and precedents that show the task to be doable. The Commerce Department's Advanced Technology program rates the performance of the technologies it supports (*Science* 2006), and the NRC has done a study of metrics for the Climate Change Science Program (NRC 2005). The NRC (2006, Ch. 2) already has made a start in developing indicators for the NNI. NNI should be able to measure its progress.

The non-research spending for nano in EPA is concentrated in OPPT. The OPPT FY 2007 budget is around $93 million. How much of this is devoted to nano is unknown, in part because OPPT employees who spend a portion of their time on nano work on

other things (e.g., non-nano new chemical notices) as well. It is safe to say that only a very small percentage (less than 5% and probably less than 1%) of the OPPT budget is spent on nano.

If we look at people instead of dollars, the FY 2007 budget requests 17,560 full-time equivalent (FTE) employees for all of EPA. This is about 400 fewer than the agency had 10 years ago (EPA 2006). In FY 2006, OPPT had a total of 382 FTEs, which was not enough to adequately perform the chemical reviews required by TSCA. No estimates are available for what portion of OPPT employee time is spent on nano, but my estimate is that it is five or six FTEs at most.

Another relevant and very scarce resource is people with expertise in nano. It does not take a Ph.D. economist to figure out that nano experts can earn more money in the private sector than in government. How many people with nano expertise have had the dedication to public service to go to work for the government is not known, but it is a very small number. Many, perhaps most, of the EPA employees dealing with nano have had little or no prior experience with the subject.

How much additional funding would EPA need to adequately oversee nano? The answer depends on how the agency will go about the task and on how much of the research on nano's effects will be done by EPA. Also, the amount will change over time. A rough estimate for the next couple of fiscal years is $50 million each year—about half to EPA's ORD, and the other half equally divided between OPPT and the other EPA programs. This would bring EPA nano research up to an adequate level, given the constraint of finding qualified researchers. It would provide funding for OPPT to review new nanomaterials and staff the voluntary program, and it would give the other EPA programs the resources necessary to begin considering what actions they should take to deal with nano.

Political Will to Address Nano Effects

Addressing nano effects requires political will. If there is enough political support, legal and resource problems can be overcome. Even the scientific and technical problems are likely to yield to a sufficient investment of research funding.

Currently the political climate generally favors free-market laissez-faire over any form of government action. This has been true for the past 30 years, and it accounts for the dearth of resources in EPA and other regulatory agencies. The anti-regulatory climate has been supported by both Congress and the executive branch at the federal level and also by many of the states. It has been opposed by environmental and consumer groups, but these groups lack the power to do much except defend the laws that are already on the books.

With respect to nano, the current situation, at least at the federal level, may be characterized as the Pangloss Gap. Pangloss was the character in Voltaire's *Candide* whose refrain was "All is for the best in the best of all possible worlds." The current administration has repeatedly stated that no new legislation is necessary, that all existing regulatory programs are well suited to deal with nano, and that research priorities and funding are just what they should be. In short, all is for the best in the best of all possible worlds. The reality is that the public is not being adequately protected from nano products and materials whose effects on health and the environment are unknown. This is the Pangloss Gap.

Industry is the swing factor politically, and reading its political position is hard because there are multiple nano industries, not one.

Nano affects almost every economic sector, and firms working on nano range from two-person start-up companies to giants such as General Electric, IBM, and DuPont. There is no single industry group for nano.

The NanoBusiness Alliance represents primarily the smaller companies whose sole or primary business is nanomaterials or products. The Alliance has opposed any additional regulation of nano and has generally supported the Republican administration's Panglossian position. However, it has supported increased funding for research on nano health and environmental effects. The large chemical companies working on nano are represented by the American Chemistry Council, which has been more sympathetic to regulation, although it has also opposed any new laws aimed specifically at nano. DuPont has cooperated with the environmental group Environmental Defense to develop a framework for managing the risks of nanomaterials (see Chapter III).

The underlying choice that nano companies face is whether government regulation will impede or even strangle innovation and growth of nano, or whether a lack of regulation will have the same result. There is evidence that some large companies (e.g., Kraft Foods [see Feder 2006]) and some venture capitalists have limited their involvement with nano because of the lack of any clear guidelines about what will be regulated and how. Public opinion polls show that the absence of government regulation could lead to public skepticism about the new technology (Macoubrie 2005; Hart 2006).

Mustering the political will to adequately manage nano will depend heavily on three factors. One is the attitude of the businesses engaged in nano. How many will perceive regulation as an asset and how many will perceive it as the opposite?

A second factor is change in the political climate. These are volatile political times, and it is hard to predict when, whether, and how the laissez-faire climate might change. Greater awareness of the debilitated condition of the federal regulatory agencies could contribute to a change. Most of the American people are still under the illusion that they are being adequately protected by EPA, the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), and the Occupational Safety and Health Administration (OSHA).

The third factor is the occurrence of an accident or some other agenda-forcing event. It is unfortunate but true that most regulatory legislation has been a response to some dramatic adverse event—poisoning from contaminated food, the Santa Barbara oil spill, Love Canal. People being injured by use of a nanoproduct or a massive fish kill caused by nano could dramatically change the climate for regulating nano. I very much hope that such an event will not occur.

EPA Experience Regulating Nano

Thus far, EPA has had limited experience dealing with nanomaterials or nanoproducts. Three statutes have been involved: TSCA, CAA, and FIFRA.

TSCA is the major law that EPA has used to address nanomaterials. A manufacturer is required to submit a pre-manufacturing notice (PMN) to EPA before it can manufacture a new chemical. How many new chemical notices EPA has received for nanomaterials are uncertain because manufacturers are not required to identify a material as being nanoscale. An agency source estimated that between January 2005 and October 2006 around 20 PMNs for nanomaterials had been received.

A search of the *Federal Register* (FR) between January 2004 and October 2006 identified only five nano PMNs. Altair Nanomaterials Inc. submitted PMNs for three chemicals: lanthanum carbonate oxide to be used for water treatment (FR 7/11/05); lanthanum for the removal of ionic phosphate from recreational water (FR 12/9/05); and lithium titanium oxide used as an anode for a lithium-ion battery (FR 1/18/06). An unidentified company submitted a PMN for siloxane-coated alumina nanoparticles in 2005 (FR 8/10/05) and began manufacture of the material in 2006 (FR 8/14/06), and another unidentified company began manufacture of siloxane coated silica nanoparticles in 2006 (FR 6/9/06).

A company making a sixth nanomaterial, a carbon nanotube, applied for a low-volume exemption from the TSCA requirements. The agency decided to grant an exemption but under a different regulation, the Low Release and Exposure Exemption (LoREX). The terms of the LoREX exemption require that the chemical will yield no exposures to the general public, no releases to air or water, and that all worker exposure will be adequately controlled (communication from EPA 11/3/06). Also, the company agreed to allow EPA to re-review the chemical in the future (Phibbs 2005).

Under questioning from a reporter, EPA revealed that in 2005 it reviewed 15 new nanoscale chemicals and found that only one—the carbon nanotube given the LoREX exemption—had "unique properties that would cause it to act differently than a larger form of the same chemical would be expected to act" (Rizzuto 2006a). The agency decided that the other 14 were not covered by the new chemicals provisions of TSCA. EPA did not reveal how it defined "unique properties" and did not indicate what evidence, if any, it used to reach its conclusion.

The EPA decision to classify most of the nanoscale chemicals it reviewed as existing chemicals and thus not subject to regulation under the TSCA new chemicals provisions relates to a category of nanoparticles that the ASTM (2006) has labeled "non-transitive nanoparticles." The ASTM defines these nanoparticles as ones that behave the same as larger versions of the material. However, there is an ambiguity about what the word *same* means in the definition. EPA seems to have decided that if a nanoparticle is **chemically** and **physically** the same as the comparable material in bulk form, it should not be reviewed as a new chemical under TSCA. The fact that the chemical at nano size might be **biologically** and **ecologically** different from the bulk chemical appears not to have entered the agency's decision process. We do not know the extent to which size alone creates a potential for harm. For instance, if size allows particles to penetrate cells or reach body organs that larger particles cannot, even non-transitive nanoparticles could present new potential health and environmental challenges. EPA's pattern of decisions with respect to new nanoscale chemicals has far-reaching implications. If the agency continues to follow the pattern, then large numbers of nanoparticles, perhaps the majority, can be marketed without any government review of their safety.

EPA's TSCA office is planning to initiate a voluntary stewardship program for nanomaterials, but the program will not start until mid-2007 at the earliest (see Chapter III). EPA is years away from having an adequate nano program under TSCA.

In October 2005, the director of EPA's Office of Pesticide Programs stated, "We're not aware of any companies who have come to us with nano pesticides" (U.S. EPA 2005a). In

January 2006, the Pesticides Office was asked to register as pesticides washing machines being sold by Samsung.

The washing machines in question, Samsung's "Silver Wash" clothing-washing machines, release nano silver particles into each load of wash. (Technically, the machines release ions, not particles, but the difference is not significant in this context.) Silver is a known bactericide, and the silver is intended to sanitize each wash load. The request that the machines be registered as pesticides came from Tri-TAC, a technical advisory group for wastewater treatment plants in California (see **www.tritac.org**). Tri-TAC noted that, "Silver is highly toxic to aquatic life at low concentrations," that it "bioaccumulates in some aquatic organisms such as clams," and that it "cannot degrade" (letter Chuck Weir to Jim Jones, 1/27/06, available at **www.tritac.org**).

Initially EPA decided that the washing machines were "devices" and not pesticides. In November 2006, it reversed itself and said it would regulate the machines as pesticides (*Daily Environment Report*, 11/21/06). However, a number of other consumer products also use silver nanoparticles as deodorants, disinfectants, or fungicides. Tri-TAC mentioned this in its initial letter, and the Natural Resources Defense Council (NRDC) wrote EPA requesting that it examine the "more than 40 consumer products . . . that contain nanosilver" and require that any of them that use nanosilver as a biocide apply for registration as a pesticide (letter Jennifer Sass and Mae C. Wu, NRDC, to Jim Jones, 11/22/06). EPA has not said what it will do about these other products, nor is it clear how it will act in relation to the Samsung washing machines. Meanwhile, nano-based disinfectants have been applied to all handle surfaces in the Hong Kong metro rail system's trains and stations, and London is considering doing the same (Land 2006). Millions of people are being exposed to the types of nanomaterials that potentially should be registered under FIFRA.

Aside from the pesticidal washing machines, the most controversial nano regulatory decision now on EPA's plate is the registration of a fuel additive under the CAA. Envirox™ Fuel Borne Catalyst, manufactured by Oxonica, contains cerium oxide nanoparticles. It is already used in fuel in Europe. One British transportation company, Stagecoach Group, now uses the nano additive in its entire fleet of 7,000 buses (*Small Times* 2005). Oxonica has applied to EPA for permission to sell the additive in the United States. The company claims that the additive improves fuel consumption and reduces diesel vehicle emissions. A decision is expected in summer 2007.

What I have described in this section is the entire experience that EPA has reported to date with regulating nano. One would not guess, based on this experience, that nano is a major new technology being commercialized at a very rapid pace. Lux Research (2006, p. iii) estimates that, by 2014, 15% of all goods manufactured globally will involve nanotechnology. What the EPA record reflects is not the pace at which nano is being developed, marketed, and adopted. Rather, it reflects the rapidly widening gap between the adoption of the technology in the private sector and the government's lagging attempts to understand nano and to ensure that it does not harm humans and the environment.

