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Nanotechnology and Environmental, Health, and Safety: Issues for Consideration

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Summary

Nanotechnology—a term encompassing nanoscale science, engineering, and technology—is focused on understanding, controlling, and exploiting the unique properties of matter that can emerge at scales of one to 100 nanometers. A key issue before Congress regarding nanotechnology is how best to protect human health, safety, and the environment as nanoscale materials and products are researched, developed, manufactured, used, and discarded. While the rapidly emerging field of nanotechnology is believed by many to offer significant economic and societal benefits, some research results have raised concerns about the potential adverse environmental, health, and safety (EHS) implications of nanoscale materials.

Some have described nanotechnology as a two-edged sword. On the one hand, some are concerned that nanoscale particles may enter and accumulate in vital organs, such as the lungs and brains, potentially causing harm or death to humans and animals, and that the diffusion of nanoscale particles in the environment might harm ecosystems. On the other hand, some believe that nanotechnology has the potential to deliver important EHS benefits such as reducing energy consumption, pollution, and greenhouse gas emissions; remediating environmental damage; curing, managing, or preventing diseases; and offering new safety-enhancing materials that are stronger, self-repairing, and able to adapt to provide protection.

Stakeholders generally agree that concerns about potential detrimental effects of nanoscale materials and devices—both real and perceived—must be addressed to protect and improve human health, safety, and the environment; enable accurate and efficient risk assessment, risk management, and cost-benefit trade-offs; foster innovation and public confidence; and ensure that society can enjoy the widespread economic and societal benefits that nanotechnology may offer. Congressionally-mandated reviews of the National Nanotechnology Initiative (NNI) by the National Research Council and the President's Council of Advisors on Science and Technology have concluded that additional research is required to make a rigorous risk assessment of nanoscale materials.

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Introduction

Nanotechnology—a term encompassing nanoscale science, engineering, and technology—is focused on understanding, controlling, and exploiting the unique properties of matter that can emerge at scales of one to 100 nanometers.[1] These properties are believed by many to offer substantial economic and societal benefits.

A key issue before Congress regarding nanotechnology is how best to protect human health, safety, and the environment as nanoscale materials and products are researched, developed, manufactured, used, and discarded. While the rapidly emerging field of nanotechnology is believed by many to offer significant economic and societal benefits, some research results have raised concerns about the potential environmental, health, and safety (EHS) implications of nanoscale materials. Potential tools the Federal government might use to address these issues include research and development, regulation, and international engagement.

Some of the properties of nanoscale materials (e.g., small size, high surface area-to-volume ratio) that have given rise to great hopes for beneficial applications have also given rise to concerns about their potential adverse implications for the environment, and human health and safety.[2] With more than 1,000 nanotechnology products reportedly commercially available,[3] there is great interest in protecting the health and safety of the scientists working with nanoscale materials, workers who manufacture the products, consumers who use the products, and members of the general public who may be exposed to nanoparticles, as well as in understanding the environmental impact of nanomanufacturing processes and the use and disposal of nanotechnology products.

Nanoscale particles can result from a variety of different processes. While nanoscale particles can occur naturally (e.g., some particles produced by forest fires, sea spray, volcanoes) and as an incidental by-product of human activities (e.g., some particles contained in welding fumes, diesel exhaust, industrial effluents, cooking smoke), EHS concerns have focused primarily on nanoscale materials that are intentionally designed and produced, often referred to as engineered nanomaterials.

Issues surrounding the potential EHS implications of nanotechnology emerged with the launch in 2000 of the National Nanotechnology Initiative (NNI). The NNI is a multi-agency federal effort to coordinate and expand federal nanotechnology research and development (R&D) efforts. Between FY2001 and FY2011, the federal government has invested approximately $14.2 billion in nanotechnology R&D, including approximately $1.8 billion in FY2011 funded under the current continuing resolution (P.L. 111-322). In addition, by one estimate, U.S. private investment

[1] Congress defined nanotechnology in the 21st Century Nanotechnology Research and Development Act (P.L. 108-153) as, "the science and technology that will enable one to understand, measure, manipulate, and manufacture at the atomic, molecular, and supramolecular levels, aimed at creating materials, devices, and systems with fundamentally new molecular organization, properties, and functions." ASTM International, one of the largest voluntary standards development organizations, has defined nanotechnology as, "a wide range of technologies that measure, manipulate, or incorporate materials and/or features with at least one dimension between approximately 1 and 100 nanometers. Such applications exploit those properties, distinct from bulk or molecular systems, of nanoscale components." One nanometer is about the width of 10 hydrogen atoms placed side-by-side, or approximately 1/100,0000 of the thickness of a sheet of paper.

[2] Nanotechnology EHS applications refers to the beneficial use of nanotechnology to improve health, safety, and the environment; EHS implications refers to known and potential adverse effects of nanoscale materials on health, safety, and the environment.

[3] Project on Emerging Nanotechnologies. Figure as of June 2010.

in nanotechnology—$2.7 billion in corporate R&D and $1.0 billion in venture capital investments—exceeded U.S. government funding of $1.9 billion in 2008. Many governments around the world have followed the U.S. lead and established their own national nanotechnology programs. The private sector has invested heavily as well. Global nanotechnology R&D investments—public and private—are estimated to have totaled more than $17 billion in 2008 alone.[4]

Such large investments and intensified efforts to capitalize on these public and private investments have caused some observers (as detailed later in this report) to suggest that there is insufficient information about the potential effects nanotechnology products and manufacturing processes may have on human health, safety, and the environment. They assert a variety of uncertainties, including: how nanoscale particles might be transported in air, water, and soil; how they might react with the environment chemically, biologically, or through other processes; how they might be distributed and deposited; and whether they might accumulate in plants or animals.

Others express the view that concerns about nanotechnology EHS implications are often overgeneralized and overstated. Among the arguments they put forth are that nanoscale materials are frequently embedded in other materials as part of the manufacturing process; that some nanotechnology products, such as semiconductors, have nanoscale features but do not contain nanoscale particles; that nanotechnology materials may replace other materials that have significant and known risks; that some nanoscale particles tend to aggregate or agglomerate in the environment into larger particles that no longer have nanoscale dimensions; and that people are regularly exposed to nanoscale particles produced naturally and as incidental by-products of human activities.

Congressionally-mandated reviews of the NNI by the National Research Council (NRC) and the President's Council of Advisors on Science and Technology (PCAST) have concluded that additional research is required to make a rigorous risk assessment of nanoscale materials. In addition, the NRC warned that, until such information is available, precautionary measures should be taken to protect the health and safety of workers, the public, and the environment.

Nevertheless, most stakeholders agree that these concerns about the potential detrimental effects of nanoscale materials and devices—both real and perceived—must be addressed. Among the issues these stakeholders have identified are characterizing the toxicity of nanoscale materials; developing methods for assessing and managing the risks of these materials; and understanding how these materials move in, and interact with, the environment.

This report identifies the potential environmental, health, and safety opportunities and challenges of nanotechnology; explains the importance of addressing nanotechnology EHS concerns; identifies and discusses nanotechnology EHS issues; and summarizes several options for congressional action, including the nanotechnology EHS-related provisions of selected legislation. The **Appendix** provides an overview of selected federal agencies' roles in the regulation of nanotechnology.

For more information on nanotechnology and the NNI see, see CRS Report RL34401, *The National Nanotechnology Initiative: Overview, Reauthorization, and Appropriations Issues*, CRS Report RL34493, *Nanotechnology and U.S. Competitiveness: Issues and Options*, and CRS Report RL34614, *Nanotechnology and Environmental, Health, and Safety: Issues for Consideration*, all by John F. Sargent. For additional information on nanotechnology-related

[4] Lux Research, as cited by *Report to the President and Congress on the Third Assessment of the National Nanotechnology Initiative*, President's Council of Advisors on Science and Technology, The White House, March 12, 2010, p. 25.

regulatory challenges, see CRS Report RL34332, *Engineered Nanoscale Materials and Derivative Products: Regulatory Challenges*, by Linda-Jo Schierow.

Opportunities and Challenges

Historically, many new technologies have delivered general societal benefits while presenting EHS challenges. For example, automobiles increased personal mobility and provided faster, less expensive transportation of goods, but soon became a leading cause of accidental deaths and injuries, as well as a source of emissions that can damage air quality and may affect the global climate. Similarly, genetically-modified (GM) plants have traits such as greater resistance to pests, pesticides, or cold temperatures that contribute to higher crop yields, while critics argue some GM foods contribute to food allergies and antibiotic resistance.[5]

Like other new technologies, nanotechnology offers potential economic and societal benefits, and presents potential EHS challenges as well. Nanotechnology advocates assert, however, that nanotechnology provides the opportunity to reduce or eliminate known risks by engineering around them. Proponents maintain that nanotechnology also offers the potential for significant EHS benefits, including:

- reducing energy consumption, pollution, and greenhouse gas emissions;
- cleaner, more efficient industrial processes;
- remediating environmental damage;
- curing, managing, or preventing deadly diseases; and
- offering new materials that protect against impacts, self-repair to prevent catastrophic failure, or change in ways that protect or aid soldiers on the battlefield.

For example, nanoscale materials show promise for preventing, detecting, tracking, and removing pollutants. According to the Environmental Protection Agency (EPA):

> nanoscale cerium oxide has been developed to decrease diesel engine emissions; iron nanoparticles can remove contaminants from soil and ground water; and nano-sized sensors hold promise for improved detection and tracking of contaminants.[6]

In the area of human health, scientists assert nanotechnology has the potential for improving disease diagnostics, sensing, monitoring, assessment, and treatment. In particular, the National Cancer Institute (NCI) views nanotechnology as likely to provide revolutionary tools to extend and improve lives. In July 2004, NCI launched a five-year, $145 million initiative focused on applying nanotechnology to the prevention, detection, and treatment of cancer and amelioration of its symptoms. At the initiative's launch, then-NCI Director Andrew von Eschenbach identified nanotechnology as a key component of the agency's strategy for ending death and suffering from cancer by 2015 (see text box, "Potential Nanotechnology Cancer Applications").[7] The NCI has reissued the program for an additional five years and expects to complete an updated plan by the end of 2010.

