

# CRS Report for Congress

## Engineered Nanoscale Materials and Derivative Products: Regulatory Challenges

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Linda-Jo Schierow  
Specialist in Environmental Policy  
Resources, Science, and Industry Division



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Committees of Congress

# Engineered Nanoscale Materials and Derivative Products: Regulatory Challenges

## Summary

Scientists and engineers are rapidly learning how to examine, design, and manipulate materials at the molecular level, termed “nanoscale,” between 1 and 100 billionths of a meter. The U.S. government has invested billions of dollars to ensure that American industry remains a global leader in the field, because the products of nanotechnology are seen to have great economic potential and offer possible solutions to national problems ranging from energy efficiency to detection of agents of biological warfare. Optimism about nanotechnology is tempered, however, by concerns about the unknown potential of nanoscale materials to harm the environment and human health. Some have called for federal regulation of potential environmental, human health, and safety (EHS) risks, arguing that the lack of federal EHS regulations increases the risks of unanticipated adverse consequences due to human or environmental exposure to engineered nanomaterials. The cost of such consequences would depend on their actual, as well as publically perceived, severity, frequency, and reversibility. The cost to the nanotechnology industry could be great, if consumers responded to a potential threat of harm by indiscriminately rejecting all products of nanotechnology, rather than the offending nanomaterial or an individual application. Others oppose federal regulatory requirements, arguing that they might unnecessarily delay the environmental, health, and economic rewards expected from nanotechnology.

Questions about the need for, and ideal form of, nanotechnology regulations are exceedingly difficult to address, given the current state of scientific understanding of engineered nanoscale materials. The purpose of this report is to consider certain challenges faced by scientists, entrepreneurs, and government officials in the 25 agencies involved in the National Nanotechnology Program, as they strive to define the characteristics of nanomaterials, the EHS risks they might pose, and how any potential risks should be addressed. Challenges include the wide variety of nanomaterials and applications; lack of basic information about their properties; lack of conventions for naming, measuring and identifying nanomaterials; the proprietary nature of some critical information; the need to prioritize federal resource needs; and a possible lack of clear statutory authority or appropriate regulatory framework to anticipate or respond to any identified risks.

These difficulties may be surmounted over time without significant legislative action, or Congress may choose to intervene. If it does, it might choose any of several approaches. Possible approaches include increasing funding for workshops in standardization or other research relevant to identifying and possibly ameliorating any environmental or human health and safety concerns associated with nanomaterials; changing the allocation of research money among agencies or the interagency research management structure; adopting a national or international research strategy; or enacting legislation that authorizes, mandates, or constrains agency actions to require information collection or to restrict production, sale, use, or disposal of nanomaterials. Each risk management approach has potential positive and negative consequences that Congress may want to consider.

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# Engineered Nanoscale Materials and Derivative Products: Regulatory Challenges

## Introduction

U.S. scientists and engineers who are working at the molecular level, or nanoscale, are developing novel materials and derivative products at a rapid pace. The unique physical, chemical, and biological properties of engineered nanoscale materials lend themselves to a huge array of applications that, some analysts believe, will transform industries, foster sustainable economic growth, deliver more effective treatments for chronic diseases, and vastly improve energy efficiency. Many nations, including the United States, are eager to lead this nanotechnology revolution, and to reap its benefits. The European Union has been particularly active, but there also is intense activity in Japan, China, and other nations.

In the United States and some other nations, enthusiasm and investment in nanotechnology are somewhat restrained, however, by questions about the possible environmental, human health, and safety (EHS) risks associated with this new technology. Does nanotechnology pose risks to human health or the environment that are not being adequately controlled? If so, how will consumers here and abroad react if possible hazards are identified? Should commerce in nanomaterials or associated products be subjected to some level of government regulation? If so, do federal agencies have sufficient statutory authority, expertise, and resources to regulate potential EHS risks of engineered nanoscale materials and derivative products? The answers to such questions may determine the nature, timing, distribution, and extent of the social and economic costs and benefits associated with nanotechnology.

Some groups are calling on Congress to regulate engineered nanoscale materials and derivative products to control potential EHS risks, arguing that lack of federal regulation might increase the risks of unanticipated adverse consequences. The cost of such consequences would depend on their actual, as well as publically perceived, severity, frequency, and reversibility. The cost to the nanotechnology industry also could be great, if consumers responded by indiscriminately rejecting all products of nanotechnology, rather than the offending nanomaterial or an individual application. Others oppose federal regulatory requirements, arguing that they might unnecessarily delay the environmental, health, and economic rewards expected from nanotechnology.

Questions about the need for, and ideal form of, regulation for nanotechnology are exceedingly difficult to address, given the current state of scientific understanding of engineered nanoscale materials. The purpose of this report is to consider certain challenges faced by federal EHS risk assessors, risk managers, and policy makers, and to discuss possible legislative approaches to address those challenges.

**The Nature of Nanotechnology.** “Nanotechnology” encompasses a broad range of techniques for producing and manipulating tiny particles, thin films, and other materials at such minute dimensions that quantum effects have a measurable influence on the constituent atoms.<sup>1</sup> At this scale, the basic chemical, physical, and biological properties of materials can vary with slight increases and decreases in dimensions between 1 and 100 billionths of a meter. For example, slightly smaller or larger nanomaterials may be more or less magnetic or able to conduct electric currents, or they may absorb and reflect different wavelengths of light. Thus, for example, nanoparticles of gold can be red, yellow, or blue, depending on size and shape. Even when the properties of nanoscale and bulk materials are similar, they may be enhanced at the nanoscale because of the very high surface area of nanoparticles relative to their total volume. Thus, for example, relatively small doses of therapeutic drugs contained in nanoparticles may be more effective than larger doses of the same drugs contained in larger particles.

**Nanotechnology in the United States.** The ability to manipulate molecules to exploit particular properties promises a wealth of potential applications. The United States is a leader in the field, with many patents for commercial applications of nanotechnology granted and pending and hundreds of products incorporating nanoengineered materials being marketed. Currently available products that incorporate nanomaterials include certain cosmetics, sunscreen, tennis balls, food additives, clothes washers, and odor-free clothing. According to experts, anticipated products of nanotechnology range “from faster-burning rocket fuel additives to new cancer treatments, filters to assist in cleaning the environment, and remarkably accurate and simple-to-use detectors for biological toxins such as anthrax.”<sup>2</sup>

To encourage and coordinate nanotechnology research and development in the United States, the President established the interagency National Nanotechnology Initiative (NNI). Launched in the President’s FY2001 budget request, the NNI was codified and further defined when Congress enacted the 21<sup>st</sup> Century Nanotechnology Research and Development Act (Public Law 108-153) in December 2003. In accordance with the act, the President’s National Science and Technology Council, through its Subcommittee on Nanoscale Science Engineering and Technology (NSET), oversees planning, coordination, and management of the National Nanotechnology Program (NNP).<sup>3</sup> The law requires the NNP to set goals, priorities, and means of measuring progress for nanotechnology research, and to authorize and

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<sup>1</sup> Quantum effects are the result of quantum physics, rules that predict the behavior of matter and energy at the atomic level, where the more familiar laws of classical physics do not apply.

<sup>2</sup> Ratner, Mark, and Daniel Ratner. 2003. *Nanotechnology: A Gentle Introduction to the Next Big Idea*. Prentice Hall: Upper Saddle River, NJ. p. 3.

<sup>3</sup> The National Science and Technology Council (NSTC) is chaired by the President and includes the Vice President, the Director of the Office of Science and Technology Policy, Cabinet Secretaries and Agency Heads with significant science and technology responsibilities, and other White House officials. According to its website, “It is the principal means within the executive branch to coordinate science and technology policy across the diverse entities that make up the Federal research and development enterprise.”

coordinate funding by federal agencies that promotes nanotechnology research and development (R&D). The NSET does not have budget authority or appropriations for the NNP. Rather, each agency allocates part of its budget to nanotechnology and reports its efforts to the NSET.