III. Tools for Dealing with Nano

Several decades of experience regulating environmental problems have resulted in a variety of different approaches and a good deal of information about the effectiveness of different regulatory tools. The tools have been reasonably effective at eliminating the types of pollution problems that sparked the environmental movement, but there is broad agreement that existing regulatory approaches need revision and that the new problems of the 21st century, such as nano, require new tools.[3]

Nano presents particular challenges to the existing system. It is neither a bulk pollutant nor a chemical in the sense that these were defined as the objects of regulation of most existing environmental laws. We are not sure what characteristics of nanomaterials determine their toxicity; nano materials and products likely follow new exposure pathways in both the human body and the environment; and, in the future, some nanomaterials may be self-replicating.

The old models of regulation are also questionable. They assumed that resources would be adequate, that the pace of innovation would be relatively slow, and that key decisions would be based primarily on the risks of individual materials. Adequate resources are still necessary, but the gap between what is adequate and what is available has become so wide that priority setting has become perhaps the most fundamental decision. The slow pace of innovation is also a thing of the past. The risks of individual materials are still critical, but more-general questions relating to such issues as the power of government, the distribution of wealth, and ethical and cultural norms have come to be an important part of decision-making about new technologies.

In this chapter, I review available tools, discuss their applicability to nano, and provide some indication of which tools may be most effective. I also suggest some directions that new forms of regulation could take. I discuss information tools, voluntary efforts, economic tools, and liability. I also consider the role of state and local governments, and the importance of public participation in implementing any effort to deal with nano's effects.

Adjusting Existing Programs

Before talking about tools, I should acknowledge the advantages of the EPA regulatory systems that are in place. The fact that they are in place is, in itself, a major advantage. The American political system is designed to obstruct new initiatives. New laws are difficult and time-consuming to enact, and even new regulations typically take years to promulgate if they are of any significant magnitude. Thus, there is a great incentive to work with the laws and regulations that are in place.

The other notable advantage of the EPA regulatory systems is their comprehensiveness. In one sense, the EPA laws are highly fragmented, and I will discuss this in Chapter IV. But during the past 35 years, Congress has enacted a large number of environmental laws, and it is hard to find any part of the environment, or any type of environmental problem, that has not been addressed, at least partially or indirectly. Thus, it is not surprising, as discussed in Chapter II, that there are many EPA laws and regulations that may

3. In general, see Durant et al. 2004; Eisner 2006; Fiorino 2006.

apply to nano. In that chapter, I briefly discussed how existing regulatory programs can be adjusted to manage the new technology. In this chapter, I discuss various other kinds of tools to deal with nano.

Information Tools

Public shame always has been used as a way to discourage bad behavior. Two programs pioneered the contemporary use of information as a regulatory or oversight tool. In 1986, the Emergency Planning and Community Right-to-Know Act initiated the Toxics Release Inventory (TRI). The inventory requires companies releasing more than a certain amount of any of several hundred toxic chemicals to report the releases to EPA annually. EPA then publishes the figures with the name and location of the company and the amount of pollutants the company released (see **www.epa.gov/triexplorer/**; also **www.scorecard. org**).

At about the same time that EPA was developing TRI, voters in the State of California approved a ballot initiative, Proposition 65. Under Prop 65, the state annually publishes a list of chemicals known to cause cancer or reproductive toxicity (**www.oehha.ca.gov/prop65**). If a company exposes individuals to any of these chemicals (or to levels of the chemical that exceed a safe level if such a level has been established) it must provide a warning, usually by labeling the product.

Both TRI and Prop 65 generally have been viewed as successful. According to Dan Fiorino (2006, p. 49), TRI has "pushed many companies to significantly reduce their environmental impacts" (also see Herb et al. in Dietz and Stern 2002). However, some argue that almost all the TRI reductions are attributable to other regulatory requirements. Weil et al. (2006, p. 172), after reviewing the literature, conclude that TRI's effectiveness in reducing toxic pollution "remains uncertain." Prop 65 has resulted in many companies removing toxic materials, such as lead, from their products so that they would not have to affix a warning label (Percival et al. 2003, pp. 130–131; also Rechtschaffen 1999).

Could a disclosure-based scheme be applied to nano? There have been proposals that consumer products containing nanomaterials be labeled (see, for example, Lin 2006). Some kinds of nanoproducts would have to be labeled now. For example, labeling is the core of the pesticide regulatory program, and if nano-containing pesticides were registered by EPA, they would have to have a label containing information approved by the government. However, the label information would not necessarily have to include the fact that the pesticide contained nanomaterials.

There is an extensive literature on the effectiveness of different labeling approaches (see Thogersen in Dietz and Stern 2002). However, a peculiarity of labeling nanoproducts is that for some people the nano label would be a plus and for others it would be a negative. Consumers seeing the nano label might think "modern, futuristic, fashionable, effective" or they might think "new, untried, dangerous." For most other labels this kind of ambiguity does not exist. Public views on nano are still largely unformed (Macoubrie 2005; Hart 2006), so the ambiguity could change in the future.

A disclosure-based approach to managing nano could be relatively simple. Both nanomaterials and nanoproducts would be required to be labeled. The label would be required to contain two pieces of information: (1) the fact that it is a nanomaterial or nanoproduct; and (2) a telephone number and e-mail address where adverse effects could be reported. A government agency (which agency would dif-

fer depending on the product) would be empowered to recall, ban, or limit products suspected of causing adverse effects.

This approach is not quite as simple as it might seem. Relevant questions that would have to be answered include how to define nano materials and products, who receives and validates the adverse effects notices, and what kind of powers should be given to the government agency.

An alternative approach would be a variant of the Prop 65 model. EPA and/or other federal agencies could promulgate a set of testing requirements appropriate to determine the safety of various kinds of nano consumer products. Manufacturers of covered products that had not conducted the tests would be required to affix a label to the product stating that the product contained nanomaterial and had not been tested for safety. The assumption is that such a label would discourage sales and thus be an incentive to companies to do testing.

This approach is also not without difficulties. At present, it is not clear that the science is adequate to promulgate testing requirements. Even if it were, it would be necessary to adjust the tests to different types of products and to determine the extent to which manufacturers could rely on testing done by others. Enforcement would not be simple—government agencies would have to be able to ask manufacturers for their test results and this in turn raises questions about what to do about tests that show that a product is unsafe.

Simplicity is not likely to be characteristic of any oversight scheme for nano. The diversity of nano products and applications is, by itself, a major complicating factor. It is difficult to structure effective disclosure policies in any case (Weil et al. 2006). Disclosure and information approaches are not likely to be a complete answer for managing nano, but they may be important supplements to other approaches.

Voluntary Efforts: Industry Initiated

A variety of programs and experiments loosely termed "voluntary" have been initiated over the past 15 years. Some are more voluntary than others, and all of them function within the context of a dense web of non-voluntary government regulations. They share a premise that government regulation has become overly cumbersome and inflexible, and that non-regulatory initiatives can supplement or provide alternatives to regulation that are both more efficient and more effective.

Some voluntary initiatives are primarily initiated by industry and others are primarily initiated by government. Within the first category, I will discuss three general types of programs: industry codes of practice; environmental management systems; and third party (other than industry and government) efforts. The categories cannot be neatly delineated. For example, the International Organization for Standardization (ISO), a third party, promulgated standards for environmental management systems, which were then used as a component of some government-initiated voluntary efforts.

Several trade associations for major industries have established codes of environmental practice for their industries, although some of these are no more than loose pledges to be good corporate citizens. In recent years, some industries, notably chemicals and pulp and paper, have placed a lot of emphasis on such codes, refining their content, utilizing enforcement mechanisms, and publicizing their members' adherence to the code. (see Nash in Dietz and Stern 2002; Eisner 2006).

The effort most relevant to nano is the Responsible Care program of the American Chemistry Council (ACC). The ACC (previ-

ously called the Chemical Manufacturers Association) represents large manufacturers of chemicals. Responsible Care was started in Canada in the 1970s and in the United States in 1988. It has undergone many changes since its inception. ACC is currently implementing a system for third-party certification of members' compliance with Responsible Care (Eisner 2006, pp. 161–162).

Starting in 2005, the environmental organization Environmental Defense has been cooperating with the DuPont Company to develop guidelines for reviewing the safety of nanomaterials and nanoproducts. A draft of the guidelines was issued in February 2007. The guidelines are based on a framework that includes describing the material and its applications, profiling its life cycle, evaluating risk from the material, and assessing and implementing risk management options. The framework will be demonstrated on some potential DuPont products. It would be logical to assume that if this effort is successful, the results could be incorporated into the Responsible Care program.

On April 12, 2007, 21 environmental and labor groups, including the Natural Resources Defense Council and the AFL-CIO, issued an open letter criticizing the Environmental Defense–DuPont framework as "fundamentally flawed." The letter did not name any of the flaws. It rejected the framework on the grounds that the process was one "in which broad public participation in government oversight . . . [was] usurped by industry and its allies" and that the framework might be used "to delay needed regulation and forestall public involvement." The letter can be interpreted as a signal that the signers want the politics of nano to be the same as the deadlocked politics of environmental policy generally, a polarized standoff between industry and enviros.

Evidence about the effectiveness of industry codes is fragmentary (see Harrison in Dietz and Stern 2002), and is complicated by the variety of different codes and different industry characteristics. Studies of Responsible Care "suggest that this code—the most highly developed of all U.S trade association efforts in environmental self-regulation—has failed to reliably improve firms' internal management practices" (Nash in Dietz and Stern 2002, p. 248; also see Morgenstern and Pizer 2007, p. 7). It has, however, probably improved the environmental practices of the suppliers, distributors, and customers of Responsible Care firms (Nash in Dietz and Stern 2002, p. 249).

The great advantages of industry codes are that they can be implemented relatively rapidly and they can be altered to deal with changes in technology. Vivian Weil (2006) has suggested that such codes could contribute to public trust in a technology if the codes were developed with public input.

The disadvantages of most industry codes are their dependence on voluntary industry conformance, their lack of specific standards, and the lack of transparency in both their development and implementation. Also, most of the major trade associations, such as the ACC, include only a few small or medium-size firms. Often it is the smaller firms that most need codes of good practice. The wide range of nanotechnology materials, applications, and products is an additional complicating factor. Many different trade associations represent firms that are or could be major users of nanomaterials, and even manufacturers of nanomaterials are not represented by any one trade association. As noted in Chapter II, the ACC and the NanoBusiness Alliance are the two most important nano trade associations, but they do not cover many of the firms that have a stake in nano policy.

A second category of industry voluntary efforts centers on environmental management systems (EMS). An EMS is a process within an individual company for identifying actual and potential environmental problems and for ensuring that steps are taken to deal with the problems.

EMSs have been used in a variety of contexts and have been the subject of an extensive literature (see, for examples, Coglianese and Nash 2001; Coglianese and Nash 2006; Mazurek in Durant et al. 2004). The ABA paper on innovative regulatory approaches (2006d, p. 6) suggests the possibility of a "nanotechnology management system" that, like an EMS, would serve as the basis of a voluntary program to manage nano. However, it does not describe what the content of such a system might be.