[5] "Genetically Modified Crops and Foods," Friends of the Earth, January 2003. http://www.foe.co.uk/resource/briefings/gm_crops_food.pdf

[6] "Fact Sheet for Nanotechnology under the Toxic Substances Control Act," Environmental Protection Agency. http://www.epa.gov/oppt/nano/nano-facts.htm

[7] "Cancer Nanotech Plan Gets Nod of Approval," Science, Vol. 305, July 23, 2004. http://www.sciencemag.org/content/vol305/issue5683/s-scope.dtl#305/5683/461c

Some characteristics of nanoscale particles could produce both positive and negative consequences. According to E. Clayton Teague, director of the National Nanotechnology Coordination Office (NNCO),

> the unique properties of these [nanotechnology] materials are a double-edged sword: they can be tailored for beneficial properties, but also have unknown consequences, such as new toxicological and environmental effects.[8]

The following examples illustrate how the same nanotechnology material may be both potentially beneficial and potentially harmful:

- Nanoscale silver is highly effective as an antibacterial agent in wound dressings, clothing, and washing machines, but some have expressed concerns that widespread dispersion of nanoscale silver in the environment could kill microbes that are vital to waste water treatment plants and to ecosystems. Some beneficial bacteria, for example, break down organic matter, remove nitrogen from water, aid in animal digestion, protect against fungal infestations, and even aid some animals in defense against predators.[9]
- Some nanoscale particles may have the potential to penetrate the blood-brain barrier, a structure that protects the brain from harmful substances in the blood but also hinders the delivery of therapeutic agents. The characteristics of certain nanoscale materials may allow pharmaceuticals to be developed to purposefully and beneficially cross this barrier and deliver medicine directly to the brain to treat, for example, a brain tumor.[10] Some critics are concerned, however, that nanoscale particles might unintentionally pass through the blood-brain barrier causing harm to humans and animals.[11]

Potential Nanotechnology Cancer Applications

The NCI Cancer Nanotechnology Plan asserts that nanotechnology can serve as an enabling technology for a variety of cancer-related applications:

- imaging agents and diagnostics that allow clinicians to detect cancer in its earliest, most easily treatable, pre-symptomatic stage;
- systems that provide real-time assessments of therapeutic and surgical efficacy;
- multifunctional, targeted devices capable of bypassing biological barriers to deliver therapeutic agents at high local concentrations directly to cancer cells and tissues that play a critical role in the growth and metastasis of cancer;
- agents capable of monitoring predictive molecular changes and preventing precancerous cells from becoming malignant;
- surveillance systems that detect mutations that may trigger the cancer process and genetic markers that indicate a predisposition for cancer;
- novel methods for managing the symptoms of cancer that adversely impact quality of life; and
- research tools that enable investigators to quickly identify new targets for clinical development and predict drug resistance.

Source: *Cancer Nanotechnology Plan: A Strategic Initiative to Transform Clinical Oncology and Basic Research Through the Directed Application of Nanotechnology*, National Cancer Institute, National Institutes of Health, Department of Health and Human Services, July 2004.

[8] *A Matter of Size: Triennial Review of the National Nanotechnology Initiative,* National Research Council, 2006. p. 148.

[9] *Nanosilver: A Threat to Soil, Water and Human Health*? Friends of the Earth, March 2007. http://www.foe.org/pdf/FoE_Australia_Nanosilver_report.pdf

[10] "Blood-Brain Barrier Breached by New Therapeutic Strategy," press release, National Institutes of Health, June 2007. http://www3.niaid.nih.gov/news/newsreleases/2007/bloodbrainbarrier.htm

[11] "Nanotechnology Risks: How Buckyballs Hurt Cells," Science Daily, May 27, 2008. http://www.sciencedaily.com/releases/2008/05/080527091910.htm

- Certain nanoscale materials are highly chemically reactive due to their high surface-to-volume ratio.[12] This is a property that might be positively exploited in catalysis, treatment of groundwater contamination, and site remediation. This property also is being explored for use in protective masks and clothing as a defense against chemical and biological agents. However, some research results indicate that the reactivity of some nanoparticles potentially can result in cell damage in animals.[13]
- Carbon nanotubes (CNTs) have potential uses in a wide range of applications (e.g., materials, batteries, memory devices, electronic displays, transparent conductors, sensors, medical imaging). However, some scientists have expressed concerns that some CNTs exhibit properties similar to asbestos fibers and might become lodged in organs (e.g., lungs, kidneys, livers), harming humans and animals.[14]

[12] *National Nanotechnology Initiative: Research and Development Supporting the Next Industrial Revolution, Supplement to the President's FY2004 Budget*, Nanoscale Science, Engineering and Technology Subcommittee, National Science and Technology Council, The White House, October 2003. http://www.nano.gov/nni04_budget_supplement.pdf

[13] Magrez, A., Kasas, S., Salicio, V., Pasquier, N., Seo, J.W., Celio, M., Catsicas, S., Schwaller, B., and Forro, L. "Cellular Toxicity of Carbon-Based Nanomaterials," *Nano Letters*, 6(6):1121-1125, American Chemical Society, May 2006. http://pubs.acs.org/cgi-bin/abstract.cgi/nalefd/2006/6/i06/abs/nl060162e.htmll

[14] *Nanotechnology: The Future is Coming Sooner Than You Think*, Joint Economic Committee, U.S. Congress, March 2007. p. 13. http://www.house.gov/jec/publications/110/nanotechnology_03-22-07.pdf

EHS Concerns About Carbon Nanotubes and Other Fullerenes

Much of the public dialogue about potential risks associated with nanotechnology has focused on carbon nanotubes (CNTs) and other fullerenes (molecules formed entirely of carbon atoms in the form of a hollow sphere, ellipsoid, or tube) since they are currently being manufactured and are among the most promising nanomaterials. These concerns have been amplified by some research on the effects of CNTs on animals and on animal and human cells. For example, researchers have reported that carbon nanotubes inserted into the trachea of mice can cause lung tissue damage;[a] that buckyballs (spherical fullerenes) caused brain damage in fish;[b] and that buckyballs can accumulate within cells and potentially cause DNA damage.[c]

There are scientists who have argued that experiments indicating CNT/fullerene toxicity are not conclusive. They suggest that toxicity reported by researchers may have resulted from uncharacterized contaminants in the samples resulting from the synthesis, purification, and post-processing methods used in the manufacture of CNTs. Thus, they assert, the experiments could be measuring the toxicity of non-nanoscale materials and, therefore, unfairly indicting nanoscale materials. They also contend that such non-nanoscale contaminants, if identified as toxic, potentially could be eliminated or controlled in the manufacturing process. The issue of contaminants is often cited by advocates for improved standards, reference materials, sensors, instrumentation, and other technologies for the characterization of nanoscale materials.

Some experiments have produced results that indicate CNTs/fullerenes are non-toxic. Research on single-walled carbon nanotubes (SWCNTs) by the Institute of Toxicology and Genetics in Karlsruhe, Germany, reported that, in three of four different types of tests conducted, SWCNTs did not show toxicity. In the fourth test, which appeared to indicate SWCNT toxicity, the researchers concluded that the results were a "false positive" and explained how the SWCNTs interacted with the materials in the assay to produce a misleading result. These researchers concluded that this result points to the need for careful selection of assays and the need for the establishment of standards for toxicity testing of CNTs and other nanomaterials.[d]

Work at Rice University's Center for Biological and Environmental Nanotechnology conducted in 2005 found cell toxicity of CNTs to be low, and that it could be reduced further through simple chemical changes to the surface.[e] Earlier research demonstrated that similar surface modifications of buckyballs reduced their toxicity. Nanotechnology may offer the potential to engineer around known and potential hazards by changing the size, molecular construction, or other property of a nanoscale material to make it safe or less hazardous. Experts advise that the potential to do so will require a thorough understanding of the properties of the various nanoparticles and their effects on humans and other organisms.

[a] Lam, C.W., James, J.T., McCluskey, R., and Hunter, R.L. "Pulmonary toxicity of single-wall carbon nanotubes in mice 7 and 90 days after intratracheal instillation," September 2003. http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=14514958

[b] Oberdörster, Eva. "Manufactured Nanomaterials (Fullerenes, C60) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass," April 2004. http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pmcentrez&artid=1247377

[c] Magrez, A., Kasas, S., Salicio, V., Pasquier, N., Seo, J.W., Celio, M., Catsicas, S., Schwaller, B., and Forro, L. "Cellular Toxicity of Carbon-Based Nanomaterials," *Nano Letters*, 6(6):1121-1125, American Chemical Society, May 2006. http://pubs.acs.org/cgi-bin/abstract.cgi/nalefd/2006/6/i06/abs/nl060162e.html

[d] Wörle-Knirsch, J.M., Pulskamp, K., and Krug, H. F. "Oops They Did It Again! Carbon Nanotubes Hoax Scientists in Viability Assays," American Chemical Society, *Nano Letters*, Vol.6, April 2006.

[e] "Modifications render carbon nanotubes nontoxic," press release, Rice University, October 2005.

Importance of Addressing EHS Issues

Nanotechnology covers a wide swath of scientific fields, engineering disciplines, and technological applications. Sufficient knowledge has been developed about the useful properties of certain nanomaterials, how they can be manufactured, and how they can be applied in useful

ways to enable commercial product development. In other areas of nanotechnology, fundamental research on nanoscale phenomena and processes is under way that may lead to greater understanding and beneficial applications in the years ahead. In general, however, nanotechnology is still an emerging field and there is a dearth of information about how nanoscale particles and devices might adversely affect human health, safety, and the environment. Accordingly, there is widespread agreement on the need for more research to better understand such implications.

In reviews of the NNI,[15] both the 2006 National Research Council and the 2008 President's Council of Advisors on Science and Technology (PCAST) reports concluded that assessment of potential nanotechnology EHS risks was not possible due to the absence of information and tools. According to the NRC,

> it is not yet possible to make a rigorous assessment of the level of risk posed by [engineered nanomaterials]. Further risk assessment protocols have to be developed, and more research is required to enable assessment of potential EHS risks from nanomaterials.[16]

Similarly, PCAST found that

> it is premature to rigorously assess the levels of risk posed by engineered nanomaterials. Adequate tools are being developed but are not yet in place.[17]

Subsequently, in its third assessment of the NNI, the NRC alluded to potential EHS risks, stating:

> Research to date suggests that some products of nanotechnology have the potential to present new or unusual risks to human health and the environment. For instance, nanoscale particles may penetrate to places in the body that are inaccessible to larger particles; radical changes in behavior at the nanoscale may render harmful materials considered to be safe in larger-scale and more conventional forms.[18]

Leaders of the NNI have argued strongly that to achieve the economic, societal, and EHS benefits of nanotechnology the nation must concurrently address its potential adverse effects. According to then-Under Secretary of Commerce for Technology Phillip J. Bond, a leading Bush Administration advocate for the NNI,

> Addressing societal and ethical issues is the right thing to do and the necessary thing to do. It is the right thing to do because as ethically responsible leaders we must ensure that technology advances human well-being and does not detract from it. It is the necessary

[15] The 21st Century Nanotechnology Research and Development Act (P.L. 108-153) requires a triennial assessment of the National Nanotechnology Program (in practice, of the NNI) by the NRC and a biennial assessment by PCAST, serving in its capacity as the National Nanotechnology Advisory Panel (NNAP). The act requires each assessment to include a review of the NNI's EHS activities. Four such assessments have been conducted, one by the NRC (*A Matter of Size: Triennial Review of the National Nanotechnology Initiative*, 2006) and three by PCAST (*The National Nanotechnology Initiative at Five Years: Assessments and Recommendations of the National Nanotechnology Advisory Panel*, May 2005; *The National Nanotechnology Initiative: Second Assessment and Recommendations of the National Nanotechnology Advisory Panel*, April 2008; and *Report to the President and Congress on the Third Assessment of the National Nanotechnology Initiative*, March 2010). In addition, in 2009 the NRC produced a report at the request of the National Nanotechnology Coordination Office entitled, *Review of Federal Strategy for Nanotechnology-related Environmental, Health, and Safety (EHS) Research.*

[16] *A Matter of Size: Triennial Review of the National Nanotechnology Initiative*, National Research Council, 2006. p. 90.