### **Federal Agencies in the National Nanotechnology Program.**

According to the NNI, “Twenty-six federal agencies participate in the [National Nanotechnology] Initiative, 13 of which have an R&D budget for nanotechnology. Other Federal organizations contribute with studies, applications of the results from those agencies performing R&D, and other collaborations.”<sup>4</sup> The distribution of the actual FY2006 total and EHS R&D budget among agencies and departments of the NNI is shown in **Table 1**. The Environmental Protection Agency (EPA), the Food and Drug Administration (FDA, within the Department of Health and Human Services), the Consumer Product Safety Commission (CPSC), and the Occupational Safety and Health Administration (OSHA, within the Department of Labor), are actively exploring the EHS implications and possible risks of nanotechnology and the possible need for regulations.<sup>5</sup> Later sections of this report refer to these four agencies as the regulatory agencies.

**Possible Risks of Nanotechnology.** While the potential economic gains and beneficial uses for nanotechnology are exciting prospects, the potential risks associated with nanoparticles are an issue for some scientists, policy makers, and consumer and environmental groups. Congress directed the NNP to ensure that such concerns would be considered as nanotechnology develops.

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<sup>4</sup> National Nanotechnology Initiative. About the NNI. [[http://www.nano.gov/html/about/home\\_about.html](http://www.nano.gov/html/about/home_about.html)], visited January 10, 2008.

<sup>5</sup> These agencies do not distinguish work conducted on nanotechnology from other work, and do not report budget figures to the NNI. Moreover, OSHA and FDA do not conduct toxicological research, although they do apply the results of such research in risk assessments as a basis for regulatory decisions.

EPA Science Advisory Board, Board of Scientific Counselors. Meeting summary, October 19-20, 2006. p. 26.

National Science and Technology Council, Committee on Technology, Subcommittee on Nanoscale Science, Engineering, and Technology. *The National Nanotechnology Initiative: Research and Development Leading to a Revolution in Technology and Industry*. Supplement to the President’s 2008 Budget, July 2007, pages 7 and 11. Hereafter cited as the FY2008 Budget Supplement.

**Table 1. FY2006 Actual Budget for  
the National Nanotechnology Initiative (NNI) and  
Environmental, Health, and Safety (EHS) Research**  
(dollars in millions)

Agency/Department	NNI	EHS <sup>a</sup>
Department of Defense	\$423.9	\$1.0
National Science Foundation	359.7	21.0
Department of Energy	231.0	0.5
Department of Health and Human Services (National Institutes of Health and National Institute for Occupational Safety and Health)	195.4	9.0
Department of Commerce (National Institute of Standards and Technology)	77.9	2.4
National Air and Space Administration	50.0	0.0
Department of Agriculture (Forest Service and Cooperative State Research, Education, and Extension Service)	6.2	0.1
Environmental Protection Agency	4.5	3.7
Department of Homeland Security	1.5	0.0
Department of Transportation	0.9	0.0
Department of Justice	0.3	0.0
<b>TOTAL</b>	<b>\$1,351.2</b>	<b>\$37.7</b>

**Source:** National Science and Technology Council, Committee on Technology, Subcommittee on Nanoscale Science, Engineering, and Technology. *The National Nanotechnology Initiative: Research and Development Leading to a Revolution in Technology and Industry*. Supplement to the President's 2008 Budget, July 2007, pages 8 and 11.

a. EHS funding also is included in total NNI funding.

Scientific concern is based in part on some of the very properties that researchers hope to exploit. For example, scientists hope to use certain nanoparticles to deliver medicine to infected tissues where it can best fight disease with a minimum of unintended side effects. The small size of nanoparticles may allow them to pass easily through the skin and internal membranes. This raises questions, however, of whether exposure to nanoparticles can be effectively confined to targeted tissues, or whether environmental releases could be captured, removed from environmental media, or rendered harmless. Similarly, while high surface-area-to-mass ratio may allow nanoparticles to deliver potent doses of medicine in tiny packages, it also might amplify any toxicity of particles inadvertently encountered.<sup>6</sup>

<sup>6</sup> Science Policy Council, Nanotechnology Workgroup. 2007. U.S. Environmental (continued...)

It is too soon to know whether such questions are serious cause for concern, but there is scientific evidence that some nanoparticles may be hazardous. For example, certain nanoparticles are known to be toxic to microbes,<sup>7</sup> and EPA has reported some studies that have found nanoparticles generally (but not always) are more toxic than larger particles of identical chemical composition.<sup>8</sup> Other studies indicate that some nanoparticles are toxic in a way that cannot be explained by differences in particle size alone.<sup>9</sup> Yet, such studies are rare, and nanoparticles are diverse, so that one study with one kind of particle may not be informative with respect to the properties of other kinds of particles. Moreover, scientists have demonstrated that toxic nanoparticles may sometimes be made nontoxic by changing the surface chemistry of the particles — for example, by oxidizing the exposed atoms.<sup>10</sup>

The unknown potential of individual nanomaterials to harm the environment or human health might lead to consumer rejection of the entire range of consumer products incorporating nanotechnology, especially if consumers perceive that there is inadequate federal oversight. As explained by one witness who testified before the House Committee on Science, “The perception that nanotechnology will cause environmental devastation or human disease could itself turn the dream of a trillion-dollar industry into a nightmare of public backlash.”<sup>11</sup> To prevent a loss of consumer confidence, academic researchers, policy analysts, and some entrepreneurs in nanotechnology have been working with federal agencies that have responsibility for protecting the environment, workers, and consumers. The remainder of this report describes some of the challenges faced by these groups as they strive to define the characteristics of nanomaterials, the risks they might pose, and how possible risks might be addressed under existing statutory authorities.

## Regulatory Challenges

The Environmental Protection Agency (EPA), Food and Drug Administration (FDA), Consumer Product Safety Commission (CPSC), and Occupational Safety and Health Administration (OSHA) are actively exploring the health and safety

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<sup>6</sup> (...continued)

Protection Agency Nanotechnology White Paper. EPA 100/B-07/001. U.S. EPA: Washington DC, p. 14. Hereafter cited as EPA White Paper.

<sup>7</sup> Silver, for example, is toxic to microbes, and some product manufacturers have made antibacterial claims for their products containing nanosilver. In addition, research has demonstrated the toxicity of C<sub>60</sub> fullerenes to bacteria in water under laboratory conditions (Fortner, J.D., D.Y. Lyon, C.M. Sayes, et al. “C60 in water: Nanocrystal formation and microbial response,” *Environmental Science & Technology*, v. 39, (2005), p. 4307-4316.)

<sup>8</sup> EPA White Paper, p. 54.

<sup>9</sup> Ibid.

<sup>10</sup> National Research Council. 2006. *A Matter of Size*. National Academies Press, Washington, DC. p. 157. Hereafter cited as National Research Council 2006.

<sup>11</sup> Colvin, Vicki L. Testimony before the Committee on Science, U.S. House of Representatives. Hearing on “The Societal Implications of Nanotechnology.” 108<sup>th</sup> Cong., 1<sup>st</sup> Sess., April 9, 2003. U.S. Govt. Print. Off., Washington, DC.



implications of nanotechnology and the possible need for regulations. Other federal agencies also are doing research on environmental, health, and safety applications or implications of nanotechnology.<sup>12</sup> They face many challenges, including those discussed below.