There is some evidence that firms that have a formal EMS pollute less than firms that do not have an EMS (Coglianese and Nash 2006, p. 17). However, cause and effect are difficult to separate. It may be that firms that pollute less are better environmental citizens and thus more likely to adopt an EMS.

There are many types of EMSs. Almost all of them suffer from similar deficiencies, although it seems elementary for any company that has the least environmental sensitivity (or that wants to avoid breaking the law) to have some kind of EMS. The deficiencies include a lack of substantive standards—an EMS is just a process, it does not deal with results or outcomes; a lack of transparency—usually public involvement is not a significant component of an EMS; and the possibility of a rigidity and intrusiveness greater than any existing environmental regulations—if a uniform pollution-control technology for an industry produces major inefficiencies, a uniform management system could be even worse. There is a slippery slope starting from government using incentives to encourage companies to have an EMS and ending with government prescribing the specifics of the EMS a company should use. If companies (and economists) do not like government prescribing technology, it is hard to see why they would like government prescribing internal-management systems for a firm.

The ISO 14000 series, which contains a uniform code for EMS, had a significant impact in encouraging adoption of EMSs (see Eisner 2006, pp. 163–175). This shows how important third-party efforts can be. ISO is a Geneva-based international nongovernmental organization that serves as a federation of standards bodies for more than 125 nations. ISO's Technical Committee 229 is currently working on standards for defining and measuring nanomaterials and on testing methods for nanomaterials (**www.iso.org**, accessed 2/14/07).

Another important standards organization, ASTM International, is also a voluntary effort, largely by industry, that is assisting in nano policy. ASTM is headquartered in the United States, but it involves technical experts from more than 100 countries in its work. ASTM has been cooperating with the American Institute of Chemical Engineers, the Japanese National Institute of Advanced Industrial Science and Technology, and several other organizations to develop consensus standards for various aspects of nano. In November 2006, it published 13 definitions of nano terms (ASTM 2006). The definitions are somewhat general and leave some key questions unanswered, but they are a useful contribution to the discussion about nano.

Voluntary Efforts: Government Initiated

Starting from the premise that alternatives to regulation could be more efficient and effec-

tive than traditional regulation, EPA has, over the past 15 years, initiated a variety of voluntary efforts (see Mazurek in Dietz and Stern 2002). A 2005 survey identified 87 EPA voluntary programs (Morgenstern and Pizer 2007, p. 2). A majority of the programs deal with energy efficiency and other ways to address the climate change problem. Ten others are focused on pollution prevention. One—the National Environmental Performance Track—is broad in scope and utilizes a negotiated agreement between EPA and a private firm to reduce the inflexibilities of existing regulations.

Several states have also experimented with voluntary programs. For example, Wisconsin has a Green Tier Program and New Jersey had a Silver and Gold Track Program (see National Academy of Public Administration 2000; Rabe 2004). The state programs are similar to the EPA programs, dealing primarily with climate change and pollution prevention. The New Jersey program, as well as some others, was modeled after the Dutch covenant system, where industry sectors reach voluntary agreements with the government about pollution reductions they will make (Eisner 2006, pp. 179–184).

There is mixed evidence about the effectiveness of government-initiated voluntary programs. Mazurek examined three of the major EPA voluntary programs (Green Lights, 33/50, and Project XL) and found that "although the EPA reports that each of these programs was a success, independent studies report otherwise" (Mazurek in Dietz and Stern, p. 225; Morgenstern and Pizer 2007). The programs suffered from a lack of flexibility because they were bound by existing legal requirements, from a lack of transparency, and from very cumbersome and time-consuming decision-making because of the need to operate by consensus.

In September 2005, EPA announced its intention to start a voluntary program for nano (see Davies 2006, p. 22). The program would ask nano manufacturers to submit to EPA, for materials chosen by the manufacturer, information on (1) material characterization, (2) hazard data, (3) use and exposure potential, and (4) risk management practices. Except for information to describe the material, the manufacturers would be asked only for information they already possess. A second program, focusing on a smaller number of materials, would ask participants to generate and report enough information to allow EPA to conduct a full risk assessment. The primary purpose of the voluntary programs is to give EPA enough information and experience to lay the groundwork for a regulatory program under TSCA.

The EPA voluntary nano program has not yet been started. Originally, it was going to start in tandem with a similar program initiated by the British Department for Environment, Food, and Rural Affairs. The British decided not to wait for EPA and launched their program in September 2006. Initial response to the British program has been disappointing, with only six submissions received during the first six months (see **www.defra.gov.uk/environment/nanotech**).

In October 2006, EPA began a series of consultations with experts and interested parties seeking advice on the questions it should ask participants in the voluntary program (Rizzuto 2006b). The agency announced that it planned to launch the voluntary program within 10 months. However, several participants in the first meeting expressed disappointment at what they perceived as EPA's lack of readiness to undertake the program, and they doubted that the agency would be able to start the program in 10 months. EPA has had difficulty preparing for the voluntary

program that is supposed to prepare for a regulatory program.

Many of the difficulties of the EPA voluntary programs stem from the lack of statutory authorization. Part of the attraction of these programs was that they did not require the long, arduous, and politically uncertain process of getting legislation enacted. However, pollution-control programs in the United States always have been driven by statutory mandates, so the voluntary programs have not been able to get the attention, resources, or flexibility that the law-based EPA programs have.

It would be possible to have a hybrid voluntary and regulatory program. This could take many forms, but basically firms would be exempted from a traditional regulatory program if they participated in some type of approved voluntary program. Any such arrangement would require safeguards. As Marc Allen Eisner (2006, p. 5) has observed, "It may be necessary to delegate greater authority to corporations, which possess the greatest knowledge about their technologies, products, and markets, and to create incentives for innovations in pollution control and prevention. This, in turn, raises important questions regarding the monitoring of corporate compliance and the maintenance of some semblance of public accountability. Without some means of forcing accountability, 'reform' may be little more than an abdication of regulatory responsibility."

Economic Tools

The free market, in and of itself, does little to protect the public from potential adverse effects of nanoproducts. Supplemented by tools such as labeling and liability, the market may be able to help prevent the kinds of acute problems that are both readily identifiable and traceable to a particular product.

In recent years, policy makers, prodded by economic theory, have used some market-like mechanisms to supplement environmental regulation and to make it more efficient. These mechanisms include taxes on pollution and cap-and-trade systems that allow buying and selling of pollution rights. These mechanisms are not appropriate for nano because they are designed to curb things that are "bad" whereas nano, in general, is a "good" that should be encouraged.

There are a few ways in which using tax-like mechanisms for nano could be considered. If the relative safety of different nanoproducts could be determined, in theory one could tax the less safe ones as a way of encouraging safer products. However, in theory one would want to prevent the adverse effects, not just discourage them, and in practice it is very unlikely that EPA or any other entity will be able to rate the relative overall safety of different products.

A more feasible variant of this approach would be for EPA to collect a fee from the manufacturer for reviewing nanoproducts for their effects. The fee could be set so as to provide an incentive for testing. The fee would be slightly above the estimated cost for doing the testing necessary to determine the safety of the product. For each test result reported by the manufacturer, the fee would be reduced by the cost of that test. If all necessary tests were conducted, there would be no fee or only a minimal fee.

The FDA charges fees for reviewing drugs. This potentially puts new drugs at a disadvantage if they are competing against generic drugs whose makers did not have to pay a fee, but this is not a common scenario. In contrast, many nano manufacturers may be competing with producers of non-nanoproducts, and they would be economically disadvantaged by a fee. Whether com-

petitiveness considerations would be significant would depend on the size of the fee and other factors. In any case, user fees may be an important component in the future funding of regulatory agencies.

Subsidies are the other major economic policy tool. The 25 agencies, including EPA, that comprise the NNI are spending almost $1.4 billion on nano in FY 2007, and nearly $1.5 billion has been proposed for FY 2008 (**www.nano.gov**). See Table 3.1 for a comparison of NNI budgets for 2001 and 2008. The spending is the total from the budgets of individual participating agencies: NNI is a coordinating group that does not have a budget of its own. Not all of the $1.4 billion could be called a subsidy, but most of it is intended to assist the private sector in developing and utilizing nano. As discussed in Chapter II, only $38.5 million, or less than 3%, is being spent on the risks of nano.

Liability Tools

In the days before environmental laws existed, the only tool available to curb pollution was tort law (and related nuisance law)—going to court and suing a polluter for damage he had caused you. The successful use of this tool required two things: proof that you had been damaged or injured in some way and proof that the party being sued caused the damage. In the modern context, neither of these requirements is likely to be met by an individual.

Interest in tort law was revived in 1980 by passage of CERCLA, also known as the Superfund law. CERCLA (section 107) used liability as a way of collecting funds for cleanup of hazardous waste spills and sites. It circumvented the traditional requirements of tort law by making any person connected in any way with the hazardous waste responsible for all cleanup costs. "Strict, retroactive,

TABLE 3.1. COMPARISON OF NNI BUDGETS BY AGENCY (IN MILLIONS OF DOLLARS)

Agency	2001 Actual	2008 Proposed
NSF	150	390
Defense	125	375
Energy[a]	88	332
Health and Human Services[b]	40	208
Commerce (National Institute of Standards and Technology)	33	97
NASA	22	24
EPA	5	10
USDA[c]	0	8
Homeland Security	0	1
Justice	1	1
Transportation	0	1
Total	**464**	**1,447**

[a] Includes the Department of Energy Offices of Science and Energy Efficiency and Renewable Energy.
[b] Includes the National Institutes of Health and the National Institute for Occupational Safety and Health.
[c] Includes the Cooperative State Research, Education, and Extension Service and Forest Service.

and joint and several liability" is the legal term applied to this aspect of CERCLA.

Traditional tort law might work to deal with some short-term acute effects of nano; however, for the reasons discussed at the beginning of Chapter II, it is not a useful tool for dealing with other, more-likely nano problems. We know from experience with other technologies that problems will often go undetected because they occur many years after exposure to the material (e.g., cancer or groundwater contamination) or because the problems are widespread and caused by many different factors (e.g., heart attacks or air pollution). Even if a problem is detected, being able to prove that it is caused by a specific product or manufacturer may be impossible. Most important, liability, even when it works, is after the fact. Only after damage has occurred can you go to court. It may have some preventive effect, but to rely on it is an unacceptably large gamble with the health of people and the environment and can be incredibly costly for businesses and governments.

A CERCLA-like fix for liability for nano seems unworkable, in part for the same reasons that a tax on nano would be unworkable and undesirable. Unlike hazardous waste, nano is not intrinsically harmful: it is and will be found in a large variety of desirable products. Nanomaterial resulting from the discarding of products, if it has been shown to be harmful, can be treated like other wastes under existing laws, including CERCLA.

State and Local Governments

Placing responsibility for a problem on state or local government has been a basic element of environmental programs. Devolution, decentralization, delegation—giving states more responsibility and the federal government less—has been advocated by reformers from all parts of the political spectrum. It is not a tool in the same sense as economic or information tools, but involving states and localities could be an element in an oversight system for nano.

More than a dozen states have active nanotechnology programs. However, these programs are essentially part of each state's economic development strategy, and they do not devote any attention to the potential adverse effects of nano. New companies might not be encouraged to settle in a state that is looking at the harm that nano might do.