[17] *The National Nanotechnology Initiative: Second Assessment and Recommendations of the National Nanotechnology Advisory Panel*, President's Council of Advisors on Science and Technology, The White House, April 2008. p. 7.

[18] *Report to the President and Congress on the Third Assessment of the National Nanotechnology Initiative*, President's Council of Advisors on Science and Technology, The White House, March 12, 2010, p. 38. http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-nano-report.pdf

> thing to do because it is essential for speeding technology adoption, broadening the economic and societal benefits, and accelerating and increasing our return on investment.[19]

The NRC's third assessment of the NNI reinforces the perspective that EHS-related uncertainty may stymie nanotechnology innovation and commercialization:

> In the absence of more detailed scientific evidence—and effective assessment and communication of the evidence that does exist—the distinction between plausible and implausible risks remains unclear. The resulting uncertainty threatens to undermine confidence and trust amongst investors, businesses, and consumers, and could jeopardize the success of nanotechnology. This is not a hypothetical threat. Consumer and advocacy groups already have raised concerns over the use of engineered nanomaterials in products as diverse as clothing, fuel additives, and sunscreens. Businesses have been hampered by regulatory uncertainty. A number of industries have shied away from nanotechnology for fear of consumer rejection in the face of speculative concerns.[20]

According to the NRC, the nanotechnology industry and a variety of environmental and public-health interest groups agree that an adequate evaluation of the potential health and environmental effects of engineered nanomaterials is necessary

> to ensure that the future of nanotechnology is not burdened by uncertainties and innuendo about potential adverse health and environmental effects of engineered nanoscale materials.[21]

A 2006 survey of business leaders in the field of nanotechnology indicated that nearly two-thirds believed that "the risks to the public, the workforce, and the environment due to exposure to nano particles are 'not known,'" and 97% believed that it is very important or somewhat important for the government to address potential health effects and environmental risks that may be associated with nanotechnology.[22]

The Project on Emerging Nanotechnologies (PEN) has warned that bad practices in nanotechnology research or production may result in a nanotechnology accident that would

> chill investment, galvanize public opposition, and generally lead to a lot of hand wringing on the part of governments who are betting large sums of money on the nanotech revolution.[23]

Successfully addressing EHS issues is seen as vital for those potentially exposed to nanoscale materials (e.g., consumers, researchers, manufacturing workers, the general public), businesses, and investors for a variety of reasons:

- protecting and improving human health, safety, and the environment;

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[19] Bond, Phillip J., Under Secretary for Technology, U.S. Department of Commerce. "Preparing the Path for Nanotechnology: Addressing Legitimate Societal and Ethical Issues," keynote address, Nanoscale Science, Engineering, and Technology Subcommittee Workshop on Societal Implications of Nanoscience and Nanotechnology, December 3, 2003.

[20] *Report to the President and Congress on the Third Assessment of the National Nanotechnology Initiative*, President's Council of Advisors on Science and Technology, The White House, March 12, 2010, p. 38.

[21] *Review of Federal Strategy for Nanotechnology-related Environmental, Health, and Safety (EHS) Research*, National Research Council, Washington, DC, December 2008.

[22] "Survey of U.S. Nanotechnology Executives," Small Times Magazine and the Center for Economic and Civic Opinion at the University of Massachusetts-Lowell, Fall 2006.

[23] Rejeski, David, Director, Project on Emerging Nanotechnologies. "Nanotech Safety 101 or How to Avoid the Next Little Accident," paper, Workshop on Disaster Prevention, Harvard University, April 27, 2006. http://www.nanotechproject.org/file_download/files/nanotechsafety101paper.pdf

- enabling accurate and efficient risk assessments, risk management, and cost-benefit trade-offs;
- ensuring public confidence in the safety of nanotechnology research, engineering, manufacturing, and use;
- preventing a problem in one application area of nanotechnology from having negative consequences for the use of nanotechnology in unrelated application areas due to public fears, legislative interventions, or an overly-broad regulatory response; and
- ensuring that society can enjoy the widespread economic and societal benefits that nanotechnology is believed by many to offer.

In addition, the U.S. regulatory environment for nanotechnology could be an enabler for innovation and contribute to a strong, sustainable economy by creating predictability, accurately assessing risks and benefits, and fostering the swift movement of safe products into the market. Such an environment is likely to favor nanotechnology-related investments and innovative activities in the United States by domestic and foreign stakeholders, as opposed to nations where such regulatory conditions do not exist.

Conversely, if the U.S. regulatory environment is not handled effectively (i.e., if it lacks predictability, if regulatory approaches do not accurately assess risks and benefits, or if approval processes are too long or expensive) it could prove a major impediment to innovation, economic growth, and job creation, as well as posing a potential threat to health, safety, and the environment. In such a regulatory environment, investment capital may be driven away from nanotechnology, potentially beneficial products may not be developed, safe products may be denied regulatory approval, or unsafe products may be allowed to enter the market.

Alternatively, nanotechnology investments, research, and production may be driven to other nations with preferable regulatory environments. On the one hand, such a regulatory system might be more desirable to investors and companies because it is more predictable, more efficient, and less costly. In such a case, the United States might miss out on nanotechnology's potential economic benefits. On the other hand, if other nations' regulatory systems are more attractive to investors and producers because those systems under-regulate or do not regulate at all, then nanotechnology research, development, and production could present increased EHS risks worldwide.

Selected Issues for Consideration

Given the widespread agreement that nanotechnology EHS concerns must be addressed, discourse on how best to do so has focused on three main issues:

- federal investment in EHS research;
- federal regulation; and
- international engagement.

These issues are closely interrelated. For example, reliable EHS research is required by regulatory bodies to determine whether and how to regulate nanotechnology products. Since all nations face the same fundamental health, safety, and environmental issues, international coordination on EHS research could help accelerate development of a common body of knowledge through the sharing of results and reduction in redundant research. This shared knowledge could, in turn, inform regulatory decision making and perhaps improve the consistency of regulations among nations. Regulations, standards, and enforcement might need to be coordinated worldwide to protect

workers and consumers as intermediate and final products are frequently produced along global supply chains and sold in industrial and commercial markets around the world. In addition, one nation's policies governing nanotechnology production, use, and disposal may have implications for nearby nations and, perhaps, for all nations.

Federal Investment in EHS Research

Current Funding Level

There is not a single, centralized source of EHS research funds that is allocated to individual agencies. Agency nanotechnology budgets are developed internally as part of each agency's overall budget development process. These budgets are subjected to review, revision, and approval by the Office of Management and Budget (OMB) and become part of the President's annual budget submission to Congress. The NNI budget—and the EHS component—is then calculated by aggregating the nanotechnology components of the appropriations provided by Congress to each federal agency. While there is some coordination of EHS-research budget requests through the Nanotechnology Environmental and Health Implications (NEHI) working group[24] and in OMB's budget development process, the decision process that establishes overall funding for nanotechnology EHS research is highly decentralized.

In FY2010, NNI funding for EHS implications research[25] was an estimated $91.6 million, approximately 5.1% of the total NNI budget of $1.781 billion. This represented an increase over the FY2009 EHS research level of $74.5 million[26] (4.4% of the total NNI budget), and the FY2008 level of $67.9 million (4.4%), both in dollars and in share of total NNI funding. President Obama requested $116.9 million (6.6%) for EHS research in FY2011. NNI EHS research funding for FY2006 through FY2010, and President Obama's request for FY2011, is provided in **Table 1.**

Table 1. NNI EHS Research Funding, FY2006-2010, FY2011 Request

	EHS research, in current dollars	EHS research's share of total annual NNI budget
FY2006 (actual)	$ 37.7 million	2.8%
FY2007 (actual)	48.3 million	3.4%
FY2008 (actual)	67.9 million	4.4%
FY2009 regular (actual)	74.5 million	4.4%
FY2009 ARRA (actual)	12.0 million	N/A
FY2010 (actual)	91.6 million	5.1%
FY2011 (request)	116.9 million	6.6%

[24] NEHI is a working group of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the White House National Science and Technology Council (NSTC). The NSET Subcommittee is the coordinating body for the NNI. For additional information about the structure of the NNI, see CRS Report RL34401, *The National Nanotechnology Initiative: Overview, Reauthorization, and Appropriations Issues*.

[25] According to the NNCO, EHS research funding data included in Tables 1 and 2 of this report are for implications research only. The NNCO also states that the figures reported in **Table 1** may understate the NNI's EHS implications research by excluding funding for instrument research, metrology, and standards that support EHS implications research but are reported separately. (Source: Private communication between the NNCO and CRS.)

[26] Regular FY2009 appropriations only; does not include supplemental funding provided under the American Recovery and Reinvestment Act of 2009 (P.L. 111-5).

Source: CRS analysis of data from the FY2008, FY2010, and FY2011 editions of "The National Nanotechnology Initiative: Research and Development Leading to a Revolution in Technology and Industry," NSET Subcommittee, NSTC, The White House, July 2007, and "National Nanotechnology Initiative: FY2009 Budget and Highlights," NSET Subcommittee, NSTC, The White House, February 2008.

NNI officials assert that the initiative also conducts EHS research as a part of its other research activities, but that these EHS investments are not easily quantified and thus are not reflected in the NNI's reported figure for EHS funding. PCAST agreed with this assertion in its 2008 assessment, arguing that

> In many instances, nanotechnology EHS research cannot be separated from the particular application(s) research and from the context for which a specific nanomaterial is intended. Such division is unproductive and neglects the whole benefit of research. Consequently, [PCAST] expects that a substantial fraction of nanotechnology research related to EHS will continue to take place under the auspices of agencies that fund applications R&D and may not be uniquely or exclusively identified as nanotechnology EHS research.... Furthermore, detailed reporting on the degree of relevance to EHS of such research is not necessarily critical to (and may actual hinder) overall prioritization and coordination.[27]

This undercounting was evidenced in part by a one-time OMB request in 2007 to all NNI research agencies to report FY2006 funding data on research related to the five categories identified in the NSET document, *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*.[28] Totals for EHS implications research spending identified in each of the five categories is shown below in **Table 2**. Preliminary analysis of this data by the NEHI working group indicated that NNI agencies spent nearly twice as much on EHS research in FY2006 than was previously reported ($67 million identified by the OMB data-call versus $37.7 million in the President's budget.