**Diversity of materials and applications.** Nanomaterials vary widely in size, structure, properties, and atomic or molecular identities (that is, chemical composition). Some are relatively simple materials, composed primarily of a single element in a particular crystal form, such as carbon nanotubes. But, even carbon nanotubes may be of various lengths and thicknesses, and may be relatively pure, containing few unneeded elements, or contaminated by unknown substances. The properties being explored or exploited by researchers and developers of products may result from any combination of these features, which may vary from batch to batch supplied by carbon nanotube manufacturers or distributors.<sup>13</sup> For example, carbon nanotubes may be “doped” to deliberately include other substances to obtain a particular electric charge or other property. Alternatively, a core nanomaterial may be coated or covered by a nanoscale film, embedded in plastic, or otherwise modified. Some carbon nanotubes are specifically treated to prevent agglomeration into larger particles.

Many other elements and compounds may be used to produce materials through nanoengineering, and some are considerably more complex than carbon nanotubes. Currently, most commercial products fall into four categories: nanotubes (which may be carbon, silicon, or another substance); metal oxides; quantum dots; and naturally occurring clays.<sup>14</sup> The physical, electrical, magnetic, and other properties of these different materials vary due to chemical composition, but also due to overall dimensions and shapes of particles. Some products of nanoengineering do not even consist of nanoscale materials, but rather incorporate spaces that are nanoscale.

The risk associated with these diverse materials may depend more on the application than on the material, and the potential uses of nanomaterials are countless. For example, because risk varies with degree of exposure, risk posed by nanomaterial is likely to vary depending on whether it is embedded in plastic or some other substance that might reduce exposure, is free-standing and easily dispersed through air or water, or is coated with a more biologically active organic molecule in order to enhance exposure. Moreover, risks would be expected to vary throughout the life cycle of a product, from manufacture through use, recycling, treatment, or

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<sup>12</sup> EPA Science Advisory Board, Board of Scientific Counselors. Meeting summary, October 19-20, 2006. p. 26.

<sup>13</sup> Busnaina, Ahmed. Director, National Science Foundation Nanoscale Science and Engineering Center for High-rate Nanomanufacturing, Northeastern University. Comments made at the EPA Peer Consultation on Materials Characterization of Nanoscale Materials, September 6-7, 2007, at Arlington, Virginia.

<sup>14</sup> Goldman, Lynn, and Christine Coussens, eds. 2005. *Implications of Nanotechnology for Environmental Health Research*, Institute of Medicine, National Academies Press, Washington, DC. pp. 6-7. These categories are not all inclusive, and there are other categorization schemes, but this scheme accounts for the vast majority of commercial applications in 2007.

disposal. Thus, the potential risk from nanomaterial in cosmetics may be greater or less than the risk of the same material washed into swimming pools or lakes. In addition to the potential risks of routine manufacture, use, and disposal, risks associated with accidental, even potentially catastrophic, releases should be considered.

This diversity means that traditional regulatory toxicology and risk assessment, which typically proceed chemical by chemical, would be prohibitively time-consuming and expensive. Thus, Vicki Colvin, Executive Director of the International Council on Nanotechnology (ICON) at Rice University, proposes a different approach, which proceeds by correlating material properties with effects on the environment and human health to determine the general factors that affect toxicity. Colvin calls this risk forecasting.<sup>15</sup>

**Lack of data characterizing nanomaterials.** The structure and chemical composition of a small sample of nanomaterials produced in a laboratory can be well understood and defined, at least for relatively simple materials like buckyballs. However, the consistency of structure and chemical composition within and between batches of manufactured nanomaterials varies widely. It is possible to measure the numerous properties of nanomaterials, but it is difficult and expensive, so properties other than the ones of particular interest are not known. For example, researchers generally do not investigate a nanomaterial to determine the temperature at which it will melt or boil, or the degree to which it is soluble in water or any other solvent.

Even among researchers whose interest focuses on toxicity, there is no agreement about which data might be useful, and therefore few data are collected. Scientists have not yet determined which physical-chemical properties (for example, size, shape, composition, stability, or electric charge) will be most important in determining ecological and toxicological properties. For example, at a recent meeting of researchers interested in studying toxicity, they agreed only that it is probably most important to determine a material's surface reactivity (a rather vague notion of how readily surface molecules combine with other substances to which they are exposed, that would be measured in various ways depending on the material).<sup>16</sup> In addition, they generated a long list of properties of possible interest and a shorter list of properties that definitely should be investigated before toxicity is assessed.<sup>17</sup>

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<sup>15</sup> Computational toxicology presumably is a form of risk forecasting. For more on computational toxicology, see CRS Report RL34118, *The Toxic Substances Control Act (TSCA): Implementation and New Challenges*, by Linda-Jo Schierow.

<sup>16</sup> EPA Peer Consultation on Materials Characterization of Nanoscale Materials, September 6-7, 2007, at Arlington, Virginia.

<sup>17</sup> EPA Peer Consultation on Materials Characterization of Nanoscale Materials, September 6-7, 2007, at Arlington, Virginia.

The shorter list was originally suggested by David Warheit of DuPont Haskell Laboratory and, included particle size and size distribution (wet state) and surface area (dry state) in the relevant media being utilized — depending upon the route of exposure; crystal structure/crystallinity; aggregation status in the relevant media; composition/surface  
(continued...)

Until data are routinely collected on a basic set of physical and chemical properties, there will be no basis for hypothesizing about relationships between size, structure, chemical composition, and toxicity, or for predicting toxicity of similar, newly created substances.

**Lack of standardization in nomenclature, metrics, and materials.**

A major obstacle to data collection is the absence of consensus on how the materials should be named, how scientific tests should be conducted, or even what constitutes a sample of a particular material. Naming conventions; standard, validated scientific methods; and standard samples of materials must be developed and made available to researchers, before the results of scientific tests will be accepted by others as valid measures and comparable across researchers and materials. If such standards were internationally accepted, it might permit international collaboration and data sharing, and speed development of an adequate data set for generalizing about nanomaterials.

The U.S. approach to standards development is voluntary. The National Institute of Standards and Technology (NIST), a non-regulatory federal agency within the U.S. Department of Commerce, is facilitating the development of a measurement system and nomenclature for use by nanotechnology scientists and engineers.<sup>18</sup> The NIST Center for Nanoscale Science and Technology (CNST) is

dedicated to partnering with interested parties from industry, academia, and government to achieve common goals.... By offering collaborative opportunities, the research program also offers access to nanoscale measurement and fabrication capabilities not elsewhere available. The CNST also offers access to the CNST Nanofab, operated by professionals dedicated to serving users and offering access to state-of-the-art tools within an economical cost-sharing model.<sup>19</sup>

EPA, the National Institute for Occupational Safety and Health, and other U.S. agencies participating in the NNP also are working with the American National Standards Institute (ANSI); ASTM International (an international organization that uses a consensus approach to developing voluntary standards); the Nanotechnology Characterization Laboratory (established by the National Cancer Institute (NCI), NIST, and the U.S. Food and Drug Administration (FDA), to characterize nanoparticles intended for cancer therapies and diagnostics); the International Organization for Standardization (ISO); and other groups on these basic issues of nomenclature, characterization, and measurement, which must be resolved prior to

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<sup>17</sup> (...continued)

coatings; surface reactivity; method of nanomaterial synthesis and/or preparation including post-synthetic modifications (e.g., neutralization of ultrafine titanium dioxide particle-types); and purity of sample.

<sup>18</sup> Center for Nanoscale Science and Technology, National Institute of Standards and Technology. About NIST's Center for Nanoscale Science and Technology. [[http://cnst.nist.gov/about\\_cnst.html](http://cnst.nist.gov/about_cnst.html)], visited January 9, 2008.