There is one potential exception to states' ignoring nano adverse effects. In March 2007, the California Department of Toxic Substances Control held a half-day symposium on the potential risks of nano (see **www.dtsc.ca.gov/technologydevelopment/nanotechnology.cfm**), and the Department has been discussing the subject with EPA's Region Nine. Whether any action will come from this activity is not clear.

There are two ways that state or local governments might become active in regulating nano. The first is the climate change model. The complete inability (or, more precisely, unwillingness) of the federal government to deal with climate change has led a number of states to take action to limit greenhouse gas emissions within the state (Rabe 2004). This is happening because of four factors: (1) state officials perceive the problem to be important; (2) the federal government is not addressing the problem; (3) the states have expertise and experience in utility regulation, solid waste disposal, traffic management, and other functions that can contribute to reduced emissions; and (4) reducing emissions can be done in ways that make a positive contribution to state goals and the state economy. These factors, especially the last two, do not apply to nano at this time.

The other model is a law enacted by the city of Berkeley, California, early in 2007. Berkeley amended its hazardous materials disclosure law to include nanoparticles. It requires that, "All facilities that manufacture or use manufactured nanoparticles shall submit a separate written disclosure of the current toxicology of the materials reported, to the extent known, and how the facility will safely handle, monitor, contain, dispose, track inventory, prevent releases and mitigate such materials" (**www.ci.berkeley.ca.us/bmc/BerkeleyMunicipalCode/Title15/12/index.html**).

Berkeley is not a typical American city. Its economic base is a large university, and its politics are quite left of center. To my knowledge, only one other community—Cambridge, Massachusetts—is considering regulating nano (Bray 2007). Cambridge is very much like Berkeley. Both cities have a heightened awareness of environmental problems and of technological "threats," and in both communities the economic base, large universities, is not likely to be threatened by any action taken by the city government.

There is really nothing about nano that lends itself to localized solutions. Its manufacture tends to be international, its markets are national or international, and its potential threats are not, for the most part, localized. TSCA, the federal law that is the center of EPA's effort to deal with nano, is the most pre-emptive law that EPA administers. EPA is not allowed to share any TSCA confidential business information with state or local governments (TSCA section 14), and a large part of the information collected under TSCA is claimed to be confidential.

If my analysis is wrong, and regulation of nano is enacted or proposed in a number of states or localities, then it could create a political climate favoring national legislation. Industry's desire to avoid multiple inconsistent state and local regulations has been a major impetus for pre-emptive national legislation. It is possible that this could happen with nano.

Public Participation

Public participation is not so much a tool for dealing with nano as it is an underlying requirement. The need to involve the public permeates all aspects of regulation and must be considered in connection with all the tools I have discussed.

There are many publics and many ways in which they can participate. An important distinction is between public participation in specific decisions and public participation in general policy. The importance of the distinction was highlighted by the controversy over agricultural biotechnology. It was not specific decisions about the risk of specific products or technologies that most disturbed people. It was more-general issues such as the ethics of certain technologies, the roles of science and government in society, and the power of large corporations (Grove-White et al. 2004). Most of the existing requirements and much of the current effort devoted to public participation is, however, focused on participation in specific decisions.

Specific risk decisions, such as whether to register a pesticide or to limit the use of a chemical, in the United States usually are made by notice-and-comment rulemaking. EPA (or whatever agency is involved) must publish a proposed rule and then allow the public time (usually 60 days) to comment on it. The agency, when it publishes the final rule, must respond to the comments it receives. If the proposed rule is particularly controversial, the agency may hold a public hearing to get people's views.

The notice-and-comment requirements provide an important avenue for the public to be heard. However, they have major limitations. The public involved is usually a small, and sometimes unrepresentative, subgroup consisting of those who would be directly affected economically by the rule and sometimes one or two representatives of the more general public. The process involves little or no dialogue or interchange. Public hearings often do not involve important parts of the public and usually very little hearing takes place.

In recent years various supplements or alternatives to notice-and-comment rulemaking have been developed. Regulatory negotiation ("reg-neg") has been tried a number of times. It entails a non-governmental, neutral third party convening the stakeholders in a decision and having them reach consensus on the text of the rule. There is usually an informal agreement that the government agency will either accept the text as the proposed rule or at least publish the text agreed to by the negotiators. There is some disagreement about whether reg-neg produces better decisions and whether it avoids court battles. It is a time-consuming process for those involved and can be used only on very important rules.

Other forms of public involvement in specific decisions have been discussed and occasionally tried. For example, in 2005 the Nanoscale Science and Engineering Center at the University of Wisconsin-Madison sponsored a citizens' consensus conference on nanotechnology (see **www.nsec.wisc.edu**). Another example is the Citizens Technology Forum on nano, funded by the National Science Foundation (NSF) and modeled on the Danish consensus conferences (Hamlett and Cobb 2006). Also, the Internet has been utilized as a way of obtaining the views of the public. For example, PEN is planning to host a two-day web dialogue to provide an easily accessible venue for people who have not typically been engaged in nanotechnology issues to discuss information and share their thoughts about nano. Participants in the dialogue will be able to question a panel of experts and access online resources about nano. The British think tank Demos has set up a Nanodialogues project blog (**www.demos.co.uk/projects/thenanodialogues/blog**), and the Foresight Nanotech Institute created Nanodot, "the original nanotechnology weblog" (**www.foresight.org/nanodot**).

Public involvement can be used as an excuse to delay or avoid a decision. EPA's efforts to obtain input for their voluntary TSCA nano program may or may not be an example of this.

Advisory committees are the primary mechanism that federal agencies have used to obtain advice on general policy. EPA, for example, has used its National Pollution Prevention and Toxics Advisory Committee to get advice about how to deal with nano. Advisory committees have the advantage of continuity in membership, which means that over time the members can become knowledgeable about the issues faced by the agency, and advisory committees also have the advantage of allowing real dialogue and interchange, both among committee members and between the members and agency representatives.

Fair representation on advisory committees of the major interested parties is required under the Federal Advisory Committee Act (FACA). However, FACA has a number of deficiencies. It discourages creation of advisory committees by requiring Office of Management and Budget (OMB) approval of each new committee. Agencies have learned

to circumvent FACA's requirements by using contractors to run their public-participation efforts. FACA often has been used by agencies as a way of discouraging public input. The Act also impedes some kinds of public participation through requirements such as that the committee be chaired by a government agency official. FACA has been in existence for several decades, and a review and revision of it is long overdue.

Participation in general policy questions is closely related to education. The line between education and indoctrination can be thin, but some education about a subject such as nano can greatly facilitate public participation. False issues can be avoided and the real issues can be discussed more intelligently. The NNI is funding several educational efforts, including preparation of school materials and support for a traveling museum exhibition on nano. These efforts are needed because a significant majority of the public in the United States knows nothing, or almost nothing, about nano (Macoubrie 2005; Hart 2006).

Any effort to involve the public must consider the issue of trust. The American public does not trust either politicians or corporate executives (Hart 2006). Participation is an important way to try to overcome mistrust, but only if it is sincerely undertaken. Sincere commitment to hearing the public and a commitment to being honest with the public are prerequisites if some degree of trust is to be restored.

Reforming Regulation

In this chapter, I have described a variety of tools that could be used to regulate nano. Although I have commented on strengths and weaknesses of the tools, a more systematic approach would list a set of criteria for "good" regulation and then rank the regulatory tools on the basis of those criteria. This kind of systematic evaluation is beyond the scope of this paper, but in Table 3.2 and Figure 3.1 I have listed two sets of criteria that could be used. (For various approaches to criteria, see U.S. Office of Technology

TABLE 3.2. CRITERIA FOR GOOD REGULATION

Criterion	U.S. Office of Technology Assessment (1995)	Davies & Mazurek (1998)
Cost-effectiveness (efficiency)	X	X
Fairness (distribution of costs and benefits)	X	X
Fairness (due process) (environmental equity and justice)	X	X
Minimal demands on government (administrative burden)	X	
Assurance of meeting goals (effectiveness)	X	X
Adaptability (to new information, technology, etc.)	X	
Technology innovation and diffusion	X	
Simplicity		
Use and encouragement of good science		

Assessment 1995; Davies and Mazurek 1998; Sparrow 2000.)

A minimum set of criteria would be effectiveness, efficiency, and fairness. A regulatory approach should accomplish its purpose; it should do so with the fewest resources necessary to get the job done; and it should operate fairly, meaning that the costs and benefits of regulation are distributed in what is perceived to be a fair manner and also that legal requirements and due process are complied with. Table 3.2 expands this minimum set of criteria, suggesting other desirable features of a regulatory approach.

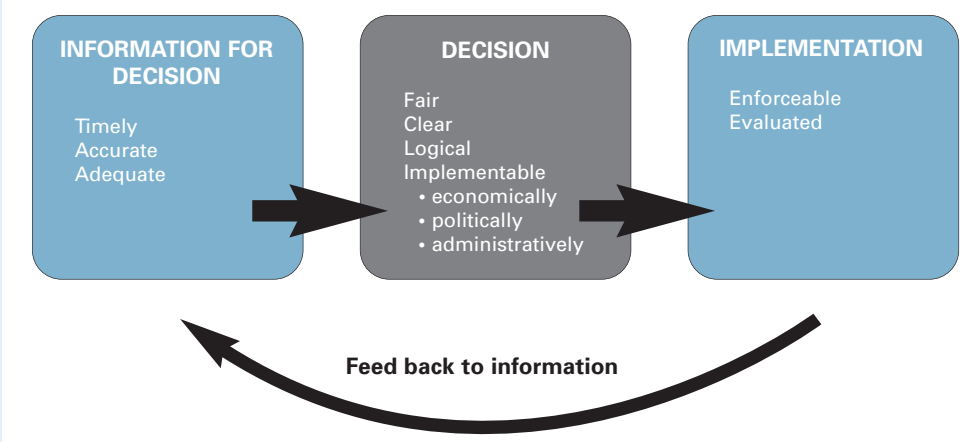
Figure 3.1 takes a somewhat different approach. It divides regulation into three stages: information for decision, decision, and implementation. Different criteria are applicable to different stages. Continuous feedback from implementation to information is crucial, and information must flow freely and accurately between each stage. For example, no matter how good the information in the first stage, the whole process can fail if that information is not successfully communicated to those making decisions in stage two.

There are steps that could be taken to streamline and improve the current regulatory process. Here I will only mention that EPA, as well as most federal agencies, has been slow to make full use of the Internet. Greater use can be made of the Internet, for example, by allowing permit applicants to file online and by utilizing the Internet for comments on proposed regulations and policies.

A new challenge, like nano, opens the possibility for new approaches to regulation. Many people have a lot vested in the status quo, and change is never easy. However, thinking about new approaches not only can lead to considering whole new programs but also can stimulate ideas for improving the existing system.

Some possible new approaches are briefly discussed below (also see Table 3.3). They overlap to some extent, they could be combined in various ways, they could even be melded together in a single proposal. They are intended simply to illustrate the application of some of the tools discussed above.