Table 2. FY2006 NNI Funding for EHS Research
by Research Needs Categories

Category	Estimated Funding
Instrumentation, Metrology, and Analytical Methods	$27 million
Nanomaterials and Human Health	$24 million
Nanomaterials and the Environment	$13 million
Health and Environmental Exposure Assessment	$ 1 million
Risk Management Methods	$ 3 million
TOTAL	**$67 million**

Source: Teague, E. Clayton, director, National Nanotechnology Coordination Office. Testimony before the Subcommittee on Research and Science Education, Committee on Science and Technology, U.S. House of Representatives. Hearing on "Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative." 110th Congress, 1st Session, October 31, 2007.

Note: Numbers may not add due to rounding.

[27] *The National Nanotechnology Initiative: Second Assessment and Recommendations of the National Nanotechnology Advisory Panel*, President's Council of Advisors on Science and Technology, The White House, April 2008. p. 34.

[28] *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*, Nanoscale Science, Engineering, and Technology Subcommittee, National Science and Technology Council, The White House, August 2007.

Critics (as detailed in the following section) assert that the current level of federal nanotechnology EHS research is too low and represents too small a share of the overall NNI budget. These critics argue that the current allocation of NNI funding may produce a flood of products for which there is inadequate information to assess and manage their EHS risks.

However, executive branch officials stress that the United States leads the world in EHS funding and, by inference, that the current funding level is adequate. White House Office of Science and Technology Policy (OSTP) director John Marburger asserted that the United States

> leads the world not only in spending for nanotechnology development, but also, by an even larger margin, in its investment in research to understand the potential health and safety issues.[29]

Similarly, NNCO director E. Clayton Teague asserted U.S. leadership in nanotechnology EHS research:

> During fiscal years 2005 through 2008, it is estimated that NNI agencies will have invested nearly $180 million in research whose primary purpose is to address the EHS implications of nanomaterials. With these investments, the United States leads all other countries by a wide margin in support of such research.[30]

In early reviews of the NNI, both the NRC and PCAST concluded that federal EHS research funding should be expanded. According to the NRC assessment,

> To help ensure the responsible development of nanotechnology ... research on the environmental, health, and safety effects of nanotechnology [should] be expanded.[31]

PCAST acknowledged potential EHS risks in its first review of the NNI but found the federal government was "directing appropriate attention" and "adequate resources" to EHS research. In its second assessment, PCAST termed the current federal investment level in EHS "appropriate," but added that

> expanded EHS research, broad-based protocol development, and particularly standardization are necessary.... the funding level for EHS [should] continue to grow consistent with the needs identified in the NNI research strategy for nanotechnology EHS as well as the available capacity for quality research.[32]

Under President Obama, PCAST struck a different tone. In its third assessment of the NNI, PCAST acknowledged the importance of adequate funding and appropriate accounting, but emphasized that

> appropriate and targeted funding for strategic nanotechnology EHS research is more important than absolute dollar amounts. To ensure that emerging EHS issues are addressed effectively and in a way that yields useful information for regulators and policymakers, the NNI needs to help the scientific community establish a substantial core of exploratory

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[29] *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*, Nanoscale Science, Engineering, and Technology Subcommittee, National Science and Technology Council, The White House, September 2006. Cover letter.

[30] Teague, E. Clayton, director, National Nanotechnology Coordination Office. Testimony before the Subcommittee on Research and Science Education, Committee on Science and Technology, U.S. House of Representatives. Hearing on "Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative." 110th Cong., 1st Sess., October 31, 2007.

[31] *A Matter of Size: Triennial Review of the National Nanotechnology Initiative*, National Research Council, 2006. p. 92.

[32] *The National Nanotechnology Initiative: Second Assessment and Recommendations of the National Nanotechnology Advisory Panel*, President's Council of Advisors on Science and Technology, The White House, April 2008. pp. 7, 27.

> research into biological and environmental interactions with nanomaterials. In addition, the Federal Government needs to ensure sufficient funds are available to mission-driven agencies to address specific issues that are arising.[33]

In this regard, PCAST credits the NNI's "substantial funding increases for nanotechnology EHS research" for agencies such as the National Institute for Occupational Safety and Health, Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and Consumer Product Safety Commission (CPSC), noting that:

> Significantly, this will be the first time that FDA and CPSC will have had a specific allocation of funds to cover nanotechnology, a welcome move and one that the NNAP hopes is sustained over a number of years.[34]

Alternative Approaches

Various alternatives have been suggested for addressing the perceived shortcoming in EHS funding. One recommendation is requiring a fixed percentage of the NNI's total funding be devoted to EHS research. A figure of 10% has been proposed for this purpose by organizations such as the NanoBusiness Alliance and the Project on Emerging Nanotechnologies. If this proposal had been in effect in FY2010, the NNI would have been required to spend $178.1 million on EHS research, nearly twice as much as the NSET-reported level of $91.6 million. In testimony before the House Committee on Science and Technology, Sean Murdock, executive director of the NanoBusiness Alliance, agreed with the level of funding represented by the 10% figure but argued the need for cross-agency flexibility in achieving it:

> The NanoBusiness Alliance believes that environmental, health, and safety research should be fully funded and based on a clear, carefully-constructed research strategy. While we believe that 10 percent of the total funding for nanotechnology research and development is a reasonable estimate of the resources that will be required to execute the strategic plan, we also believe that actual resource levels should be driven by the strategic plan as they will vary significantly across agencies.[35]

Others have suggested a different approach, proposing fixed dollar amounts or minimum levels. For example, the Environmental Defense Fund has called for $100 million or more in federal nanotechnology EHS research funding.[36]

In its 2008 assessment, PCAST disagreed with both approaches:

> growing research in nanotechnology EHS must be strategic, guided by ... a comprehensive set of scientifically determined priorities and needs rather than arbitrary percentages or funding figures.[37]

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[33] *The National Nanotechnology Initiative: Third Assessment and Recommendations of the National Nanotechnology Advisory Panel*, President's Council of Advisors on Science and Technology, The White House, March 12, 2010. p. 45.

[34] Ibid.

[35] Murdock, Sean, executive director, NanoBusiness Alliance. Testimony before the Committee on Science and Technology, U.S. House of Representatives. Hearing on "The National Nanotechnology Initiative Amendments Act of 2008." 110th Cong., 2nd Sess., April 16, 2008.

[36] Denison, Richard A. "A Proposal to Increase Federal Funding of Nanotechnology Risk Research to at least $100 Million Annually," Environmental Defense, April 2005. http://www.edf.org/documents/4442_100milquestionl.pdf

[37] *The National Nanotechnology Initiative: Second Assessment and Recommendations of the National Nanotechnology Advisory Panel*, President's Council of Advisors on Science and Technology, The White House, April 2008. pp. 7, 27.

By establishing a 10 percent requirement (or setting a specific dollar figure), the United States could accelerate the growth in EHS research spending. However, in testimony before Congress in 2007, then-PCAST co-chair Floyd Kvamme warned against a rapid increase:

> In general, increasing funding too rapidly does not lead to equivalent increases in high quality research. It is crucial to note that EHS research also depends on advances in non-EHS areas, such as instrumentation development and basic research on nanomaterials.[38]

Some non-governmental organizations (NGOs) have advocated for a more restrained approach to nanotechnology research and development. They assert that the federal government is pushing ahead too quickly in developing nanotechnology and encouraging its commercialization and use without sufficient knowledge and understanding of EHS implications and how they might be mitigated.[39] They argue that the very characteristics that make nanotechnology promising also present significant potential risks to human health and safety and the environment. Some of these groups argue for application of the "precautionary principle,"[40] which holds that regulatory action may be required to control potentially hazardous substances even before a causal link has been established by scientific evidence.[41] In 2006, Friends of the Earth warned that

> The early warning signs surrounding nanotoxicity are serious and warrant a precautionary approach to the commercialization of all products containing nanomaterials ... there should be a moratorium on the further commercial release of sunscreens, cosmetics and personal care products that contain engineered nanomaterials, and the withdrawal of such products currently on the market, until adequate public, peer-reviewed safety studies have been completed, and adequate regulations have been put in place.... [42]

The Action Group on Erosion, Technology, and Concentration (ETC Group) has called for a moratorium on the conduct of nanotechnology R&D and use of commercial products incorporating man-made nanoparticles:

> Given the concerns raised over nanoparticle contamination in living organisms, Heads of State ... should declare an immediate moratorium on commercial production of new

[38] Kvamme, Floyd, co-chair, President's Council of Advisors on Science and Technology. Testimony before the Subcommittee on Research and Science Education, Committee on Science and Technology, U.S. House of Representatives. Hearing on "Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative," 110th Cong., 1st Sess., October 31, 2007.

[39] Maynard, Andrew, chief science advisor, Project on Emerging Nanotechnologies, a joint venture of the congressionally-chartered Woodrow Wilson Center for International Scholars and the Pew Charitable Trusts. Testimony before the Subcommittee on Research and Science Education, Committee on Science and Technology, U.S. House of Representatives. Hearing on "Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative," 110th Cong., 1st Sess., October 31, 2007.

[40] The precautionary principle has been used in other countries on some issues and is the official policy in the European Union. For international agreements a precautionary approach is sometimes embraced. For example, the Biosafety Protocol to the 1992 Convention on Biological Diversity incorporates provisions applying the precautionary principle to the safe handling, transfer, and trade of genetically modified organisms. For further information, see CRS Report RL30594, *Biosafety Protocol for Genetically Modified Organisms: Overview*, by Alejandro E. Segarra and Susan R. Fletcher.

[41] "NGOs urge precautionary principle in use of nanomaterials," EurActiv.com, June 14, 2007, http://www.euractiv.com/en/environment/ngos-urge-precautionary-principle-use- nanomaterials/article-164619; Sass, Jennifer, "Nanotechnology and the Precautionary Principle," presentation, Natural Resources Defense Council, 2006. http://docs.nrdc.org/health/hea_06121401A.pdf

[42] *Nanomaterials, Sunscreens, and Cosmetics: Small Ingredients, Big Risks*, Friends of the Earth, May 2006. http://www.foe.org/camps/comm/nanotech/nanocosmetics.pdf

> nanomaterials and launch a transparent global process for evaluating the socio-economic, health and environmental implications of the technology.[43]

In 2003, the ETC Group expanded the breadth of its proposed moratorium:

> In the absence of toxicology studies, ETC Group believes that governments must also urgently consider extending the moratorium to products that place consumers in direct contact with synthetic nanoparticles through their skin, lungs or digestive systems.[44]

In contrast to these views, a report prepared by the NSET Subcommittee concluded that conducting EHS research in parallel with the development of nanomaterials and their applications will help to ensure the full, safe, and responsible realization of the promise of nanotechnology.[45]

In 2003, then-Under Secretary of Commerce for Technology Phillip J. Bond addressed called for a moratorium or slowdown in nanotechnology R&D, casting the issue in ethical terms:

> Those who would have us stop in our tracks argue that it is the only ethical choice. I disagree. In fact, I believe a halt, or even a slowdown, would be the most unethical of choices.... Given the promise of nanotechnology, how can our attempt to harness its power at the earliest opportunity—to alleviate so many of our earthly ills—be anything other than ethical? Conversely, how can a choice not to attempt to harness its power be anything other than unethical?[46]

Management of Federal EHS Research

Research Priorities and Strategies

In order to manage the Federal EHS portfolio, policymakers will need to establish research priorities. In its first review of the NNI, the NRC recommended that

> Assessing the effects of engineered nanomaterials on public health and the environment requires that the research conducted be well defined and reproducible and that effective methods be developed and applied to (1) estimate the exposure of humans, wildlife, and other ecological receptors to source material; (2) assess effects on human health and ecosystems of both occupational and environmental exposure; and (3) characterize, assess, and manage the risks associated with exposure.[47]

In 2005, PCAST concluded that EHS research should give highest priority to workplace exposure, noting

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[43] "No Small Matter," Communique, ETC Group, May/June 2002. http://www.etcgroup.org/upload/publication/pdf_file/192 The ETC group is a non-governmental organization focused on the global societal impacts of emerging technologies.