<sup>19</sup> National Institute of Standards and Technology website. General Information. [[http://www.nist.gov/public\\_affairs/general2.htm](http://www.nist.gov/public_affairs/general2.htm)], visited January 9, 2008.

toxicity data development.<sup>20</sup> The U.S. government is cooperating with its trading partners in the Organization for Economic Cooperation and Development to ensure development of standards that are consistent internationally.

Among the highest priorities for EHS risk assessment is development of physical standards, that is, reference materials for each nanomaterial of interest. Physical reference standards are needed to allow identification of materials being examined. Without standard samples of materials for comparison, materials being studied cannot be identified with precision, making research results impossible to interpret.<sup>21</sup>

Vicki Colvin, executive director of ICON, has argued that experts repeatedly identify the development of standards for conducting and reporting research as the critical first step in EHS research for nanotechnology.<sup>22</sup> They need protocols that specify, for example, what constitutes a toxicologically relevant dose, or whether chemical purity is a critical property, so that research reports will provide information useful to EHS risk analysts. Such standards could be developed through workshops, but there is no federal funding for such workshops, she contends.<sup>23</sup> Others have suggested that funding is necessary to permit travel to workshops by academics and federal employees.<sup>24</sup>

**Proprietary nature of information.** Much of the on-going research and development of nanomaterials is being conducted by private entities with an economic interest in protecting information about their work. These entities generally will not voluntarily reveal details about production processes or even the chemical composition or physical structure of their nanomaterials, due to concerns about competition, potential effect of regulatory decisions, and potential liability. Furthermore, due to the very technical and often resource-intensive nature of nanotechnology development, scientists working for private entities generally are familiar with a limited set of nanomaterials: while one laboratory studies carbon nanotubes, another might focus exclusively on metal oxides, or even on a single metal oxide. This means that scientists generally do not have access to data that are needed to detect patterns in the relationships between toxicity and other

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<sup>20</sup> EPA Peer Consultation on Materials Characterization of Nanoscale Materials. September 6-7, 2007, Arlington, Virginia.

EPA White paper, p. 32.

<sup>21</sup> Small, John. Group Leader, Center for Nanoscale Science and Technology, NIST. EPA Peer Consultation on Materials Characterization of Nanoscale Materials. September 6-7, 2007, Arlington, Virginia.

<sup>22</sup> U.S. Congress. House. Committee on Science and Technology. Subcommittee on Research and Science Education. Testimony on "Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative." Hearing, 110<sup>th</sup> Cong., 1<sup>st</sup> Sess. October 31, 2007.

<sup>23</sup> Ibid.

<sup>24</sup> EPA Peer Consultation on Materials Characterization of Nanoscale Materials. September 6-7, 2007, Arlington, Virginia.

characteristics of various nanomaterials. Without such data, there is no basis for building theoretical models for hypothesis testing. In short, the proprietary nature of nanotechnology arguably impedes the scientific study of nanoscale matter, and nanotoxicology in particular, by discouraging data sharing.

**Difficulty of communicating among academic disciplines.** Only a few laboratories have been able to generate data for diverse categories of nanomaterials, and none has access to information about the full spectrum of materials in development. There is some hope, however, that scientific understanding of nanomaterials might be advanced by augmenting data on synthesized materials with available data on naturally occurring or incidentally produced nanomaterials, such as those found in dust or diesel exhaust. A few years ago, more than 500 peer-reviewed publications were available on naturally occurring nanoparticles. In addition, there were more than 10,000 peer-reviewed articles on incidental nanoparticles that result largely as byproducts of human activities such as mining, cooking, and metal working.<sup>25</sup> On the other hand, synthesized nanomaterials vary in many ways from those that are naturally occurring.<sup>26</sup>

Accessing data is one problem, but understanding the meaning of data across academic disciplines is another. At an EPA workshop on characterizing nanoparticles, toxicologists and physicists struggled to express their concerns to one another, and admitted frankly their ignorance of the others' areas.<sup>27</sup> Agreement on common terminology is likely to help, but the lack of commonality is deeper than terminology. Perhaps in time, scientists collaborating routinely at interdisciplinary research centers (and occasionally at workshops) may help to bridge the gap.

**Limited resources.** There are limited federal resources available to evaluate EHS implications and regulate nanomaterials, because the *overall* budgets of the executive agencies that are responsible for monitoring and regulating potential risks to human health and the environment have been steady or declining in recent years, while the agencies' areas of responsibility have grown.<sup>28</sup> For example, according to an analysis by the Congressional Research Service of data provided by the President's Office of Management and Budget, EPA's overall budget authority has remained relatively flat for the past 20 years, and has declined slightly since 2003. During the same period, Congress enacted legislation that expanded the agency's duties, and the Superfund tax authority expired. As the Superfund was depleted, EPA's budget absorbed the costs of cleaning up hazardous waste sites on the National Priority List.

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<sup>25</sup> Goldman and Coussens, 2005, p. 7, citing Eva Oberdorster, unpublished.

<sup>26</sup> Naturally occurring particles will vary in shape, size, and properties, while synthesized nanomaterials are designed to be more uniform. Thus, synthesized materials often may be redesigned and re-engineered to eliminate or ameliorate problems (such as toxicity) that emerge.

<sup>27</sup> EPA Peer Consultation on Materials Characterization of Nanoscale Materials. September 6-7, 2007, Arlington, Virginia.

<sup>28</sup> However, the Administration has stated that the budget is adequate to the task.

Recent hearing testimony reveals an equally constrained budget situation at the Consumer Product Safety Commission (CPSC).<sup>29</sup> “While the CPSC has thus far been successful at facing these new and evolving challenges with diminishing resources, the 2008 funding level will challenge the Commission’s ability to maintain its existing level of standards development, enforcement, public information, and international activities.”<sup>30</sup>

The Food and Drug Administration (FDA) also faces resource constraints.<sup>31</sup> Its funding issues have been summarized in the proceedings of a workshop addressing FDA challenges generally that was convened by the Institute of Medicine.<sup>32</sup> Workshop participants agreed that “the Administration should request and Congress should approve substantially increased resources in both funds and personnel” for FDA.<sup>33</sup> Two organizations were formed in 2006 to advocate for more FDA funding across the board (that is, not just for nanotechnology).<sup>34</sup> A recent report by the Subcommittee on Science and Technology of FDA’s Science Board concluded with respect to all FDA programs (again, not just nanotechnology) “that science at the FDA is in a precarious position: the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities.” According to the Subcommittee, those deficiencies stem from the growth in demands on the agency without commensurate growth in resources.<sup>35</sup> The report states:

- *The demands on the FDA have soared* due to the extraordinary advance of scientific discoveries, the complexity of the new products and claims submitted to FDA for pre-market review and approval, the emergence of challenging safety problems, and the globalization of the industries that FDA regulates.

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<sup>29</sup> U.S. Consumer Product Safety Commission, 2008 Performance Budget Request, submitted to Congress, February 2007, page vii. [<http://www.cpsc.gov/CPSCPUB/PUBS/REPORTS/2008plan.pdf>], visited January 16, 2008.

<sup>30</sup> *Ibid.*

<sup>31</sup> Michael R. Taylor. 2006. *Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?* Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, DC. pp. 46-47.

<sup>32</sup> Institute of Medicine. 2007. *Challenges for the FDA: The Future of Drug Safety, Workshop Summary*. National Academies Press, Washington, DC, p. 2. [<http://books.nap.edu/catalog/11969.html>], visited January 16, 2008.

<sup>33</sup> *Ibid.* p. 13.

<sup>34</sup> Each group has a website: the FDA Alliance site is at [<http://www.StrengthenFDA.org>], while the Coalition for a Stronger FDA website is at [<http://www.FDACoalition.org>]. Both sites were visited December 14, 2007.