FIGURE 3.1. CRITERIA BY STAGE OF REGULATORY PROCESS



Collaborative regulation. Manufacturers of nanomaterials and products containing such materials would be required to develop a sustainability plan. EPA—perhaps jointly with FDA, the U.S. Department of Agriculture (USDA), and the CPSC—would promulgate a rule that specifies what the content of the plan should be. The plan would have three components: (1) a life cycle analysis of the material or product; (2) data on toxicity and exposure; and (3) risk management steps (including labeling) that the manufacturer will take and an explanation of why these steps are adequate to prevent unacceptable risks. The plan would be submitted to EPA (or another agency if the other agency has jurisdiction), but it would not be subject to government approval. The agency would publish a notice in the FR stating that it had received the plan and identifying the material covered. The plan would be reviewed by EPA if a citizen petition requested review or if there were reason to suspect that adverse effects are occurring or that the information in the plan was insufficient or incorrect. Manufacturers would be required to report any new information about possible adverse effects. Strict penalties would be imposed for marketing a product without a plan, and EPA would be empowered to take actions to prevent unacceptable risks. (A variant of this approach is described in Davies 2006, pp. 18–20.)

Voluntary plan with strict liability. This approach draws on the Superfund (CERCLA) model. Manufacturers of nanomaterials and nanoproducts would not be subject to pre-market review or approval but would be strictly liable for any health or environmental adverse effects caused by their products. The government would be authorized to sue firms for damages under a law specifying what kind of evidence is required to demonstrate liability. EPA would be given resources and legal authority to establish a monitoring and reporting network sufficient to detect adverse effects.

Insurance as leverage. The insurance industry could refuse to insure any nano manufacturer who did not adopt some oversight system similar to the Environmental Defense–DuPont framework. This would reduce risk to insurers as well as provide some protection to the public. It would supplement, not substitute for, government regulation. The effort could be enforced and supported by state insurance regulators.

Disclosure-based approaches. Similar to the Berkeley law discussed above, facilities that manufacture or use manufactured nanomaterials would be required to make public any known risks of the materials and what steps are being taken by the manufacturer to prevent such risks throughout the life cycle of the product. EPA, as well as state and local governments, would be empowered to ensure that firms make the information public, that the information is accurate, and that the risk management steps are adequate. Alternatively, or in addition, an approach similar to California's Prop 65 could be used. All nanoproducts would be required to carry labels identifying them as nano. EPA and/or other agencies would promulgate testing requirements for different kinds of products. Products that had not been subject to the required tests would have to so state on the label, e.g., "This product has not been tested for adverse health and environmental effects."

Labeling and liability. Law professor Albert Lin (2006) has proposed legislation that combines several approaches. All manufacturers of products containing nanomaterials would be required to notify EPA before

marketing the products, and the products would have to have a label identifying them as nano. For products containing nanomaterials in a "free" form (i.e., not bound to some other material), which pose potentially greater risks, there would be a screening process, post-marketing monitoring, and a requirement that the manufacturer post a bond to cover potential liabilities. This proposal, in my view, has some problems (for example, I think the bond would have to be set at such a high figure that it would keep small companies out of the market), but it illustrates the useful ideas that can come from combining different approaches.

Trust but verify. EPA, in cooperation with other relevant agencies and trade associations would promulgate specifications for sector codes of conduct with respect to nano. These would not be detailed, but would simply outline content and procedures in general terms. Trade associations would adopt the codes. Compliance with the codes would be verified by EPA or a third party reporting to EPA. EPA would also promulgate detailed requirements for nano testing, reporting, and safeguards. These requirements would apply to firms not covered by the codes or to firms that repeatedly were not in compliance.

Coalition. As a variant of the above, EPA could take the lead in pulling together insurers, venture capitalists, and nano industry groups to form a Coalition for Responsible Nanotechnology. The goal of the coalition would be to have nano manufacturers agree to follow something like the Environmental Defense–DuPont Nano Risk Framework. Those who agreed to do so would be entitled to use a label indicating compliance. Questions like third-party certification, public consultation, and the details of the risk framework would be decided by the coalition.

Regulation with reward. EPA would establish requirements for testing and reporting of nanomaterials and nanoproducts. Any product that is subjected to the tests and shows no significant adverse effects could carry a label saying that the product has met the EPA requirements for safety. Products that are tested and show adverse effects would have to submit to EPA a management plan to prevent the adverse effects from occurring. Companies with good testing and reporting records would be eligible for EPA technical assistance, would receive advance notice of available NNI grants, would get priority for issuance of air and water permits, etc.

Exposure-based regulation. Nano manufacturers would be required to submit a life cycle exposure profile of each product they make. The profile would be reviewed collaboratively by OSHA, various EPA programs (air, water, hazardous waste), and any other relevant agency. Any of the reviewing agencies, or a designated agency for particular types of exposures, would have authority to require steps to limit or manage the exposure if there were reason to believe damage might result from failure to do so. If there were direct exposure to humans, the government could require the manufacturer to conduct toxicity testing on the product. If there were direct environmental exposure, ecological testing could be required.

In recent years, a number of policy experts have converged on a group of regulatory reforms. As summarized by Fiorino (2006, pp. x–xi), one of the most perceptive environmental analysts, the new environmental regulation "will be based more on performance than on a narrow definition of compliance. It will allow regulated firms, especially the better performers, more flexibility in determin-

TABLE 3.3. TOOLS APPLIED IN EXAMPLES OF REGULATORY APPROACHES

Approach	Key Features[a]	Tools						
		Information Tools	Voluntary Efforts: Industry Initiated	Voluntary Efforts: Government Initiated	Economic Tools	Liability Tools	State and Local Governments	Public Participation
Collaborative regulation	• Manufacturers develop and submit sustainability plans to EPA • Recorded in FR • Penalties if no plan or adverse effects not prevented							X
Voluntary plan with strict liability	• Superfund model • Manufacturers strictly liable for any adverse health or environmental effects • EPA monitors			X		X		X
Insurance as leverage	• Insurers refuse to insure any nano manufacturer that did not adopt internal oversight system		X		X			
Disclosure-based approaches	• Manufacturers make risk information public through reporting or labeling	X			X		X	X
Labeling and liability	• Manufacturers notify EPA pre-marketing • Screening, post-marketing review, and bond requirement for free form nanomaterials	X			X	X		X
Trust but verify	• Industry codes of conduct specified, adopted, and compliance verified by EPA or third party • EPA sets testing, reporting, and safeguarding requirements			X				X
Coalition	• Manufacturers agree to follow internal oversight system • Can then label product indicating compliance	X	X	X	X			
Regulation with reward	• EPA sets testing and reporting requirements • Products carry label if meet them; if not, producers submit plan to prevent adverse effects • Rewards for good testing and reporting	X			X			X
Exposure-based regulation	• Manufacturers submit life cycle exposure profiles, reviewed by OSHA and EPA • Possible testing required							X

[a] "Manufacturers" refer to those producing nanomaterials and nanoproducts.

ing how to achieve environmental goals. It will aim to complement the way that business decisions are made in the private sector rather than just imposing more legal obligations on firms . . . [it] will go beyond the conventional rules-and-deterrence approach and rely on a more diverse set of policy instruments and strategies. . . . "

Many of the premises and conclusions of this school of thought are insightful and useful. In particular, rapid economic and technological change and the impoverishment of government regulatory programs mean that government cannot possibly direct all companies in a sector to implement specific remedies. Government cannot know enough and it cannot move fast enough.

However, other premises of the "new regulation" are more problematic. Most of the literature focuses on pollution and media programs, so its applicability to product regulation is often unclear. More fundamentally, there is often an assumption that environmental improvement is in the interests of most firms, that the "better performers" can mostly be left on their own to meet environmental requirements, and that the conflict between the profit motive and environmental good citizenship is a thing of the past. While companies are generally more environmentally enlightened than they were 30 years ago, I have difficulty accepting these premises. Profits and good environmental behavior often conflict. When they do, the firm's primary allegiance is to profits. Firms can survive even if they are bad environmental citizens, but they cannot survive if they ignore profit margins and market share.

There are environmentally better companies and worse ones, and some of the better ones have made outstanding contributions to environmental improvement. But there is a long list of "bad" things associated with "good" companies—one thinks of Union Carbide and Bhopal, and BP Amoco and the leaking Alaska pipeline. In its day, Enron was considered a "good" company. Fiorino (2006, p. 16) notes that, "Many studies confirm that regulation is still the most important influence on environmental behavior by firms."

All of this makes the task of regulatory reform more difficult. I have sketched some possibilities above. They could be combined in various ways, and many other approaches could be suggested. The ones I have outlined are intended only to give some idea of the variety of directions that could be explored.

Dialogue Is Necessary

The existing and potential tools for dealing with nano vary widely, but they share some underlying choices and trade-offs. The most basic choice involves the burden of proof. Should a nano manufacturer be required to demonstrate to the government that a product is safe (by conducting prescribed tests) before the product can be marketed or, conversely, should the government be required to show that the product is harmful before it can take any action? FIFRA is an example of the former; TSCA is an example of the latter. There are many intermediate positions, some of which I have sketched above.

Other trade-offs include obtaining more complete and detailed information about a product vs. delay in bringing the product to market, flexibility in the regulatory regime vs. predictability, and degree of trust in private firms vs. government oversight and verification procedures. All of these are matters of degree: extreme options for any of them are likely to be unworkable and unrealistic.

I have outlined a variety of regulatory approaches and some criteria for evaluating them. I have not recommended any particular approach for two very important reasons. First, a mix of tools is necessary for both substantive and political reasons. Second, a dialogue among interested parties (including consumers) is necessary before any oversight system can be put in place.

No single approach, including traditional command-and-control regulation, can accomplish what needs to be done to avoid adverse effects from a broad technology like nano. A mix is necessary. Any successful management regime must contain elements of information, public participation, and education. Most require economic and legal sanctions of various kinds. And voluntary efforts are required, if only because there can never be enough resources to monitor and police everyone. Everything from traffic rules to medical drug use requires a high degree of voluntary cooperation to be effective.

A mix of approaches is also often required for political reasons. Each type of approach has a different distribution of costs and benefits, and thus a different set of supporters and opponents. A winning coalition—a sufficient number of supporters to gain and maintain acceptance of the program—may require a mix of tools.

The most desirable mix, and the specifics of each approach, can be determined only by those affected by the programs and those impacted by the absence or inadequacy of programs. As a policy analyst, I can transmit the body of experience with programs and can suggest the likely strengths and weaknesses of various tools and approaches. However, the choice of mixes and the specifics of proposed programs are matters of values and politics, and they require discussion, debate, and negotiation. Dialogue is necessary, and the sooner it begins with respect to nano, the better off everyone will be.

IV. EPA in the 21st CENTURY

In the 1960s and early 1970s, when environment first became a significant part of the national agenda, many thought that environmental protection was a transient function. They believed that society would eliminate air and water pollution, and that would take care of the problem. It is now almost universally recognized that the relationship between humans and the natural environment cannot be taken for granted. Environmental protection must be a continuing and important responsibility of government. Rather than disappearing, environmental protection is likely to become increasingly important as technology becomes increasingly powerful and thus gives humans ever more ability to impact their natural surroundings. Nano is a prototype of the environmental challenges of the 21st century.

Responsibility for environmental protection is widely shared, especially in the United States. State governments are at least as important as the federal government. Private corporations, universities, and non-profit organizations all have significant roles. Even within the federal government, EPA's expenditures are a small part of total funding for environmental protection. However, as its name implies, EPA has a central responsibility. It is the focal point for policy and regulation regarding environmental threats.