[44] "No Small Matter II: The Case for a Global Moratorium," Occasional Paper Series, ETC Group, April 2003. http://www.etcgroup.org/upload/publication/pdf_file/165

[45] *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials,* Nanoscale Science, Engineering, and Technology Subcommittee, National Science and Technology Council, The White House, September 2006. p. vii.

[46] Bond, Phillip J., Under Secretary for Technology, U.S. Department of Commerce. "Nanotechnology: Economic Opportunities, Societal and Ethical Challenges," keynote address, NanoCommerce 2003, December 9, 2003.

[47] *A Matter of Size: Triennial Review of the National Nanotechnology Initiative,* National Research Council, 2006. p. 92.

> the greatest likelihood of exposure to nanomaterials is during manufacture, and therefore [we] agree with the prioritization of research on potential hazards from workplace exposure.[48]

In its 2008 assessment, PCAST reiterated this point stating, "the greatest risk of exposure to nanomaterials at present is to workers who manufacture or handle such material," but also acknowledged a broader range of risks:

> environmental, health, and safety risks in a wide range of settings must be identified and the necessary research performed so that real risks can be appropriately addressed.[49]

In February 2008, the NSET published its much-awaited *Federal Strategy for Environmental, Health, and Safety (EHS) Research Needs for Engineered Nanoscale Materials*. The report describes the NNI's EHS research strategy, identifies lead agencies for each of five research categories, and asserts that it provides "a framework to guide and inform agency efforts to address prioritized research areas and to sustain a diverse program to advance knowledge and support risk decision-making."[50]

Subsequently, the NSET requested the NRC independently review this strategy document. In 2009, the NRC published the results of its review, Review of Federal Strategy for Nanotechnology-related Environmental, Health, and Safety (EHS) Research.[51] While complimentary of the widespread collaboration and coordination required to produce the report and its potential usefulness in "communicating the breadth of federally supported research associated with developing a more comprehensive understanding of the environmental, health, and safety implications of nanotechnology," the NRC review asserted that:

- research needs in risk management and exposure assessment were "poorly defined and incomplete;"
- research needs were not presented as "concrete, measurable objectives" and that no explanation was provided of how success would be measured or the amount of resources required to achieve them;
- the NSET overstates federal funding specifically addressing nanotechnology-related EHS issues and that funding may be inadequate;
- the approach used by the NSET for its gap analysis is "flawed and is neither accurate nor complete in laying a foundation for a research strategy"; and
- federal EHS nanotechnology funding is dominated by agencies traditionally focused on exploratory and investigator-driven research (such as NIH and NSF) and that if these agencies are to continue to lead, their approaches may need to be modified "to ensure that the research they support feeds into an effective EHS risk research strategy based on appropriate, targeted research."

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[48] *The National Nanotechnology Initiative at Five Years: Assessments and Recommendations of the National Nanotechnology Advisory Panel*, President's Council of Advisors on Science and Technology, The White House, May 2005. p. 35.

[49] *The National Nanotechnology Initiative: Second Assessment and Recommendations of the National Nanotechnology Advisory Panel*, President's Council of Advisors on Science and Technology, The White House, April 2008. p. 2.

[50] *Federal Strategy for Environmental, Health, and Safety (EHS) Research Needs for Engineered Nanoscale Materials*, Nanoscale Science, Engineering, and Technology Subcommittee, National Science and Technology Council, The White House, February 2008.

[51] *Review of Federal Strategy for Nanotechnology-related Environmental, Health, and Safety (EHS) Research*, National Research Council, Washington, DC, December 2008.

The NRC concluded that what was needed was an effective "national strategy" that involves a range of stakeholders beyond the federal government, including academia, industry, consumer and environmental groups, and others. Such a plan, according to the NRC, would

> identify research needs clearly and estimate the financial and technical resources needed to address identified research gaps. A national strategic plan would be focused on providing solutions to challenges that do not necessarily fit neatly into disciplinary and institutional silos, and ensure important research does not fall between the gaps. Such a plan would also provide specific, measurable objectives and a timeline for meeting them.[52]

Proposals for a Research Roadmap: Differing Perspectives

Some stakeholders assert that a comprehensive approach to federal EHS research has been hampered by the lack of an NNI roadmap for these efforts.[53] In general, these stakeholders seek a multi-year roadmap with specific milestones, metrics, and funding levels. Such a roadmap, they assert, would contribute to a more coordinated approach among agencies and between the executive branch and Congress on the magnitude, timing, prioritization, and management of federal EHS research.

NNI officials argue that the NSET Subcommittee, the coordinating body for the NNI, has developed an EHS research strategy and articulated it in three reports (see text box, "NNI EHS-focused Reports"), though they acknowledge that these documents do not constitute a roadmap. Some Members of Congress have expressed concerns about the time required by the National Nanotechnology Coordination Office to produce a prioritized, detailed implementation plan for NNI EHS research.[54] While acknowledging the challenges faced by the NNCO in developing consensus among the 25 NNI agencies, some Members suggested that these challenges were emblematic of the need for a more top-down approach to EHS research.

NNI EHS-focused Reports

Environmental Health and Safety Research Needs for Engineered Nanoscale Materials, published in September 2006, identified the research and information needed to enable sound risk assessment and risk management decision making with respect to nanoscale materials and products that incorporate them.

Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials, published in August 2007, identified five broad categories of EHS research and information needs, and five specific research areas in each category.

The National Nanotechnology Initiative: Strategy for Nanotechnology-related Environmental, Health, and Safety Research, published in February 2008, defined the NNI's strategy for addressing priority research on EHS aspects of nanomaterials. The document reviewed current agency research using the taxonomy developed in the second report; identified research gaps; and articulated a framework for prioritizing research, implementing the strategy, and coordinating agency efforts.

Opposition to an EHS roadmap stems primarily from doubts of the practicality and efficacy of such an approach. Some argue that it is unlikely that OMB would commit to a multi-year, multi-agency roadmap accompanied by specific funding levels. Such an approach would depart from the current executive branch annual budget development process and reduce OMB's flexibility in future years. In addition, agencies often have to respond to new requirements based on emergent circumstances, Congressional

[52] Ibid.

[53] Rejeski, David, director, Project on Emerging Nanotechnologies. Public comments on the Nanoscale Science, Engineering, and Technology Subcommittee's report, *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials: An Interim Document for Public Comment*, September 12, 2007. http://www.nanotechproject.org/process/files/5891/nehi_comments_070912_final.pdf

[54] Hearing on "Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative." 110th Cong., 1st Sess., October 31, 2007.

direction, or other factors. Agency funding is often redirected from planned efforts to new, often imminent, priorities. The need for such redirection of funding could impede the achievement of roadmap milestones and metrics or, conversely, impede the movement of funding to new priorities.

To overcome the obstacles associated with the development of a roadmap by the agencies, some have suggested the National Academies produce such a roadmap. Some experts assert that this approach worked well with respect to the development of a federal research roadmap to reduce EHS uncertainties associated with airborne particulate matter. Others argue that the particulate matter effort focused only a narrow field and covered research conducted by only a single agency (EPA); in contrast, nanotechnology spans a broad range of materials and applications across many fields, and requires EHS research efforts by several agencies.

In February 2007, 19 environmental and business organizations, large and small companies, and research organizations signed a letter to the Senate Appropriations Subcommittee on Interior, Environment, and Related Agencies requesting $1 million be appropriated for the development of a federal roadmap and research strategy. The letter recommended that this work be done by the National Institute of Environmental Health Sciences (NIEHS).[55]

The Senate Appropriations Committee report (S.Rept. 110-91) accompanying the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2008[56] urged the Environmental Protection Agency (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.[57]

In July 2009, the National Academies' Board on Environmental Science and Toxicology began an EPA-sponsored project, titled "A Research Strategy for Environmental, Health, and Safety Aspects of Engineered Nanomaterials." According to the National Academies, the project is to produce two reports over four years. The first report, due 18 months from project inception, is to

> present a conceptual framework and priorities for the research program, identify the most important short-term and longer-term research priorities, develop a strategy for monitoring and evaluating research progress, and estimate the resources needed to implement this strategy.[58]

The second report, due at the end of the study period (approximately July 2013), is to

> evaluate research progress and update the research priorities and resource estimates based on results of studies and emerging trends in the nanotechnology industry.[59]

Budget Development, and Coordination and Integration of Efforts

The process used to develop research priorities and the federal EHS budget has also raised management concerns. As discussed earlier, the federal nanotechnology EHS research portfolio

[55] An electronic copy of this letter, dated February 22, 2007, was provided to the Congressional Research Service (CRS) by the American Chemistry Council.

[56] Incorporated as division F of the Consolidated Appropriations Act, 2008 (P.L. 110-161).

[57] S.Rept. 110-91, p. 54.

[58] *Study in Progress: A Research Strategy for Environmental, Health, and Safety Aspects of Engineered Nanomaterials,* National Academies website. http://dels.nas.edu/Study-In-Progress/Research-Strategy-Environmental-Health/BEST-K-08-01-A

[59] Ibid.

results from research funding requests made by individual agencies pursuing their missions and by decisions made in the congressional appropriations process. Informal research coordination among EHS funding agencies occurs through the NEHI working group and more formally through the OMB budget development process.

In its third review of the NNI, PCAST recommended that

> the NSET Subcommittee implement organizational changes that support consequential cross-agency action on addressing nanotechnology EHS issues. In particular, the NNCO should create a senior-level position to lead interagency coordination of efforts in the area of EHS.[60]

In 2010, the NNCO established and filled a new position with the dual titles of Deputy Director and EHS Coordinator. A primary duty of this position is the coordination of EHS research among NNI agencies.

Some proponents for an integrated federal EHS research effort have called for a more top-down approach. The Woodrow Wilson Center's Project on Emerging Nanotechnologies (PEN) has been a leading advocate on this issue. PEN's chief science advisor, Andrew Maynard, asserted that

> to realize nanotechnology's benefits ... the federal government needs a master plan for identifying and reducing potential risks. This plan should include a top-down risk research strategy, dedicated and sufficient funding to do the job, and the mechanisms to ensure that resources are used effectively.[61]

PEN has recommended increasing the authorities of the NEHI working group to empower it to develop and implement the top-down research plan, increasing EHS funding, and appointing a full-time director to support the NEHI working group.