<sup>35</sup> FDA Science Board, Subcommittee on Science and Technology. November 2007. *FDA Science and Mission at Risk*. Report. The report is marked “confidential” but is posted on the website of the Science Board. [[http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b\\_02\\_01\\_FDA%20Report%20on%20Science%20and%20Technology.pdf](http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf)], visited January 16, 2008.

- *The resources have not increased in proportion to the demands.* The result is that the scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the food, drug, cosmetic and device regulatory system, and hence the safety of the public.<sup>36</sup>

On the other hand, within the constraints of the overall federal budget and overall budgets of the 26 National Nanotechnology Initiative (NNI) agencies, the President's Office of Management and Budget and the Congress have been encouraging agencies to allocate increasing portions of their budgetary authorities to research related to nanotechnologies.<sup>37</sup> A total of \$1.3512 billion was appropriated for these programs in FY2006, according to the President's Office of Management and Budget.<sup>38</sup> However, less than three percent of that funding was allocated to research on the potential "applications and implications of nanotechnology" for the environment and human health and safety (EHS).<sup>39 40</sup> The regulatory agencies are responsible for a small fraction of this EHS research funding. EPA's EHS budget for nanotechnology in FY2006 was \$3.7 million, and some of this funding was directed toward development of environmentally beneficial applications of nanotechnology, for example, to remove arsenic from surface water, rather than research relevant to evaluating potential toxicity. EPA was the only regulatory agency identified as a contributor to NNI funding in the President's budget.<sup>41</sup> However, it should be noted that given the rudimentary understanding of nanomaterials, it is not surprising that a relatively large portion of research funding goes to basic scientific studies. Such research is funded by the National Science Foundation, which receives the bulk of the EHS research budget, some \$21 million in FY2006. In addition, substantial research is conducted to develop standardized tools and measures of nanomaterials and to understand their interactions with living things.

**Possibly inadequate statutory authority.** A final potential obstacle to federal risk management for nanotechnology is a lack of clear statutory directives or appropriate regulatory frameworks to guide federal risk managers. Although the Bush Administration<sup>42</sup> and several legal reviews of existing environmental, health,

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<sup>36</sup> Ibid., p. 2.

<sup>37</sup> The NNI is coordinated through the White House National Science and Technology Council's Nanoscale Science, Engineering and Technology (NSET) subcommittee. NSET does not have budget authority or appropriations. Rather, each agency allocates part of its budget to nanotechnology and reports its efforts to the NNI.

<sup>38</sup> FY2008 Budget Supplement.

<sup>39</sup> Ibid.

<sup>40</sup> For FY2007, estimated NNI and EHS funding levels are somewhat higher, and higher still in the President's FY2008 budget request.

<sup>41</sup> The National Institute for Occupational Safety and Health informs regulatory activities by the Occupational Safety and Health Administration (OSHA), but is not itself an agency that issues EHS regulations.

<sup>42</sup> Marburger, John H. III, and James L. Connaughton. Principles for Nanotechnology Environmental, Health, and Safety Oversight, memorandum for the heads of Executive (continued...)

and safety statutes have concluded that they probably provide adequate authority for federal regulators over nanotechnology, such laws were not written with nanomaterials in mind.<sup>43</sup> As a result, agencies would have to develop new policies, produce guidance, and possibly issue regulations to translate statutory requirements with respect to nanomaterials. These tasks almost certainly would be controversial, because agencies would be making decisions that might, on the one hand, delay or restrict commerce or, on the other hand, allow entrepreneurs to market products whose effects on health or the environment are unknown or uncertain.

One concern about existing environmental, health, and safety statutes is that most apply to a specific category of chemical products intended for a particular application, for example, as a food additive, drug, cosmetic, pesticide, or consumer product. This might lead to redundant or inconsistent regulation of a nanomaterial under more than one federal law. For example, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),<sup>44</sup> EPA must evaluate and regulate commerce in, and use of, all products that are intended to control pests, including bacteria. EPA already has stated its intent to regulate nanosilver under FIFRA when it is released from certain washing machines and other products for which manufacturers claim antibacterial properties. Other EPA program offices (the Offices of Air and Radiation, and of Water, for example) also have responsibilities for managing nanomaterials, including nanosilver, under certain conditions. To address this challenge, EPA's Science Policy Council, an internal policy group, formed a Nanotechnology Workgroup in December 2004 and charged it with describing "key science issues EPA should consider to ensure that society accrues the important benefits to environmental protection that nanotechnology may offer, as well as to better understand any potential risks from exposure to nanomaterials in the environment."<sup>45</sup> The Toxic Substances Control Act (TSCA),<sup>46</sup> which applies to all categories of chemical uses not otherwise regulated, also allows coordination to reduce any potential regulatory burden. TSCA Section 9(d) requires that the EPA Administrator achieve "the maximum enforcement of [TSCA] while imposing the least burdens of duplicative requirements on those subject to the Act."

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<sup>42</sup> (...continued)

departments and agencies, November 8, 2007. [[http://www.ostp.gov/html/Nano%20EHS%20Principles%20Memo\\_OSTP-CEQ\\_FINAL.pdf](http://www.ostp.gov/html/Nano%20EHS%20Principles%20Memo_OSTP-CEQ_FINAL.pdf)], visited January 22, 2008.

<sup>43</sup> Breggin, Linda K. 2005. *Securing the Promise of Nanotechnology: Is U.S. Environmental Law Up To the Job?* Environmental Law Institute, Washington, DC. Hereafter cited as Breggin 2005. [<http://www.elistore.org/>], visited October 11, 2007.

American Bar Association (ABA) Section of Environment, Energy, and Resources, Briefing documents. [<http://www.abanet.org/enviran/nanotech/>], visited October 11, 2007.

<sup>44</sup> 7 U.S.C. 136-136y

<sup>45</sup> Science Policy Council, Nanotechnology Workgroup. 2007. *U.S. Environmental Protection Agency Nanotechnology White Paper*. EPA 100/B-07/001. U.S. EPA: Washington DC. 120 pp.

<sup>46</sup> 15 U.S.C. 2601 et seq.



On the other hand, current laws sometimes exclude certain nanomaterials from requirements. For instance, TSCA Section 8(b)(1) clearly excludes from its requirements substances that are produced and used only in research laboratories. This exclusion might apply to most of the various nanomaterials currently in existence. Less clearly, TSCA excludes nanomaterials that are not “chemical substances” as defined in the law.<sup>47</sup> TSCA Section 2 defines a “chemical substance” as “any organic or inorganic substance of a particular molecular identity” that is not a mixture. Based on this definition, it is not clear whether any nanoparticle that consists of a core inorganic material coated by an organic material would qualify as a TSCA “chemical substance.” Other nanomaterials, like nanotubes or fullerenes, have clear chemical identities in terms of chemical composition and crystal structure, but have variable properties due to differences in size or shape of particular particles. Size and shape are not normally considered in identifying molecular identity, or in distinguishing one chemical substance from another. Therefore, EPA has indicated that it does not consider size a relevant feature under TSCA.<sup>48 49</sup> But, of course, size is a central issue with nanomaterials.

In some cases, it is the regulations rather than the statute itself that complicate agency decisions and actions with respect to nanomaterials. For example, laws often direct agencies to exclude from regulatory requirements small quantities of chemicals, particularly chemicals not yet in commerce. If the agencies define “small quantities” in terms of weight, as EPA does for purposes of the periodic TSCA inventory updates, nanomaterials may well be excluded, because few are produced in large quantities by weight. Another example might be the exclusion of nanomaterials from food additive regulations, if the Food and Drug Administration were to decide that they fit into a category normally exempted, such as that for substances “Generally Recognized As Safe” (GRAS). Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, this includes any substance that is “generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use.”<sup>50</sup> For more information on the possible limitations of existing laws, see reports issued by the Environmental Law

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<sup>47</sup> TSCA Sections 4 and 8 also authorize reporting requirements. For more information about TSCA, see CRS Report RL34118, *The Toxic Substances Control Act (TSCA): Implementation and New Challenges*.