EPA's Problems

EPA has had a difficult history since it was cobbled together in 1970 out of a dozen existing programs. A comprehensive 1998 evaluation of the pollution-control regulatory system came to four general conclusions. First, the fragmented system is seriously broken. Its effectiveness in dealing with current problems is questionable, it is inefficient, and it is excessively intrusive. Second, the problems cannot be fixed by administrative remedies, pilot programs, or other efforts that tinker at the margins. They are problems that are built into the system of laws and institutions that Congress has enacted over 35 years. Third, the picture is not all bleak. The system has accomplished some solid victories in the quest for environmental quality. Fourth, a dearth of information of all kinds characterizes pollution control. The system lacks monitoring data to tell whether environmental conditions are getting better or worse; it lacks scientific knowledge about both the causes and the effects of threats to human and environmental health; and it lacks information that would tell us which programs are working and which are not (Davies and Mazurek 1998, p. 269).

More broadly, a distinguished trio of environmental policy experts recently summarized the premises of the leading environmental reform efforts as "(1) the need to reconceptualize what the aims and organizing principles are of environmental governance in the twenty-first century; (2) the need to reconnect . . . with citizens estranged from or disadvantaged by the environmental governance process . . . ; (3) the need to redefine administrative rationality as we have known and practiced it historically. . ." (Durant et al. 2004, p. xv).

In the context of dealing with nano, the areas in which major improvements are needed are agency science, policy integration, personnel, international cooperation, and evaluation.

EPA as a Science Agency

Nano oversight should be based on the generation and use of the best possible science. However, throughout its history, EPA's internal culture has been dominated by lawyers and engineers. Scientists have often been considered peripheral. This internal view has been reinforced by the outside world, in particular by other government science agencies, which often have viewed EPA science as not being of the highest quality and have questioned whether a regulatory agency should be doing any scientific work. The current EPA administrator is the first scientist to head the agency. How much impact he will have in changing the culture remains to be seen.

There are two reasons why EPA should conduct scientific research. The first is that EPA programs and regulations require scientific information, and the information will not be provided by any other agency. There is no question that it is very difficult to do high-quality science in an agency whose primary function is not research. However, every attempt to divide regulatory research from a regulatory agency has failed. The National Institute for Environmental Health Sciences (NIEHS), which is part of the National Institutes of Health, was created to provide EPA with the health research necessary for environmental regulations. The arrangement never worked. The National Institute of Occupational Safety and Health was created to provide the scientific information needed by OSHA. OSHA wound up getting most of its "science" from the labor unions or industry. The kinds of scientific questions posed by regulation and the need for interaction between regulators and scientists require that regulatory agencies have their own internal scientific capability. The alternatives are not to regulate or to regulate using poor and inadequate science.

The other reason for EPA to conduct research is that there are important areas of environmental research not covered elsewhere. Foremost among these areas are ecological research and research on the effects of pollutants. In both these areas, EPA research is considered to be necessary and is deemed to be of high quality. Both are high-priority research areas for nano.

If EPA is to become as much a science agency as a regulatory agency, and I believe that its becoming so would greatly benefit both environmental science and regulation, then it will require an infusion of scientific resources. The EPA dollars devoted to research and development now are not insignificant—about 7% or 8% of the EPA budget—but science in EPA is eclipsed in terms of resources, as well as in other ways, by other agency functions.

The best way to give EPA new scientific resources would be to transfer one or more existing environmental science units from other federal agencies. Likely candidates include environmental components of some of the Department of Energy's independent laboratories (e.g., Oak Ridge, Argonne, Brookhaven, Pacific Northwest); portions of the National Oceanic and Atmospheric Administration (now part of the Department of Commerce); and parts of the Geological Survey in the Department of Interior. Any of these would have a more logical and congenial home as part of EPA than as part of their current organizational location.

The internal organization of EPA should also be changed to reflect the elevated role of science. A few years ago, the National Research Council (2000) recommended creation of a deputy administrator for science and technology in EPA. The creation of such a position would send a signal, both within the

agency and outside it, that EPA was an important player in the science world and that it accorded scientific information the importance it was due.

The Need for Integration

In 1970, when EPA was created, the staff that had worked on the reorganization plan creating the agency also produced a plan for how the agency should be organized. The organizational plan called for a functional approach—there would be an office for research, for enforcement, for standards, for intergovernmental relations, and so forth. The media programs (air, water, solid waste) would be broken apart and their functions distributed among the new offices. When the agency became a reality, William Ruckelshaus, the first administrator, went half way towards implementing the functional plan. However, he balked at dismantling the media offices because of the imperative of showing early results and the realistic fear that if they were broken apart it would be several years before the agency could start showing concrete progress in cleaning up the environment. The result was an agency organized half along functional lines and half along media lines, an awkward compromise that has not changed since 1970.

EPA's internal fragmentation is also driven by the fragmented nature of environmental law. Each environmental statute is focused on a particular sub-portion of the environment and, for the most part, ignores all the other laws and parts of the environment. Some of the laws are focused on media, some are focused on types of products, and some cut across these categories. The whole is not more than the sum of the parts.

The advantage of this jumble is that when a new problem such as nano comes along there are lots of offices and laws that are potentially relevant to it. This is a disadvantage, however, because it makes a coordinated, integrated approach to the problem difficult to formulate and achieve.

The internal EPA problems are compounded by the multitude of agencies involved in nano. As noted earlier, 25 agencies participate in the NNI. For preventing adverse effects as well as for research, EPA needs to take account of what other agencies are doing. Obviously, to the extent that EPA is not internally coordinated it makes it more difficult for it to coordinate with other agencies.

The best solution for the fragmentation within EPA would be to have a single, integrated environmental protection law. This is theoretically possible (I have drafted such a law [see Conservation Foundation 1988]) but politically impossible. To deal with nano, it will be necessary for the agency to have an agency-wide plan that specifies what each EPA office will do and how it relates to other offices and other agencies. The decision to make the Office of Pollution Prevention and Toxics the lead office is an important first step in such a coordinated strategy.

EPA's relations with other agencies are more problematic. NNI is intended to serve as the federal government-wide coordinator for nano, and it has established a Nanotechnology Environmental and Health Implications (NEHI) Working Group whose purpose is, in part, to coordinate the work of the regulatory agencies. However, the members of the NEHI mostly come from the research parts of their agencies, and NNI is much more focused on science and research than on regulation. Also, the overall emphasis of NNI on promoting nano creates a tension with any consideration of regulating nano.

It would be desirable for EPA to initiate discussions with the FDA, OSHA, and CPSC

about coordinating and sharing relevant information about nano. This would serve to supplement, not replace, NNI's coordination.

Getting Good People

Institutions, administrative structures, and laws are important determinants of whether a government agency functions well. But no organization can work well without competent leadership and good employees. This has always been a problem for U.S. government agencies. The problem is compounded with respect to nano because the relative newness of the subject means that few people have experience or training in dealing with nano.

Getting and retaining good employees is particularly a problem for EPA. Many, perhaps most, EPA employees have been motivated largely by dedication to environmental protection and public health. Many of the original leaders and experts were officers in the Public Health Service, a semi-military corps with its own personnel system and its own perquisites. There are still about 75 Public Health Service officers on detail to EPA. A whole generation of civil servants who have been with EPA since it started in 1970 is now retiring. How will they be replaced?

There is a large literature on the civil service, and it is beyond the scope of this paper to review it. I will note only that it is hard to see what would attract good people to go to work for EPA or any other federal agency. The pay is significantly below what most potential employees could get in the private sector. Job security, which used to be an attraction, is less certain now—layoffs and arbitrary transfers occur with increasing frequency. Dedication to benefiting society remains an important motive, but after 25 years of politicians identifying government as part of the problem rather than part of the solution, the importance of this motive has been reduced. If society wants to attract good people to work for the government, it is going to have to figure out better ways to attract them.

Agency heads can influence the quality of the civil service by their rhetoric, by their own leadership, and by the quality of the appointments they make. Good leadership can inspire an entire agency. Bad leadership can erode morale and scar an agency for many years. The president, Congress, and the American electorate share responsibility for the quality of agency leaders.

At present, there is a vicious downward spiral at work. As the quality of government employees declines, the competence of the agency deteriorates, it becomes harder to attract good civil servants, and agency competence deteriorates still further.

One way of getting around the problem of attracting good government employees is to contract with the private sector for the performance of functions that formerly were performed by civil servants. There is no limit to what kinds of functions can be contracted out. In Iraq, we are seeing a war in which almost half the U.S. personnel are civilian contractors.

Since its inception, EPA has done a lot of contracting with the private sector. In part this is because OMB and Congress ration both money and personnel slots, and for EPA, money has often been more available than slots. It is also because of the broad range of expertise needed to implement the environmental laws. The laws touch every economic sector, so if, for example, the agency wants an expert in water pollution control in the steel industry, or an expert in waste management in paper mills, it makes more sense for EPA to contract with an expert in the private sector than to hire and retain experts in all the areas it covers. By contracting, the agency can buy

not only expertise but also credibility with the regulated industry, which often uses the same contractors.

However, there are significant drawbacks to contracting. In many cases, it is more expensive to use contactors than government personnel. Contractors' work is usually less transparent and less responsible to the public than work done in-house. Contractors may be less familiar with the requirements of government policy processes than civil servants.[4]

As with the civil service, there is a large literature on contracting out government functions, and it is beyond this paper to analyze it. For EPA, contracting will likely remain an important element in meeting the agency's personnel needs. Nano is an area where consultants and contractors can give the agency some of the expertise it requires.

The International Context

International cooperation is a requirement for dealing successfully with nano, but EPA suffers from at least two impediments in dealing with international matters. The first is the structure and traditions of the federal government, which give primacy in international matters to the State Department. In recent years, as international meetings and negotiations increasingly have involved specialized knowledge, this primacy has been eroded. Leadership in international meetings is now often the responsibility of the substantive agency. For example, Dr. Jim Willis, Director of the EPA Chemicals Control Division, chairs the Organization for Economic Cooperation and Development (OECD) Working Party on Manufactured Nanomaterials (described below). However, especially for major environmental meetings, there is still jockeying for primacy between State and EPA.

The other, and probably more serious, impediment has been the indifference of some EPA leaders to the international dimension of environmental problems. William Reilly, the EPA administrator from 1989 to 1993, cared deeply about international environmental matters, and he elevated the EPA International Office to the same level as the media (air, water) offices. However, some of his predecessors and successors have shown a remarkable lack of concern for the role of other countries and international organizations and a notable insensitivity to the international dimension of EPA's responsibilities. Currently the EPA Office of International Affairs has a grand total of 77 FTEs, less than half of one percent of agency employees.

International cooperation on nano is essential because the amount of research and testing needed for nano exceeds the capacity of any one country, even the United States. Testing of nanoproducts should be supplemented by reporting of any adverse effects resulting from using the products, and this reporting needs to be worldwide. Nano regulatory requirements will also require cooperation among nations. Both the manufacture and the marketing of nanoproducts is likely to involve many countries. No regulatory effort will work if it does not deal successfully with imports and exports of nano materials and products. It is probably unrealistic in the short term to have an internationally harmonized regulatory scheme for nano. However, the lack of regulatory harmonization will likely result in both economic distortions and greater risk to health and the environment.