Responding to the PEN recommendation, E. Clayton Teague, director of the NNCO, testified before Congress that there was a consensus among NNI agencies that a centralized office with budgetary authority to oversee the NNI's EHS research program would have significant detrimental effects. According to Dr. Teague,

> No one agency or centralized organization would have the breadth of scientific expertise and knowledge of regulatory authorities and needs currently represented by the 20 agencies participating in the NEHI working group.
>
> Creation of a new central authority would undermine the existing successful interagency coordination.
>
> Moving the management of all nanotechnology EHS research into a single office would likely decouple such research from related efforts within NNI agencies and from the knowledge base in the agencies that is currently networked into the NNI's EHS research effort.
>
> Creating a separate office would, on the one hand, give mission agencies a disincentive for doing nanotechnology-related EHS research. They would reasonably assume that another agency is responsible, and they therefore could redirect their limited resources to address

[60] *The National Nanotechnology Initiative: Third Assessment and Recommendations of the National Nanotechnology Advisory Panel*, President's Council of Advisors on Science and Technology, The White House, March 12, 2010. p. xiii.

[61] Maynard, Andrew, chief science advisor, Project on Emerging Nanotechnologies. "Public Meeting on Research Needs and Priorities Related to Environmental, Health, and Safety Aspects of Engineered Nanoscale Materials," comments, January 4, 2007. http://www.nano.gov/html/meetings/ehs/uploads/20070103_1505_Nanotechnology_Maynard_NNCO_Comments.pdf

> other priorities. A likely result could be that the level of research would actually decrease. Conversely, creating a separate office could lead to duplicative work being funded, thereby wasting tax dollars and not optimizing progress.[62]

Andrew Maynard counters that "it should be possible to develop a functional structure that enables agencies to work within a broader plan." According to Maynard, while a centralized office is not necessary,

> top-down leadership with authority and the ability to ensure resources get to where they are needed is necessary.... [Such] leadership does not take away from agencies' expertise and missions, but rather empowers agencies to do the best they can, while coordinating and partnering as effectively as possible with each other.[63]

A Cooperative Approach to Addressing EHS Concerns

Some organizations have taken a cooperative approach to promote EHS research. For example, the Environmental Defense Fund, an environmental advocacy group, partnered with the American Chemistry Council, a trade group, to issue a Joint Statement of Principles in June 2005 that recognizes the "significant societal and sustainable development benefits" expected from nanotechnology, while calling for a multi-stakeholder dialogue to achieve the timely development of nanomaterials "in a way that minimizes potential risks to human health and the environment." The statement also called for increased federal investments in EHS research and

> development of an international effort to standardize testing protocols, hazard and exposure assessment approaches, and nomenclature and terminology ... to maximize resources and minimize inconsistent regulation of nanomaterials.[a]

There is general agreement among stakeholders that these activities can contribute to creating an environment where research results can be reliably shared and compared, to protecting human health and safety, and to creating a common language about nanotechnology that increases clarity in the sharing of ideas and information. However international standardization efforts are often time- and resource-consuming, and can divert resources from more pressing needs. In addition, such efforts can be used by nations and other organizations for competitive advantage (e.g., by securing the adoption of a favorable standard, slowing others' progress).

In June 2007, the Environmental Defense Fund and DuPont issued a Nano Risk Framework "to assist with the responsible development and use of nanotechnology and to help inform global dialogue on its potential risks."[b] The framework is a six-step process to identify, address, and manage potential risks: (1) describe the material and the intended application; (2) profile the material's lifecycle in the application; (3) evaluate associated risks; (4) assess risk management options; (5) decide on and document actions; and, (6) regularly review new information and adapt actions accordingly.[c]

[a] *Environmental Defense and American Chemistry Council Nanotechnology Panel: Joint Statement of Principles*, Comments on EPA's Notice of a Public Meeting on Nanoscale Materials, June 23, 2005.

[b] "DuPont and Environmental Defense Launch Comprehensive Tool for Evaluating and Addressing Potential Risks of Nanoscale Materials," press release, E. I. du Pont de Nemours and Company, June 21, 2007. http://vocuspr.vocus.com/VocusPR30/Newsroom/Query.aspx?SiteName=DupontNew&Entity=PRAsset&SF_PRAsset_PRAssetID_EQ=106677&XSL=PressRelease&Cache=False

[c] *Nanorisk Framework*, Environmental Defense-DuPont Nano Partnership, June 2007.

[62] Teague, E. Clayton, director, National Nanotechnology Coordination Office. Testimony before the Subcommittee on Research and Science Education, Committee on Science and Technology, U.S. House of Representatives. Hearing on "Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative." 110th Cong., 1st Sess., October 31, 2007.

[63] E-mail communication, November 21, 2007.

Project on Emerging Nanotechnologies Recommendations

The Project on Emerging Nanotechnologies (PEN), a joint venture of the congressionally-chartered Woodrow Wilson Center for International Scholars and the Pew Charitable Trusts, has produced inventories of both nanotechnology-based products and government-funded EHS research. PEN has asserted the need for more EHS research, more aggressive oversight, and a more centralized federal government approach to funding EHS research.

In addition, PEN contends that the increasing complexity of systems incorporating nanoparticles with multiple functions will make the behaviors more complex and difficult to predict. To minimize the likelihood of a nanotechnology accident, PEN made the following recommendations:

- Creating a Nano Safety Reporting System where people working with nanotechnology can anonymously report safety issues and concerns. PEN states that the information gleaned from this system could be used to inform the design of educational materials, better structure technical assistance programs, and provide an early indicator of emerging safety issues.
- Creating technologies that provide an early-warning system to allow for risk to be assessed early in research efforts. Such a technology might enable low-cost, fast-screening for novel properties that would allow for risk assessment integrated and concurrent with the R&D process.
- Pushing information out to small businesses, start-ups, and laboratories that, due to their size and resources, are unlikely to be able to devote significant resources to EHS issues. PEN states that existing assistance programs could be used to deliver this information, as well as the development of peer-to-peer mentoring programs within industrial supply chains.
- Application of lessons learned in other technology areas to make nanotechnology more inherently safe, using strategies such as multiple levels of protection, learning from failures, not oversimplifying the complex, awareness of operations, and building in resilience to prevent cascading of errors.

Source: Rejeski, David, director, Project on Emerging Nanotechnologies. "Nanotech Safety 101 or How to Avoid the Next Little Accident," paper, Workshop on Disaster Prevention, Harvard University, April 27, 2006.

Federal Regulation

Some have raised concerns about whether current laws, regulations, and authorities are adequate to protect human health, safety, and the environment from potential adverse implications of nanotechnology. Several factors may affect the ability of the regulatory system to keep pace with advances in technology, both broadly and specifically with respect to nanotechnology.

Broadly, market forces have increased the pace of global innovation, challenging institutions' ability to identify and cope with the societal implications of rapid change. Speed-to-market has become a driving factor in competition for many industries as a result of the entry of new and nimble competitors in the global marketplace, increased public and private investments in R&D, global models of innovation, increased flows of scientific and technical knowledge, and greater numbers of scientists and engineers around the world. In addition, growing global markets enable companies to recoup their investments faster and enable earlier investments in subsequent generations of technology, further accelerating the pace of innovation. The increased pace, scope, and complexity of technological innovation may pose challenges to the existing regulatory system. While these factors may affect a broad range of technologies, nanotechnology may be especially affected due to the rapid growth in public and private R&D investments in the field since the year 2000 and the potential for nanomaterials to be used in a wide array of products.

Unique Properties Emerge at the Nanoscale

Scientists have discovered that elements and materials with the same chemistry can exhibit fundamentally different properties at the nanoscale. For example, platinum, which exhibits no magnetism in its bulk form, shows significant magnetic properties in nanoscale clusters of 13 atoms. The optical properties of gold also can change with particle size. At 10 nanometers, gold particles absorb green light and appear red, not gold.

Not only can nanoscale particles differ in properties from bulk material with the same chemical composition, they may also differ from other nanoscale materials with the same chemical composition. For example, the melting point of an element—which was believed to be constant regardless of the element's particle size—can change with particle size. Nanotechnology research has demonstrated that the melting temperature of gold decreases when the particle's radius drops below 10 nanometers (from a melting temperature of approximately 1,000°C at 10 nanometers to approximately 500°C at 2 nanometers).

Source: Roduner, Emil. "Nanoscopic Materials: Size-Dependent Phenomena," University of Stuttgart, Germany, August 2006.

Nanotechnology also may pose unique challenges to the regulatory system. For example, historically, regulatory agencies have defined a chemical by its chemical composition, usually without regard to its particle size. In contrast, the essence of nanotechnology is that a material may exhibit different properties at the nanoscale than it does at a bulk, molecular, or atomic scale. (See text box, "Unique Properties Emerge at the Nanoscale.") Accordingly, questions are being raised by representatives of the scientific, advocacy, and regulatory communities about how an EHS research portfolio might be structured when particle size may affect a material's properties, whether it may be necessary to incorporate particle size into regulatory regimes, and how this might be accomplished given the vast spectrum of particle sizes that might affect the characteristics of a particular material.

Some experts argue that EHS concerns about nanotechnology products can be handled under existing laws and regulations, while others see legal obstacles to adequate EHS regulation. In both of its assessments of the NNI, PCAST concluded that existing regulatory authorities were adequate for the current activities; that appropriate regulatory mechanisms should be used to address instances of harmful human or environmental effects of nanotechnology; and that new regulatory policies related to nanotechnology should be rational, science-based, and consistent

across the federal government. Similarly, Sean Murdock, then-executive director of the NanoBusiness Alliance, asserted that

> The apparatus for effective nanotechnology regulation is largely in place through various statutes and agencies, but it lacks data and resources. To enable these agencies and for the nanotech regulation effort to succeed we must increase the level of funding available to them for nanotech environmental, health and safety research; coordinate efforts between agencies; establish metrics and standards that can be used to characterize nanomaterials; conduct ongoing research; and more.[64]

Others believe that new laws and regulations, or modifications to existing ones, may be required. J. Clarence Davies, senior advisor to the Project on Emerging Nanotechnologies and former EPA Assistant Administrator for Policy, Planning, and Evaluation argued that

> Nanotechnology is difficult to address using existing regulations. There are a number of existing laws—notably the Toxic Substances Control Act; the Occupational Safety and Health Act; the Food, Drug and Cosmetic Act; and the major environmental laws (Clean Air Act, Clean Water Act, and Resource Conservation and Recovery Act)—that provide some legal basis for reviewing and regulating [nanotechnology] materials. However, all of these laws either suffer from major shortcomings of legal authority, or from a gross lack of resources, or both. They provide a very weak basis for identifying and protecting the public from potential risk, especially as nanotechnologies become more complex in structure and function and the applications become more diverse.
>
> A new law may be required to manage potential risks of nanotechnology. The law would require manufacturers to submit a sustainability plan which would show that the product will not present an unacceptable risk.[65]

In a 2008 PEN report, *Oversight of Next Generation Nanotechnology*, Davies asserted that nanotechnology, along with other advanced technologies, have characteristics that challenge conventional methods of risk assessment, standard setting, and oversight implementation, severely hampering the effectiveness of the existing regulatory structure.