<sup>48</sup> EPA. TSCA Inventory Status of Nanoscale Substances — General Approach, p. 4. Distributed at the EPA Peer Consultation on Materials Characterization of Nanoscale Materials. September 6-7, 2007, Arlington, Virginia. Also available in the EPA docket EPA-HQ-OPPT-2004-0122-0057 at [<http://www.regulations.gov/>], visited October 19, 2007.

<sup>49</sup> However, according to J. Clarence Davies (2007, *EPA and Nanotechnology: Oversight for the 21<sup>st</sup> Century*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, DC, p. 31), EPA did determine that carbon nanotubes have properties different from other forms of carbon and did decide that it could be regulated under TSCA.

<sup>50</sup> U.S. Food and Drug Administration. Center for Food Safety and Applied Nutrition. Guidance for Industry: Frequently Asked Questions About GRAS. December 2004. [<http://www.cfsan.fda.gov/~dms/grasguid.html#Q1>], visited January 16, 2008.

Institute, the American Bar Association, and the Woodrow Wilson International Center for Scholars' Project on Emerging Nanotechnologies.<sup>51</sup>

## Voluntary Initiatives

As agencies consider the possible need for and shape of regulations, some stakeholders are voluntarily engaging in what is called “responsible development” of nanotechnologies. Professional organizations, industries, universities, environmental organizations, and government have been involved in such efforts. A few of the better known initiatives are described below.

The IEEE (formerly the Institute of Electrical and Electronics Engineers) is developing standard methods needed to mass produce and market electronics and photonics products while protecting workers and addressing environmental concerns.<sup>52</sup>

Intel, DuPont, and other large companies voluntarily adhere to responsible principles that have served in the past to minimize EHS problems associated with production of materials that are not nanoscale. They complain, however, that the adequacy of such practices with respect to nanotechnologies is unknown, and urge the federal government to sponsor additional research to “shed more light on what the best approach to protecting health and safety should be.” The National Institute for Occupational Safety and Health (NIOSH) is working with industry to gather data on exposure and worker health that should help guide the design of studies in occupational settings.

In its 2007 White Paper, EPA expressed the view that

partnerships with industrial sectors will ensure that responsible development is part of initial decision making. Working in partnership with producers, their suppliers, and users of nanomaterials to develop best practices and standards in the workplace, throughout the supply chain, as well as other environmental programs, would help ensure the responsible development of the production, use, and end of life management of nanomaterials.<sup>53</sup>

In that spirit, EPA has been working with stakeholder groups to develop a voluntary Nanoscale Materials Stewardship Program. The program would pertain to engineered nanoscale materials that are in commerce or about to enter commerce. A public

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<sup>51</sup> Breggin 2005.

J. Clarence Davies, 2007, *EPA and Nanotechnology: Oversight for the 21<sup>st</sup> Century*; Breggin, Linda K., and John Pendergrass, *Where Does the Nano Go? End-of-Life Regulation of Nanotechnologies*; and Michael R. Taylor, 2006, *Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?* Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, DC. [<http://www.nanotechproject.org/>], visited January 16, 2008.

<sup>52</sup> National Research Council 2006, p. 153.

<sup>53</sup> EPA White paper, p. 63.

meeting about risk management practices under this program was held October 19-20, 2006. Possible elements of a stewardship program, according to EPA, include

- collection of existing data and information from manufacturers and processors of existing chemical nanoscale materials;
- encouraging the development of test data needed to provide a firm scientific foundation for future work and regulatory/policy decisions; and
- identifying and encouraging use of a basic set of risk management practices in developing and commercializing nanoscale materials.

The agency intends to use the information gained from the stewardship program to guide development of its TSCA program for nanoscale materials. However, the stewardship program is not yet launched, and there are few indications that launch is imminent.<sup>54</sup>

Another voluntary initiative produced a guidebook for responsible corporate behavior called the *Nano Risk Framework*. The six-point program was developed by DuPont Corporation working in partnership with Environmental Defense, an advocacy group, and was announced June 21, 2007, at a seminar sponsored by the Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies. The framework presents a process “for identifying, managing, and reducing potential environmental, health, and safety risks of engineered nanomaterials across all stages of a product’s ‘lifecycle.’”<sup>55</sup>

A final example of a voluntary initiative that aims to promote responsible development of nanotechnology is spearheaded by the International Council on Nanotechnology (ICON) at Rice University. As described on its website, “ICON is a technically driven organization whose activities are broadly supported by industry, non-profit foundations, and governments. Its multi-stakeholder partnerships and governance, with members that span the globe, make it uniquely positioned to ensure global coordination and cooperation in nanotechnology risk management.”<sup>56</sup> Its mission is “to develop and communicate information regarding potential environmental and health risks of nanotechnology, thereby fostering risk reduction while maximizing societal benefit.”<sup>57</sup> ICON encourages close work between developers of nanotechnology and toxicologists. As explained by Vicki Colvin, executive director of ICON, “If we understand why a material is cytotoxic [that is, toxic to cells], we should be able to make it less reactive and knock out its

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<sup>54</sup> Kinney, Jeff. 2007. EPA Expects Participation to Start in January For Nanotechnology Stewardship Program. *Daily Environment Report*, November 14, 2007. p. A-1.

<sup>55</sup> Nanorisk Framework. [<http://nanoriskframework.com/page.cfm?tagID=1095>], visited January 16, 2008.

<sup>56</sup> ICON website. Background. [[http://icon.rice.edu/about.cfm?doc\\_id=4380](http://icon.rice.edu/about.cfm?doc_id=4380)], visited January 16, 2008.

<sup>57</sup> ICON website. Mission and Strategy. [[http://icon.rice.edu/about.cfm?doc\\_id=4379](http://icon.rice.edu/about.cfm?doc_id=4379)], visited January 16, 2008.

toxicity....”<sup>58</sup> Thus, she advises, “chemists making systematic changes in materials must work with people who can measure their biological effects. Tight collaboration between materials engineers, chemists, and toxicologists could provide the essential data that can enable us to engineer safer nanomaterials from the beginning.”<sup>59</sup>

## Legislative Options

The regulatory challenges posed by nanomaterials and nanotechnologies may be resolved over time and to some extent without significant legislative action, as stakeholders work together, scientists learn more about processes and properties on the nanoscale, and federal regulators gradually adapt rules to implement existing statutory authorities. Congress might, therefore, continue to take a wait-and-see approach to nanotechnologies, perhaps combined with congressional oversight of agencies’ activities. However, should Congress choose to intervene, a range of legislative strategies is available, as described below.

### **Increase and/or reallocate funding for health and safety research.**

The overall contribution from agencies’ budgets to the National Nanotechnology Initiative (NNI) has grown substantially over the years.<sup>60</sup> It is more difficult to characterize trends in the allocation of funds devoted to research on the potential EHS implications and applications of nanotechnologies, although it too appears to have grown significantly.<sup>61</sup> In some cases, however, this growth arguably has been at the expense of agencies’ other programs. This is particularly likely for the regulatory agencies, EPA, FDA, and the CPSC.<sup>62</sup> For example, the National Research Council observed that although there had been “pockets of increased funding for EHS-related research,” including a proposed \$4 million increase in the FY2007 budget for nanotechnology research within EPA, “there was a 4 percent cut in EPA’s overall FY2007 budget.”<sup>63</sup>

The National Research Council has recommended an increase in funding for research relevant to evaluating the potential health and safety risks associated with nanotechnologies, including work to develop requisite definitions, protocols, and

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<sup>58</sup> National Research Council. 2006. *A Matter of Size*. National Academies Press, Washington, DC. p. 157.