4. For examples, see Shane and Nixon 2007.

The primary international effort on nano is in the OECD, which includes Europe, the United States, Canada, and Japan. The OECD Chemicals Committee has established a Working Party on Manufactured Nanomaterials. The first meeting of the Working Party was in October 2006, and it is scheduled to meet again in April 2007. Its Program of Work addresses three main areas: (1) identification, characterization, definitions, terminology and standards; (2) testing methods and risk assessment; and (3) information sharing, cooperation, and dissemination. The OECD intends, among other activities, to develop a global strategy for environmental health and safety research on manufactured nanomaterials and to establish a database of such research (*Nanowerk News*, 1/11/07).

In February 2007, the United States and the European Union signed an agreement to cooperate on various aspects of environmental research (*Nanowerk News*, 2/9/07). "Uses and impacts of nanotechnology" was prominently listed as one of the topics. Cooperation under the agreement is expected to take many forms, including direct collaboration on research, joint sponsorship of conferences, and exchanges of information and data.

There is no existing formal effort to cooperate internationally on nano regulation in part because no nation has established regulations primarily directed at nano. The OECD Working Party intends to be a forum for exchanging information on national regulatory programs and voluntary regulatory schemes. The European Commission recently has enacted a far-reaching regulatory approach for chemicals, REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals, Directive 2006/121/EC), but it contains nothing specific about nano. There is uncertainty about how and to what extent it will cover nano since its requirements are based primarily on the volume of a substance produced (see **ec.europa.eu/enterprise/reach**).

The international dimension should get more attention and priority within EPA. It becomes ever clearer that no nation can successfully deal with environmental problems on its own. The issues raised by nano show, in part, why this is true.

Evaluating Programs, Measuring Progress

Rational public policy requires program evaluation. Without an ongoing evaluation function there is no way of telling whether programs are working, whether the agency's mission is being accomplished, or how agency activities can be improved in the future.

Despite the obvious need for evaluation, the evaluation capability of most federal agencies has steadily eroded. EPA used to have a policy office that evaluated programs and prodded the agency to take a more integrated approach. Administrator Carol Browner abolished the office, and none of her successors has seen a need to re-create it. EPA, like most agencies, now has essentially no internal capability to determine whether its programs are working. (A partial exception in EPA and other agencies is the inspector generals' offices. However, these offices usually focus only on cases of negligence and criminal activity. Also, EPA has a small evaluation group within what is left of the policy office, but it has fewer than 10 people.)

Evaluation is difficult to perform within an agency because it is often a form of self-criticism and because, in the short run, it takes resources away from the direct performance of program functions. The erosion of evaluation throughout the government has

resulted from a long period of scarce resources combined with a general climate of caring more about united fronts and public relations than about whether an agency's job was getting done.

The Government Accountability Office (GAO), an arm of Congress that maintains a good deal of independence, continues to do high quality evaluations of federal programs. Within the Executive Branch, there are two efforts devoted to evaluation—the Government Performance and Results Act (GPRA) and the Program Assessment and Rating Tool (PART).

GPRA, the culmination of a long line of programs that began in the Department of Defense in the 1960s, attempts to provide a system whereby each agency establishes program goals and measures its progress toward reaching them. Ideally, the GPRA benchmarks are tied to the agency's budget, so Congress and the public can know what they are buying with appropriated funds. Many agencies, including EPA, have found it difficult to establish a close connection between GPRA and the budget. The goals in EPA's five-year Strategic Plan (**www.epa.gov/ocfo/plan/2006/**), required by GPRA, mention nanotechnology both as an environmental asset and as a potential source of novel risks. However, the goals are vaguely worded, not quantifiable in any way, and overall not much use either for evaluation or for strategic planning.

PART is administered by OMB. It rates selected government programs on several dimensions and gives the detailed results on a very accessible website (**www.whitehouse.gov/omb/part**). At present, it contains nothing specifically related to nano. PART has rated 51 EPA programs. The majority, 33 programs, were rated "adequate," meaning that the programs need to "set more ambitious goals, achieve better results, improve accountability or strengthen . . . management practices." No EPA programs got the highest rating, "effective." Twelve were rated "moderately effective," three were rated "ineffective," and three were categorized as "results not demonstrated."

If EPA is to be responsible for nano oversight, it needs to establish measures of progress and be able to evaluate the extent to which progress is being made. I suggest that EPA should consider using four measures to assess its nano efforts:

1. the number of substances (or products) that have been tested for adverse effects as a proportion of those that need to be tested—one aspect of the adequacy of knowledge about nano health and environmental effects;

2. the incidence of actual adverse effects from nano—at the moment, as far as we know, this number is zero;

3. the dollar growth in nano manufacturing and/or sales—this serves both as a measure of EPA's task and as a reminder that the effort to ensure safety needs to be tempered by minimal interference with the development of the technology; and

4. a measure of the number of green nanoproducts.

The data for each of these measures will be difficult to collect, and undoubtedly the measures will be modified or altered in the light of experience. However, the principle that the agency should track such measures and make them public on a regular basis is fundamental.

EPA should also re-establish an internal evaluation capability. This is necessary not only to do evaluation but also to give the administrator some control over agency programs and thereby provide greater integration among programs. Technologies such as nano do not fit neatly into the agency boxes established to implement the separate environmental laws. They require interaction among the different EPA programs. This will be even truer if the science capability of EPA is enlarged. The agency needs a policy office to cope with nano.

A policy office could also assist EPA in broadening its mission from environmental protection to sustainable development. Sustainable development is a much abused term which has been given many meanings. I am using it to encompass three dimensions: environmental protection, economic development, and equity. The term was originally popularized by the 1987 report of the World Commission on Environment and Development. The commission defined it as "development that meets the needs of the present without compromising the ability of future generations to meet their own needs." The International Institute for Environment and Development (1996, p. 5) elaborated this to be a development path that is socially desirable, economically viable, and ecologically sustainable.

This definition of sustainable development is relevant to EPA and nano because, while recognizing the agency's responsibility for protecting health and the environment from any adverse effects of nano, it would also acknowledge the responsibility of the agency not to unduly impede nano's economic development. The equity element is relevant in acknowledging EPA's responsibility to encourage the application of nano for beneficial uses, such as green nano products. It also recognizes the agency's concern for "environmental justice."

I have sketched a vision of a new EPA—stronger in science, far more integrated, aware of its international responsibilities, capable of evaluating its efforts and measuring its progress, and inspired by a new vision of sustainable development. None of this will happen easily or quickly. But nano, the technology of the future, can provide an opportunity to create the EPA of the future. Nano, EPA, and future technological development will benefit if this happens.

V. Next Steps

Throughout this report, I have described steps that, in my view, should be taken to ensure the safety and progress of nanotechnology. I have also referred to proposals made by others that would further creation of an oversight system for nano. In this chapter, I pull these proposals together to describe an action agenda for nano.

The chapter is organized into actions that should be taken in the next one or two years, the next two to five years, and the more distant future. Items are numbered for ease of reference and the numbers do not indicate any priority. Within each time period, I have organized the items loosely by their primary focus—research, regulation, and other.

Unlike the list of possible regulatory approaches in Chapter III, the list of next steps is not a matter of picking and choosing. *All* of the next steps should be taken.

The most important steps relate to the establishment of an adequate oversight system. This effort should proceed on two fronts. The first is using TSCA in its current form. Deficient as it is, TSCA is still the only existing law that can serve as the basis of a general oversight system for nano. EPA should revise the TSCA regulations to better deal with nano (recommendations #7 and #8) and it should launch its voluntary program (#6) to improve its ability to know what information on nano to collect and how to analyze the information. Using TSCA for nano oversight will also require coordination both within EPA (#9) and between EPA and other regulatory agencies (#10).

The other front is longer range. It involves fixing the major problems with TSCA, which requires legislation (#23), and the formulation of new and better oversight approaches (#5 and #15). Although the outcome of the attempt to develop better approaches cannot be predicted, the formulation of such approaches is essential and pressing.

The other two priority areas are research and improving EPA. The need for more research on nano and for giving more focus to the research being done has been well documented by others (see Maynard 2006a, 2006c). More progress has to be made on understanding whether nano has adverse health and environmental effects, what the effects are, and what characteristics of nano materials and products are associated with any adverse effects. A number of next steps are directed at obtaining this knowledge.

In Chapter IV, I described several areas in which EPA needs to change if it is to successfully meet the challenge of overseeing nano. Formulating detailed recommendations to bring these changes about will require obtaining a lot of information from EPA and stakeholders and doing a lot of thinking. Therefore, I recommend (#16) that a commission be established to consider and make recommendations to revitalize EPA.

The next steps are described below (and listed in Table 5.1). The agenda is long, and many of the proposals will be difficult to get approved and implemented. The challenge is important. For those of us concerned with making sure that society reaps the benefits of nano while not causing harm to people or the environment, there is no shortage of work to do.

One to Two Years

Research

1. NNI should immediately revise its existing research plan for nano health and environmental effects, drawing on the expertise of non-governmental nano researchers.

2. The National Nanotechnology for the Twenty-First Century Act (117 Stat1923) should be amended to require NNI to issue a research plan for health and environmental effects every three years and to circulate the plan for public comment before finalizing it.

3. EPA and/or the NIEHS should initiate discussions with major nano companies about creation of a joint government-industry institute, the Nanotechnology Effects Institute, to conduct scientific research on the effects of nano. The new institution could be modeled on the Health Effects Institute, which was created by EPA and the automobile industry.

4. Funding for strategically targeted research on health and environmental effects of nano should be increased to at least $50 million annually.

Regulation

5. NNI, PEN, the Congressional Nano Caucus, or some other group should convene industry, environmental groups, and other stakeholders to begin a dialogue, facilitated by a neutral third party, to discuss the optimal form of oversight for nano. The group should coordinate with Congress and the relevant federal agencies, and they in turn should set a deadline for the group to agree on specific recommendations and next steps for nano oversight.

6. EPA should launch its nano voluntary program.

7. EPA should formulate changes to TSCA to deal with nano. These should include both changes in regulations (e.g., low-volume exemption) and changes in the law (see #23). The changes in regulation should be implemented.

8. EPA should promulgate a significant new use rule under TSCA that covers all nanomaterials.

9. EPA should formulate and implement an internal coordination plan for nano. The plan should delineate the responsibilities of each EPA office with respect to nano. In cases of overlap (e.g., FIFRA and the CWA with respect to silver washing machines), the plan should decide how the cases will be handled.

10. EPA should work with FDA, OSHA, CPSC, and USDA to create an interagency nano regulatory coordinating group. This group should meet approximately monthly to formulate and coordinate regulatory actions with respect to nano. It should agree on which agency has the lead in cases of overlapping jurisdiction and, to the extent that it is reasonable, it should agree on uniform ways to treat nano products and materials.

11. Congress should request that the GAO, in cooperation with the State Department, conduct a study of what other nations are doing with respect to nano regulation and oversight.

12. The NNI should establish and publish metrics to evaluate the success of the program. The measures should be updated annually.

13. The NNI, perhaps with funding from NSF, should commission a study, or series of studies, on the economics of nano. The studies should examine the likely impact of nano on the U.S. economy, identify the areas of the economy most likely to be affected by nano, and analyze the economic impact of the NNI and how net benefits can be maximized.

14. The NNI should commission a study of the pros and cons of labeling nanomaterials and nanoproducts. The study should consider the effectiveness, cost, and feasibility of labeling, and also consider alternative types of labels and the extent to which different types of nanoproducts should be covered.