> Since 1980, the capability of the federal agencies responsible for environmental health and safety has steadily eroded. The agencies cannot perform their basic functions now, and they are completely unable to cope with the new challenges they face in the 21st century.[66]

As an alternative, Davies put forward a concept for a Department of Environmental and Consumer Protection, "a scientific agency with a strong oversight component, in contrast to the current regulatory agencies, which are primarily oversight bodies." The agency would incorporate six existing regulatory and science agencies and establish new units for risk assessment, forecasting, technology assessment, health monitoring, and collection of environmental statistics.[67]

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[64] "Nanotechnology Leaders to Converge in Washington, D.C., This Week for NanoBusiness Alliance Public Policy Tour," article, nanotechwire.com, February 16, 2006. http://nanotechwire.com/news.asp?nid=2929

[65] Davies, J. Clarence. *Managing the Effects of Nanotechnology*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, DC, January 2006. p. 3. http://www.nanotechproject.org/process/assets/files/2708/30_pen2_mngeffects.pdf

[66] Davies, J. Clarence. *Oversight of Next Generation Nanotechnologies*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, DC, April 2009. http://www.nanotechproject.org/process/assets/files/7316/pen-18.pdf

[67] Ibid.

Davies also stated that new mechanisms and institutional capabilities—including research programs, tax breaks, acquisition programs, and regulatory incentives—are needed to encourage beneficial applications of nanotechnology.

In developing the regulatory structure, some in the business and financial communities argue that stability and predictability are key characteristics for attracting investment and spurring commercial applications. According to Matthew Nordan, then-vice president of Lux Research, the

> ambiguity surrounding environmental, health, and safety regulation of nanoparticles is hampering commercialization. Firms do not want to play a game whose rules may change at any time.... That doesn't mean they want more regulations or more onerous regulations. They're just looking for a roadmap on how federal agencies such as the EPA or OSHA [Occupational Safety and Health Administration] plan to approach nanoparticles.[68]

Some tension exists between the goals of promoting the development of nanotechnology, ensuring the global competitive position of the United States, addressing potential EHS implications of nanotechnology, and coping with the unique challenges nanotechnology poses to the current regulatory regime. To prevent health and safety concerns from becoming an impediment to innovation, some suggest that health and safety research and regulation must be done near-concurrently with product development, keeping pace with the speed of innovation. Alternatively, others argue that the potential health, safety, and environmental implications are either unknown or of such significance that EHS research and regulation must precede nanotechnology development and commercialization. "By the time monitoring catches up to commerce the damage will already have been done," asserted Ian Illuminato, health and environment campaigner for Friends of the Earth.[69] AFL-CIO industrial hygienist Bill Kojola warned that

> Even though potential health hazards stemming from exposure have been clearly identified, there are no mandatory workplace measures that require exposures to be assessed, workers to be trained, or control measures to be implemented. [Nanotechnology] should not be rushed to market until these failings are corrected and workers assured of their safety.[70]

The National Research Council assessment of the NNI acknowledged the need for additional reproducible, well-characterized EHS data to inform risk-based guidelines and best practices and warned that until such information is available precautionary measures should be taken to protect the health and safety of workers, the public, and the environment.[71]

In its 2008 assessment of the NNI, PCAST asserted that risk research must not be considered in isolation, but rather in the context of the overall risks and benefits of a particular material or technology. This perspective is shared by many industry advocates who argue that regulatory decisions must balance the potential risks associated with a nanotechnology product against the benefits it delivers and the risk it displaces. Further, they maintain that nanotechnology products should not be held to a higher standard than non-nanotechnology products. PCAST also noted that manufacturers and sellers of nanotechnology products had responsibilities for ensuring workplace and product safety, and asserted that the NNI has a vital role in supporting federal regulatory agencies by providing them with EHS research results.

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[68] "U.S. Risks Losing Nano Lead," article, physorg.com, July 6, 2005. http://www.physorg.com/news4963.html

[69] "International Coalition Calls for Oversight of Nanotechnology," press release, Friends of the Earth, July 31, 2007. http://action.foe.org/dia/organizationsORG/foe/pressRelease.jsp?press_release_KEY=248

[70] Ibid.

[71] *A Matter of Size: Triennial Review of the National Nanotechnology Initiative*, National Research Council, 2006. p.11.

International Engagement

International engagement on EHS issues is believed by many to be important to the responsible development and successful commercialization of nanotechnology. NNI officials assert that the United States has played a central role in convening international efforts to address EHS concerns. In its 2008 assessment, PCAST encouraged the NNI to coordinate its efforts with other nations to avoid duplication and to leverage investments, characterizing such work as "non-competitive."[72] In its 2010 assessment, PCAST acknowledged the wide range of international engagement by the NNI and its member agencies and recommended that these efforts be "continued and expanded."[73]

Federal agencies have engaged internationally (e.g., with agencies of other nations, international organizations, standards organizations) across a wide range of nanotechnology-related areas, including standards, nomenclature, and EHS research. The NSET established the Global Issues in Nanotechnology (GIN) working group in 2005 to monitor foreign nanotechnology programs, promote U.S. commercial and trade interests in nanotechnology, and broaden international collaboration on nanotechnology R&D, including research on safeguarding the environment and human health.

Advocates for international engagement assert a variety of potential benefits. For example, transparency and/or harmonization of standards and regulations may contribute to assurance of global supply chains and market confidence in nanotechnology products. Increased globalization of production and markets means that companies and consumers around the world are increasingly part of a common network. Manufacturers of final products generally rely on inputs from multiple suppliers in their global supply chains. The reliability of a final product often depends on the reliability of inputs, such as materials or components. Transparent and common standards and regulations may help to ensure the integrity of supply chains and final products. While this is an issue for a variety of non-nanotechnology products (e.g., the recent discovery of lead-tainted toys and other products imported from China), nanotechnology may present a unique challenge in that at least some nanoscale particles can be incorporated into materials and products in ways that cannot be easily detected or detected at all. Thus, producers and the consumers they serve must rely, in large measure, on standards and regulatory systems to ensure that nanoscale materials are properly produced and represented throughout the supply chain. In the absence of such standards and regulatory systems, producers may not be able to rely on inputs or may incur additional costs for testing and verification; substandard inputs may be incorporated in final products making them underperform or unsafe, and possibly resulting in loss of market confidence and/or potential litigation; or nanotechnology materials may be incorporated without disclosure.

Internationally agreed upon standards could also contribute to greater comparability of research results, improving understanding of EHS-related aspects of nanotechnology, and promoting regulations that help protect human health and the environment. Common standards and nomenclature also may contribute to more effective global R&D collaboration, accelerating the realization of nanotechnology's economic and societal potential.

Global engagement may help to establish a common environment for the development and production of nanotechnology products and to promote access to global markets. In the absence

[72] *The National Nanotechnology Initiative: Second Assessment and Recommendations of the National Nanotechnology Advisory Panel*, President's Council of Advisors on Science and Technology, April 2008. p. 33.

[73] *Report to the President and Congress on the Third Assessment of the National Nanotechnology Initiative*, President's Council of Advisors on Science and Technology, The White House, March 12, 2010, p. 42.

of such an environment, some nations may seek to attract investments in their markets by adopting lower environmental, health, and safety standards and regulations.

Finally, while much remains unknown about the transport and fate of nanoscale materials released into the environment, it is possible that countries and populations other than those where research and production activities take place may be affected. Efforts to promote the adoption of best practices in nanotechnology research, production, use, disposal, and recycling may protect human health and the environment worldwide.

International engagement on EHS research may pose problems, including the time, cost, difficulty, and alleged ineffectiveness of such collaborations. For example, while some advocates assert the need for swift action in advancing EHS research, international engagements often entail slow processes. Also, given the strong U.S. position in nanotechnology, broadly, and in nanotechnology EHS research, specifically, some may argue that other countries have little to contribute, that such efforts tax limited federal EHS financial and human resources, and that such diffusion of resources may slow overall EHS progress. Others might assert that international engagement efforts focused explicitly on nanotechnology are unnecessary given the wide variety of existing mechanisms and pathways for sharing academic research and environmental, health, and safety information across national borders.

Some may oppose international engagement efforts because they lack faith in the goodwill of participating parties due to the potentially strong national interests at stake (e.g., military applications, economic growth, job creation). In 2003, then-Under Secretary of Commerce for Technology Phillip J. Bond questioned whether global calls for a slowdown in nanotechnology R&D to address EHS concerns were intended to allow other nations to close the nanotechnology leadership gap with the United States:

> I wonder very often if there are really calls for a slow-down so that other governments and countries might catch up.[74]

Others assert that the research required to understand and address EHS implications may be closely linked to applications-related R&D to create nanotechnology materials, products, or processes. In such cases, companies and countries may be reluctant to reveal EHS concerns and efforts, to cooperate in EHS research, or to share results as such actions may reveal competitive strategies, provide information others might use to compete against them (e.g., insights into promising materials or manufacturing processes), or result in unwanted scrutiny by regulators.

Concluding Observations

Advocates and critics agree that potential environmental, health, and safety implications of nanotechnology must be addressed if the full economic and societal benefits of nanotechnology are to be achieved. There is also general agreement that the current body of knowledge of how nanoscale materials might affect humans and the environment is insufficient to assess, address, and manage the potential risks. While there is agreement on the need for more EHS research, there are differing views on the level of funding required, how it should be managed, and related issues.

In the 111th Congress a variety of legislation was considered seeking to address, in some manner, EHS-related issues, including: H.R. 5116 (111th Congress) (Title I, Subtitle A); H.R. 554 (111th Congress) and S. 1482 (111th Congress), both titled "National Nanotechnology Initiative

[74] *Regional, State, and Local Initiatives in Nanotechnology*, Nanoscale Science, Engineering, and Technology Subcommittee, National Science and Technology Council, The White House, 2005. p. 33.

Amendments Act of 2009," which would reauthorize and amend the 21st Century Nanotechnology Research and Development Act; S. 2942 (111th Congress), the Nanotechnology Safety Act of 2010; H.R. 820 (111th Congress), the Nanotechnology Advancement and New Opportunities Act; and the appropriations bills that fund the NNI agencies' nanotechnology EHS research.