<sup>59</sup> Ibid.

<sup>60</sup> FY2008 Budget Supplement.

<sup>61</sup> Ibid.

National Research Council. 2006. *A Matter of Size*. National Academies Press, Washington, DC. p. 151. Hereafter cited as National Research Council, 2006.

<sup>62</sup> Although FDA does not conduct toxicological research, it does interpret research conducted by manufacturers and apply the results of such research in risk assessments as a basis for regulatory decisions.

<sup>63</sup> National Research Council, 2006, p. 91.

methodologies.<sup>64</sup> Many companies, public interest groups, and the NanoBusiness Alliance (a trade group) also have asked Congress for additional funding for EHS-related research.<sup>65</sup> According to the Chairman of the House Subcommittee on Research and Science Education of the Committee on Science, “The basic position of most outside observers from industry and non-governmental organizations is that the funding level should be on the order of 10% of the initiative’s total funding, rather than the current 4%.”<sup>66</sup>

Congress also might wish to consider whether to change the allocation of research money among agencies. For example, it might wish to increase or decrease basic research through the National Science Foundation relative to research that might inform risk assessments at the National Institutes of Health. See **Table 1**, above, for the distribution of the FY2006 actual budget among agencies and departments of the NNI.

It is difficult to assess the need for additional federal funding or the adequacy of its allocation among agencies without detailed information about research priorities. Many policy analysts have argued that the foremost need with respect to nanotechnology-related EHS research is a strategy or plan “to avoid duplication of research and to set priorities.”<sup>67</sup> The House Committee on Science has asked repeatedly for the NNI to develop such a strategy. In September 2006, the NNI delivered to the Committee a general framework for EHS research, which was developed by the interagency Nanotechnology Environmental and Health Implications (NEHI) Working Group.<sup>68</sup> The report identified five research categories and some specific needs within each, but it did not prioritize within or among categories. The five research categories include

- instrumentation, metrology, and analytical methods;
- nanomaterials and human health;
- nanomaterials and the environment;
- health and environmental surveillance; and
- risk management methods.

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<sup>64</sup> Ibid., p. 6 - 8, 11-12, 38, 92.

<sup>65</sup> Ibid., p. 91.

<sup>66</sup> U.S. Congress. House. Committee on Science and Technology. Subcommittee on Research and Science Education. Testimony on “Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative.” Hearing, 110<sup>th</sup> Cong., 1<sup>st</sup> Sess. October 31, 2007. Opening statement of Chairman Brian Baird.

<sup>67</sup> For example, Carol Henry of the American Chemistry Council: National Research Council. 2006. *A Matter of Size*. National Academies Press, Washington, DC, p. 161.

<sup>68</sup> National Nanotechnology Initiative. 2006. *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*. Nanoscale Science, Engineering, and Technology Subcommittee, Committee on Technology, National Science and Technology Council, Washington DC. 62 p.

Some experts who advocate for a stronger federal role in managing the risks of nanotechnology argue that this NNI categorization provides insufficient direction for managers, researchers, and research grant authorities. They would prefer a more “top-down” approach to EHS research management, in order to ensure that the information being collected is most useful for risk managers.<sup>69</sup> Their priorities were published in November 2006.<sup>70</sup> Some of the same individuals co-authored a paper published in November 2007 that was based on a workshop held in April 2006.<sup>71</sup> That paper identified six critical information needs for evaluating and predicting the toxicity of nanoparticles:

- extensive physico-chemical characterization;
- capacity for macromolecular perturbation (for example, for interfering with repair of DNA or with proteins important to the immune system);
- potential for unintended carriage of toxic molecules;
- translocation (for example, from the surface of skin into the blood stream);
- agglomeration state; and
- chemical composition.

The Director of the National Nanotechnology Coordination Office and the Co-Chair of the President’s Council of Advisors on Science and Technology (PCAST) disagree that a top-down approach is needed, arguing that no single individual could have the breadth of expertise necessary to adequately oversee all aspects of nanotechnology EHS research.<sup>72</sup> Rather, an interagency working group can “cast the

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<sup>69</sup> U.S. Congress. House. Committee on Science and Technology. Subcommittee on Research and Science Education. Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative. Hearing, 110<sup>th</sup> Cong., 1<sup>st</sup> Sess. October 31, 2007. Testimony of Andrew Maynard.

<sup>70</sup> Maynard, Andrew D., Robert J. Aitken, Tilman Butz, Vicki Colvin, Ken Donaldson, Günter Oberdörster, Martin A. Philbert, John Ryan, Anthony Seaton, Vicki Stone, Sally S. Tinkle, Lang Tran, Nigel J. Walker, and David B. Warheit. 2006. Safe Handling of Nanotechnology. *Nature*, v. 444, (16 November) pp. 267-269.

<sup>71</sup> Balbus, John M., Andrew D. Maynard, Vicki L. Colvin, Vincent Castranova, George P. Daston, Richard A. Denison, Kevin L. Dreher, Peter L. Goering, Alan M. Goldberg, Kristen M. Kulinowski, Nancy A. Monteiro-Riviere, Günter Oberdörster, Gilbert S. Omenn, Kent E. Pinkerton, Kenneth S. Ramos, Kathleen M. Rest, Jennifer B. Sass, Ellen K. Silbergeld, and Brian A. Wong. 2007. Meeting Report: Hazard Assessment for Nanoparticles — Report from an Interdisciplinary Workshop. *Environmental Health Perspectives*, v.115, n.11, (November) p. 1654-1659.

<sup>72</sup> U.S. Congress. House. Committee on Science and Technology. Subcommittee on Research and Science Education. Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative. Hearing, 110<sup>th</sup> Cong., 1<sup>st</sup> Sess. October 31, 2007. Testimony of Clayton Teague and Floyd Kvamme.

wide net necessary to address the array of nanotechnology-related EHS issues,” and this “interagency process will lead to a sound research strategy.”<sup>73</sup>

Proponents of the top-down approach have found these arguments unconvincing, arguing instead that a top-down approach can involve many agencies and other stakeholders. Environmental Defense, a group that advocates for responsible development of nanotechnology, has suggested that NNI responsibilities are potentially in conflict, because they include EHS oversight of research and development on the one hand, and promotion of nanotechnology research and development on the other. Thus, the group argues, some portion of the NNI should be given “independent budgetary and management authority, responsibility, accountability, and sufficient resources to develop and direct the overall Federal nanomaterial risk research strategy.”<sup>74</sup> Environmental Defense modeled this proposal on the approach taken by the federal government with respect to nuclear power.<sup>75</sup>

In December 2007, the National Science and Technology Council (NSTC) released an update of its strategic plan for the development of nanotechnology.<sup>76</sup> It noted that “A document that describes the NNI strategy for addressing the identified priorities for nanotechnology-related EHS research is in preparation.”<sup>77</sup>

The Senate Committee on Appropriations expressed its desire for a research strategy in S.Rept. 110-91, which accompanied S. 1696, a bill providing FY2008 appropriations for the Department of the Interior, environment, and related agencies.<sup>78</sup>

The Committee is committed to ensuring that all Federal environmental, health and safety research is prioritized and coordinated so that nanotechnology’s potential benefits to the economy and environment are realized at the same time

<sup>73</sup> Ibid. Testimony of Floyd Kvamme.

<sup>74</sup> Environmental Defense. Potential model for restructuring National Nanotechnology Initiative offered to better address nano risks. Press release. November 19, 2007. [<http://www.environmentaldefense.org/pressrelease.cfm?contentID=7346>], visited January 16, 2008.