15. Congressional leaders should establish a new temporary committee in each house to consider options for a regulatory mechanism for nano. The House and Senate groups should facilitate coordination among the relevant committees in each house, including the conduct of joint hearings on nano oversight by the relevant committees.

Other

16. The president and the congressional leadership should convene an EPA Modernization Commission. The commission should be composed of experts from outside the government, including experts from business and from the environmental community. It should consider how to update environmental law, how to improve the functioning of EPA, and how to address future environmental problems. The commission's mandate should include consideration of both existing and new legislation.

17. Congress should commission GAO to do a study of what resources (dollars, FTEs, expertise) federal agencies are currently devoting to nano health and safety, both research and regulation. (In March 2007, the Senate Commerce Committee sent GAO a letter asking it to do such a study.) Congress should then conduct a hearing to consider whether these resources are adequate.

18. NNI, with funding primarily from NSF, should increase its public education and participation efforts. A primer on nanotech, aimed at lay audiences, should be produced and widely distributed. An Internet dialogue and chat room on nano should be started. Consideration should be given to holding televised town meeting and science court sessions on nano.

19. EPA should re-establish a policy office with responsibilities for coordinating agency programs, program evaluation, and measuring progress toward agency goals.

20. Congress should hold hearings for the purpose of amending the Federal Advisory Committee Act to update the Act and to facilitate public participation.

Two to Five Years

Research

21. The National Nanotechnology Act should be amended to provide a mechanism that facilitates NNI funding the priorities it identifies. One mechanism, for example, would be to establish a separate pot of money (5–10% of agency nano budgets) distributed by the Office of Science and Technology Policy (OSTP) and OMB to fill gaps identified in the NNI research

plans. An alternative would be to have an NNI steering committee (including OMB and OSTP) that was authorized to reallocate a certain percentage of each agency's budget to better meet NNI-identified priorities.

22. The Nanotechnology Effects Institute should begin operation. Congress should provide separate funding for the Institute in the EPA or NIEHS budget.

Regulation

23. Congress should amend TSCA.
    - **A.** It should delete the constraints that make rulemaking nearly impossible. EPA should not be required to show that a rule uses "the least burdensome requirements" (sec. 6(a)). EPA should not have to show that the risk being regulated could not be sufficiently reduced under any other federal law (sec. 6c(1)).
    - **B.** It should change the criterion for judicial review to the "arbitrary and capricious" standard that is used for most other federal regulations instead of "supported by substantial evidence in the rulemaking record."
    - **C.** It should amend the part of the Act allowing EPA to require testing of a substance (section 4) to make clear that the absence of data is sufficient evidence that the substance may present an unreasonable risk. This would allow EPA to require a manufacturer to produce enough data to determine whether a chemical actually was an unreasonable risk.
    - **D.** It should authorize EPA to share confidential business information with states and foreign governments, provided the data are adequately protected.

24. The recommendations of the EPA Modernization Commission should be considered for implementation.

25. Relevant trade associations, such as the American Chemistry Council and the Nanotechnology Business Alliance, should establish industry codes of conduct related to nano. The codes should cover testing, safe handling, and requirements for suppliers and customers. The codes should be open to public review before being made final, and compliance with the codes should be subject to third-party verification.

26. EPA, working with the State Department and other relevant agencies, should fully support the OECD mechanisms for exchange of nano research results.

Beyond Five Years

Crystal balls get cloudy when trying to foresee more than five years ahead. The only thing that can be said with certainty is that the political, cultural, and technological landscape is likely to look different in 2012 or 2015 than it does now.

If the general argument of this paper is accepted, then over the next five years a coordinated and effective oversight system for nano should be put in place. Whether it will be able to adjust to the rapid evolution of the technology will be its severest test.

A major thrust of this report has been that nano can serve as the catalyst for a born-

TABLE 5.1. PROPOSED ACTIONS (NUMBERS REFER TO ACTION ITEMS IN TEXT)

	Proposed Agenda Items for the Next 1 to 2 Years
Research	1. NNI revise its research plan for nano health and environmental effects.
	2. Congress amend the National Nanotechnology for the Twenty-First Century Act to require NNI to issue a research plan for health and environmental effects every three years.
	3. EPA and/or NIEHS initiate discussions with nano companies about creation of a joint government-industry nano effects research institute.
	4. Congress increase funding for strategically targeted research on health and environmental effects of nano to at least $50 million annually.
Regulation	5. Industry, environmental groups, and other stakeholders begin a dialogue.
	6. EPA launch its nano voluntary program.
	7. EPA formulate changes to TSCA to deal with nano.
	8. EPA promulgate a significant new use rule under TSCA that covers all nanomaterials.
	9. EPA formulate and implement an internal coordination plan for nano.
	10. EPA work with FDA, OSHA, CPSC, and USDA to create an interagency nano regulatory coordinating group.
	11. Congress request that the GAO conduct a study of what other nations are doing with respect to nano regulation and oversight.
	12. NNI establish and publish evaluation metrics.
	13. NNI commission a study on the economics of nano.
	14. NNI commission a study of the pros and cons of labeling nanomaterials and nanoproducts.
	15. Congress establish a temporary committee in each house to consider options for a regulatory mechanism for nano.
Other	16. The president and Congress convene an EPA Modernization Commission.
	17. Congress commission GAO to study what resources federal agencies are currently devoting to nano health and safety, both research and regulation, and then conduct a hearing to consider whether these resources are adequate.
	18. NNI, with funding primarily from NSF, increase its public education and participation efforts.
	19. EPA re-establish a policy office with responsibilities for coordinating agency programs, evaluating programs and measuring progress toward agency goals.
	20. Congress hold hearings to amend the Federal Advisory Committee Act to facilitate public participation.
	Proposed Agenda Items for the Next 2 to 5 Years
Research	21. Congress amend the National Nanotechnology Act to facilitate NNI funding the priorities it identifies.
	22. The Nanotechnology Effects Institute begin operation; Congress provide separate funding for the Institute in the EPA or NIEHS budget.
Regulation	23. Congress amend TSCA to remove the constraints that make rulemaking nearly impossible, to change the criterion for judicial review to the "arbitrary and capricious" standard, to require manufacturers to produce enough data, and to authorize EPA to share confidential business information with states and foreign governments, provided the data are adequately protected.
	24. The White House consider the recommendations of the EPA Modernization Commission for implementation.
	25. Trade associations establish industry codes of conduct related to nano.
	26. EPA, working with the State Department and other relevant agencies, fully support the OECD mechanisms for exchange of nano research results.

Note: For acronyms used, see list at end of report.
Row shading corresponds with lead organization for each action item.
Key: NNI = ■ Congress = ■ EPA = □ White House = ■ Nano industry = ■

TABLE 5.2. ACTION ITEMS BY LEAD ORGANIZATION (NUMBERS REFER TO ACTION ITEMS IN TEXT)

Lead Organization	1–2 Years	2–5 Years
Congress	2,4,11,15,16,17,20	21,22,23
President	16	24
NNI	1,12,13,14,18	
EPA	3,6,7,8,9,10,19	26
Nano industry	3,5	25

again EPA. In five years, we could hope to see the beginnings of an agency with a new mission, an improved competence, and new energy and dedication.

A summary list of the proposals is provided in Table 5.1. Table 5.2 summarizes which organizations should take the lead in initiating action.

My hope is that this report, by planting a few ideas and stimulating a few activities, will contribute to realizing these changes. Nano is on the verge of having a huge positive impact on our lives. It can improve our health, increase energy supplies, facilitate environmental cleanup in rich countries, and provide potable water in poor countries. The possibilities are hard to exaggerate, but they rest on a major vulnerability—the lack of an adequate oversight system to deal with potential adverse health and environmental effects. We need to remedy this vulnerability to secure the benefits of the technology.

Nano has great promise and presents great challenges. If we can meet its challenges, we will ensure that its promise will be fulfilled.

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Acronyms

ABA	American Bar Association
ACC	American Chemistry Council
ASTM	(originally the American Society for Testing and Materials)
CAA	Clean Air Act
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CPSC	U.S. Consumer Product Safety Commission
CWA	Clean Water Act
ELI	Environmental Law Institute
EMS	Environmental Management System
EPA	U.S. Environmental Protection Agency
FACA	Federal Advisory Committee Act
FDA	U.S. Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FR	Federal Register
FTE	full-time equivalent positions
FY	fiscal year
GAO	U.S. Government Accountability Office
GPRA	Government Performance and Results Act
ISO	International Organization for Standardization
LoREX	Low Release and Exposure Exemption (under TSCA)
NEHI	NNI Nanotechnology Environmental and Health Implications Working Group
NIEHS	National Institute of Environmental Health Sciences
NNI	National Nanotechnology Initiative
NRC	National Research Council
NRDC	Natural Resources Defense Council
NSF	National Science Foundation
OECD	Organization for Economic Cooperation and Development
OMB	U.S. Office of Management and Budget
OPPT	EPA Office of Pollution Prevention and Toxics
ORD	EPA Office of Research and Development
OSHA	U.S. Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
PART	Performance Assessment and Ratings Tool
PEN	Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars
PMN	Pre-Manufacturing Notification (under TSCA)
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals (EC Directive 2006/121)
SAR	structure-activity relationship (of chemicals)
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
USDA	U.S. Department of Agriculture

Selected Additional Products from the Project on Emerging Nanotechnologies*

Reports

PEN 1: Jane Macoubrie, *Informed Public Perceptions of Nanotechnology and Trust in Government*, September 2005.

PEN 2: J. Clarence Davies, *Managing the Effects of Nanotechnology*, January 2006.

PEN 3: Andrew D. Maynard, *Nanotechnology: A Research Strategy for Addressing Risk*, July 2006.

PEN 4: Jennifer Kuzma and Peter VerHage, *Nanotechnology in Agriculture and Food Production: Anticipated Applications*, September 2006.

PEN 5: Michael R. Taylor, *Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?*, October 2006.

PEN 6: Karen F. Schmidt, *NanoFrontiers: Visions for the Future of Nanotechnology*, March 2007.

PEN 7: Mark Greenwood, *Thinking Big about Things Small: Creating an Effective Oversight System for Nanotechnology*, March 2007.

PEN 8: Karen F. Schmidt, *Green Nanotechnology: It's Easier Than You Think*, April 2007.

Congressional Testimonies

David Rejeski, "Environmental and Safety Impacts of Nanotechnology: What Research Is Needed," United States House of Representatives, Committee on Science, November 17, 2005.

J. Clarence Davies, "Developments in Nanotechnology," United States Senate, Committee on Commerce, Science and Transportation, February 15, 2006.

David Rejeski, "Promoting Economic Development Opportunities Through Nano Commercialization," United States Senate, Committee on Commerce, Science and Transportation, Subcommittee on Trade, Tourism and Economic Development, May 4, 2006.

Andrew D. Maynard, "Research on Environmental and Safety Impacts of Nanotechnology: What Are the Federal Agencies Doing?" United States House of Representatives, Committee on Science, September 21, 2006.

Inventories

Nanotechnology Environment, Health and Safety Risk Research, released November 2005.

Nanotechnology Consumer Products, released March 2006.

Agrifood Nanotechnology Research and Development, released March 2006.

Nanotechnology and Medicine, released October 2006.

* These and other materials are available at http://www.nanotechproject.org.

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