<sup>75</sup> According to the Nuclear Regulatory Commission, “The NRC was created as an independent agency by the Energy Reorganization Act, signed into law October 11, 1974, which abolished the Atomic Energy Commission. The NRC, which took over the regulatory functions of the AEC, formally came into being on January 19, 1975. The Energy Research and Development Administration, also created by the Energy Reorganization Act, took over the other functions of the AEC and is now part of the Department of Energy.”

<sup>76</sup> Subcommittee on Nanoscale Science, Engineering, and Technology, Committee on Technology, National Science and Technology Council. 2007. *The National Nanotechnology Initiative: Strategic Plan*. 45p. [[http://www.nano.gov/NNI\\_Strategic\\_Plan\\_2007.pdf](http://www.nano.gov/NNI_Strategic_Plan_2007.pdf)], visited January 11, 2008.

<sup>77</sup> Ibid., p. 20.

<sup>78</sup> U.S. Congress. Senate. Committee on Appropriations. Department of the Interior, Environment, and Related Agencies Appropriations Bill, 2008. Report to Accompany S. 1696. S.Rept. No. 110-91, 110<sup>th</sup> Cong., 1<sup>st</sup> Sess. Washington, U.S. Govt. Print. Off., 2007. p. 54.

that human health and the environment are protected. To further these goals, the Committee urges EPA to contract or enter into a cooperative agreement with the National Academy of Sciences' Board on Environmental Studies and Toxicology within 90 days of enactment to develop and monitor implementation of a comprehensive, prioritized research roadmap for all Federal agencies on environmental, health and safety issues for nanotechnology.<sup>79</sup>

The Senate did not act on S. 1696, but in accord with the explanatory statement for the Consolidated Appropriations Act, 2008, which became Public Law 110-161, the report language for S. 1696 is being treated as approved.<sup>80</sup> According to Celia Merzbacher, who is co-chair of the NSTC Subcommittee on Nanoscale Science, Engineering, and Technology, therefore, the National Academy review of the NNI strategy will take place.<sup>81</sup>

### **Mandate/constrain reporting by manufacturers of nanotechnology.**

Congress also might intervene to ensure an appropriate level of information collection by regulatory agencies. If Congress wants to ensure that information about the potential risks of nanotechnology and nanomaterials is collected and does not want to rely on voluntary programs, or conversely, if Congress wants to prevent agencies from imposing reporting requirements, legislation might be necessary. Congress could direct or constrain agency action that would require manufacturers of nanotechnology materials or products to determine physical and chemical properties, to conduct toxicity tests, or to report information that already is reasonably available and potentially relevant to EHS. Either requirements or constraints could be phased into effect in order to ensure that requirements would be commensurate with risk and investments by the regulated community. For example, increasing demands for information could be tied to the introduction or marketing of new applications, new products, or threshold quantities of products. Alternatively, agencies might be instructed to refrain from requiring long-term and costly studies, at least until a certain production threshold is attained.

For some chemical substances and applications, regulatory agencies already have certain regulatory authorities. For example, under the Toxic Substances Control Act (TSCA), Section 8(d), EPA requires that manufacturers submit lists of unpublished health and safety studies known to have been conducted, and copies of such studies, on request. If that authority is not sufficient, too broad, or not clear with respect to nanomaterials, TSCA and other statutes could be amended. Alternatively, reporting and testing requirements, limitations, or prohibitions could be included in free-standing legislation. A third option might be to tie requirements for reporting or testing to legislation authorizing research funding.

These options might have unintended consequences. For example, depending on the specific provisions, new reporting or testing requirements might be considered an impediment to innovation by small or medium-sized enterprises, or too burdensome for manufacturers who embed nanomaterials in hard plastics or other

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<sup>79</sup> Ibid.

<sup>80</sup> Congressional Record — House, December 17, 2007. p. H16122.

<sup>81</sup> Personal communication, January 15, 2008.



substances. A variety of methods are available to reduce unintended consequences. For example, to reduce the burden imposed by a testing requirement, Congress might allow manufacturers to share test data (and costs of testing), grant exclusive production or marketing rights within the United States for a number of years to manufacturers who conduct testing (to compensate them for their expenditures), or exempt particular categories of products or manufacturers from requirements. Again, existing law provides an example of how some requirements might be tailored. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) directs EPA to promulgate testing and reporting requirements for pesticides, mechanisms for simplifying requirements for relatively safe pesticides, and compensation rules, and grants those who conduct tests a period of exclusive data use.

On the other hand, attempts to tailor requirements, limitations, or prohibitions might be viewed as unfair by some regulated entities, if they are perceived to treat manufacturers differently, conferring advantages on some but not others. Moreover, any exemptions for small or medium-sized enterprises would reduce the amount of information collected, information that might be important to risk assessors.

A potential benefit of requiring testing or reporting is that useful information might become available to the regulatory agencies, allowing them to better evaluate the significance of potential EHS risks or to assess the potential value of benefits. This could lead to regulations that were more focused, reasonable, and economically efficient, because agencies could target regulations toward technologies or products posing greater relative risks (and perhaps smaller benefits).

**Clarify, enlarge, or restrict agencies' authority to regulate.** Congress also might legislate to ensure that nanotechnology would, or would not, be regulated to manage any EHS risks that might be identified. Congress could either authorize or restrict agencies' authorities to regulate any stage in the lifecycle of nanomaterials: production, sale, use, or disposal.

Imposing requirements on manufacturers might delay the environmental, health, and economic rewards expected from nanotechnology. At the same time, EHS regulations might reduce any risk of adverse consequences from exposure to nanomaterials. The Bush Administration has issued guidelines for any regulations that might be imposed under existing statutes.<sup>82</sup>

If, on the other hand, Congress chose to prohibit or restrict agencies' authority to regulate nanotechnology or products, the potential economic benefits of the new technology might be more quickly realized, but the risks of unanticipated adverse consequences might be greater. The cost of such consequences would depend on their actual, as well as publically perceived, severity, frequency, and reversibility. The cost to companies developing nanotechnology products also could be great, if

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<sup>82</sup> Marburger, John H. III, and James L. Connaughton. Principles for Nanotechnology Environmental, Health, and Safety Oversight, memorandum for the heads of Executive departments and agencies, November 8, 2007. [[http://www.ostp.gov/html/Nano%20EHS%20Principles%20Memo\\_OSTP-CEQ\\_FINAL.pdf](http://www.ostp.gov/html/Nano%20EHS%20Principles%20Memo_OSTP-CEQ_FINAL.pdf)], visited January 22, 2008.

consumers responded by indiscriminately rejecting all products of nanotechnology, rather than a single offending nanomaterial or application.

## **Conclusion**

The need for additional research to identify the potential hazards that might be associated with nanotechnology and to evaluate risks related to the environment and human health and safety (EHS) is not in dispute. However, there is a range of views about whether there is a need for increased federal intervention at this time. The regulatory challenges posed by nanomaterials and nanotechnologies are many — the diversity of nanomaterials, lack of data characterizing the materials, lack of standardization in nomenclature and metrics, the proprietary nature of private research results, limited resources in regulatory agencies, and possibly inadequate statutory authority. These difficulties may be surmounted over time without legislative action, or Congress may choose to intervene. If it does, it might choose any of several approaches. Selected approaches include increasing funding for workshops in standardization and other EHS research, changing the allocation of research money among agencies, adopting and implementing a national and/or international research strategy, or enacting legislation that authorizes, mandates, or constrains agency actions to require information collection or to restrict production, sale, use, or disposal of nanomaterials.

It is noteworthy that Congress is considering its options at this early stage of technology development, when only a few nanomaterials are being manufactured on a large scale. Risk management decisions nonetheless are pressing, as the rate of nanotechnology development and commercialization is rapidly escalating.