None of these bills were enacted. The 112th Congress may again seek to address nanotechnology EHS implications issues, including:

- Is there a need for a national EHS research strategy to identify and address knowledge gaps? If so, which institutions should be a part of such a strategy? Which institution(s) should develop such a strategy?
- Should the federal approach to EHS research be bottom-up, driven by individual agency decisions and coordinated by the NNCO? Should it be top-down with a central controlling authority? Or should the federal government take a hybrid approach, using a central office with its own funding to address research needs not addressed by other agencies?
- How much should the federal government appropriate for EHS research? Should the amount of EHS funding be proportionate to the overall NNI budget? How should the research be prioritized? How can the federal EHS research investment be better accounted for? How can EHS research results and best practices be shared more broadly?
- Can voluntary programs effectively provide needed information about industrial nanotechnology production activities? Are existing laws, regulations, guidelines, and regulatory structures adequate? Should agencies be more aggressive in their use of regulatory authority to collect more information from companies about the nanotechnology and nanotechnology-enabled products they manufacture? Is there sufficient coordination among federal regulatory agencies?
- How can efforts to develop common nomenclature and standards be improved? What types of international engagement on nanotechnology research and regulatory issues could best foster responsible development of nanotechnology and ensure confidence in supply chains?

Congress' approach to each of these issues may have a substantial effect on U.S. leadership in nanotechnology R&D and commercialization, the realization of the potential societal benefits of nanotechnology, public health and safety, the environment, and the public policy decisions and investments made by other nations.

Nanotechnology EHS-Related Legislation in the 111th Congress

Five bills introduced in the 111th Congress contained provisions that sought to address nanotechnology EHS concerns. The following section summarizes selected EHS-related provisions of these bills.

Title I, Subtitle A, H.R. 5116 (111th Congress)—National Nanotechnology Initiative Amendments Act of 2010

The provisions of Title I, Subtitle A of H.R. 5116 (111th Congress), the National Nanotechnology Initiative Amendments Act of 2010, are nearly identical to H.R. 554 (see "H.R. 554—National Nanotechnology Initiative Amendments Act of 2009" below). H.R. 5116 changes the name of the act from the "National Nanotechnology Initiative Amendments Act of 2009," to "National Nanotechnology Initiative Amendments Act of 2010," and removes the term "interdisciplinary" from a provision establishing "green nanotechnology" research centers.

H.R. 554 (111th Congress)—National Nanotechnology Initiative Amendments Act of 2009

H.R. 554 (111th Congress), the National Nanotechnology Initiative Amendments Act of 2009, was introduced on January 15, 2009, and referred to the House Committee on Science and Technology. On February 11, 2009, the bill was brought to the floor on a motion to suspend the rules and passed by voice vote. The bill was received in the Senate and referred to the Committee on Commerce, Science, and Transportation. This act would revise the 21st Century Nanotechnology Research and Development Act in a variety of ways, several of which specifically address nanotechnology EHS concerns. The legislation:

- directs the National Nanotechnology Coordination Office to develop and maintain a public database of NNI EHS projects, including the agency funding source and funding history;
- requires the National Nanotechnology Advisory Panel (NNAP) to be established as a "distinct entity" (the NNAP's functions are currently performed by the President's Council of Advisors on Science and Technology), and requires the establishment of a subpanel to assess whether societal, ethical, legal, environmental, and workforce concerns are adequately addressed by the NNI;
- directs that the National Research Council, as part of its triennial review of the NNI, evaluate the adequacy of the NNI's efforts to address ethical, legal, environmental, human health, and other appropriate societal concerns;
- requires the designation of an associate director of the White House Office of Science and Technology Policy to serve as Coordinator for Societal Dimensions of Nanotechnology with responsibility for developing an annual research plan for federal nanotechnology EHS activities, monitoring and encouraging agency EHS efforts, and for encouraging agencies to engage in public-private partnerships to support EHS research;
- requires certain interdisciplinary research centers supported under the NNI to include EHS research to develop methods for developing environmentally benign nanoscale products and processes, to foster the transfer of research results to industry, and to provide interdisciplinary study programs to educate scientists and engineers in these methods;
- directs NNI agencies to support the activities of standards setting bodies involved in the development of standards for nanotechnology, including authorizing agency reimbursement of travel costs of scientists and engineers participating in these activities; and

- requires activities supported under the NNI's Education and Societal Dimensions program component area to include environmental, health, and safety education in its informal, pre-college, and undergraduate nanotechnology education efforts.

S. 1482 (111th Congress)—National Nanotechnology Amendments Act of 2009

S. 1482 (111th Congress), the National Nanotechnology Amendments Act of 2009, was introduced on July 21, 2009, and referred to the Senate Commerce, Science, and Transportation Committee. The purpose of the bill is to reauthorize the 21st Century Nanotechnology Research and Development Act and to expand the scope of the National Nanotechnology Program (NNP).

Among its provisions, the bill:

- requires the NNP to solicit and draw upon the perspectives of the industrial community to promote the rapid commercial development of nanoscale-enabled devices, systems, and technologies and to coordinate research in determining the key physical and chemical characteristics of nanoparticles and nanomaterials that may pose environmental, health, and safety risks;
- requires the NNCO and other appropriate agencies and councils to issue guidance to agencies that describes a strategy for transitioning research into commercial products and technologies and how the program will coordinate or conduct research on the environmental, health, and safety issues related to nanotechnology;
- requires each participating agency to provide funds to support the work of the NNCO. Authorizes appropriations to: (1) NIST for the development of nanotechnology standards; and (2) NSF, for use by the NNCO, to develop and maintain a public information database of NNP projects in EHS; education; public outreach; ethical, legal, and other societal issues; and of nanotechnology facilities accessible for use by individuals from academia and industry;
- makes the National Nanotechnology Advisory Panel (NNAP) a distinct entity, and requires the NNAP to establish a subpanel to enable it to assess whether societal, ethical, legal, environmental, and workforce concerns are adequately addressed by the NNP;
- requires the designation of a "coordinator for societal dimensions of nanotechnology," within OSTP, to convene a panel to develop a research plan, and requires the coordinator to enter into an arrangement with the National Science Board to create a report that identifies the broad goals and needs of EHS researchers;
- directs the NSTC to establish an interagency Education Working Group to coordinate, prioritize, and plan formal and informal educational activities supported under the NNP, including activities to help participants understand the EHS implications of nanotechnology; and
- requires the NNP to support nanotechnology R&D in areas of national importance (e.g., economic competitiveness, energy production, water purification, agriculture, and health care; in environmental, health, and safety research on the risks of nanoparticles) and in ethical, legal, and societal issues related to nanotechnology.

S. 2942 (111th Congress)—Nanotechnology Safety Act of 2010

S. 2942 (111th Congress), the Nanotechnology Safety Act of 2010, was introduced on January 21, 2010, and referred to the Senate Committee on Health, Education, Labor, and Pensions. The bill would require the Secretary of Health and Human Services to establish within 180 days a program for the scientific investigation of nanoscale materials included or intended for inclusion in FDA-regulated products, to address the potential toxicology of such materials, the effects of such materials on biological systems, and interaction of such materials with biological systems. The bill would authorize $25 million per year for fiscal years 2011 to 2015.

H.R. 820 (111th Congress)—Nanotechnology Advancement and New Opportunities Act

H.R. 820 (111th Congress), the Nanotechnology Advancement and New Opportunities Act, was introduced on February 3, 2009, and referred to the House Science and Technology Committee; the House Ways and Means Committee; the House Energy and Commerce Committee; and the House Homeland Security Committee. Among its provisions, the bill would require the NNCO to produce an annual research strategy that establishes priorities for the development and responsible stewardship of nanotechnology, as well as providing recommendations regarding the funding required to implement the strategy.

Appendix. Overview of Selected Federal Agencies' Roles in the Regulation of Nanotechnology

Several federal regulatory agencies have begun to grapple with the EHS issues raised by nanotechnology in their spheres of responsibility. Some critics argue that there is a potential conflict of interest among some regulatory agencies that are, on the one hand, conducting and promoting nanotechnology research and that are, on the other hand, responsible for regulating nanotechnology applications. The following section provides an overview of selected federal agencies' roles in the regulation of nanotechnology.

Environmental Protection Agency

The Environmental Protection Agency (EPA) has both a research function and a regulatory function. The agency has asserted a need for more information to assess the potential EHS impacts of most engineered nanoscale materials. According to EPA, this information is needed

> ... to establish a sound scientific basis for assessing and managing unreasonable risks that may result from the introduction of nanoscale materials into the environment.[75]

In this regard, EPA is supporting research on the toxicology, fate, transport, transformation, bioavailability, and exposure of humans and other species to nanomaterials to obtain information for use in risk assessment, a central aspect of EPA's mission.[76]

EPA plays a central role in coordinating the federal governments research efforts to address nanotechnology EHS issues, serving as co-chair of the NSET Nanotechnology Environmental Health Implications (NEHI) working group. The National Institute for Occupational Safety and Health (NIOSH), a research institute within the Department of Health and Human Services, is EPA's co-chair of the NEHI working group.

EPA also works with international organizations engaged in nanotechnology-related regulatory issues, such as the International Organization for Standardization and the Organization for Economic Cooperation and Development.

With respect to its regulatory function, multiple statutes govern EPA's authority to regulate nanotechnology materials and devices, including the Clean Air Act (CAA, 42 U.S.C. 7401 et seq); Clean Water Act (CWA, codified generally as 33 U.S.C. §§1251-1387); Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, 7 U.S.C.136-136y); and Toxic Substances Control Act (15 U.S.C. 2601 et seq.).[77]

Important issues have been raised about the application of EPA's authorities to regulate nanotechnology. Several issues revolve around TSCA, which authorizes regulation of chemical commerce.[78] Under the provisions of TSCA, producers of a "new" material must provide EPA

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[75] "Fact Sheet for Nanotechnology under the Toxic Substances Control Act," Environmental Protection Agency. http://www.epa.gov/oppt/nano/nano-facts.htm

[76] "Exploratory Research: Nanotechnology Research Grants Investigating Fate, Transport, Transformation, and Exposure of Engineered Nanomaterials: A Joint Research Solicitation - EPA, NSF, & DOE," Environmental Protection Agency. http://es.epa.gov/ncer/rfa/2007/2007_star_nanotech.html

[77] For additional information, see CRS Report RL30798, *Environmental Laws: Summaries of Major Statutes Administered by the Environmental Protection Agency*, coordinated by David M. Bearden.

[78] For more information about TSCA and nanotechnology, see CRS Report RL34118, *The Toxic Substances Control Act (TSCA): Implementation and New Challenges*, by Linda-Jo Schierow.

with a premanufacture notification (PMN). EPA then has 90 days to approve manufacture, to require information from manufacturers, or to restrict chemical use. Other TSCA provisions permit EPA regulation of existing chemicals already in commerce, but these rely on EPA fact-finding and rulemaking before EPA can require testing or restrict uses. Several NGOs have urged EPA to consider all nanoscale materials "new" regardless of whether the material is on the EPA inventory list in its bulk form.[79] However, some nanotechnology materials have the same chemical composition as materials that are already in commerce, raising the question of whether the nanotechnology materials are "new" and thus subject to PMN requirements.

When nanomaterials are intended to control pests, including microbes, FIFRA may offer EPA more authority to regulate nanotechnology than TSCA, according to Lynn Bergeson, chair of the American Bar Association's Section on Environment, Energy, and Resources:

> Under TSCA, once a substance is on the approved inventory list, any use is legitimate, but FIFRA is use-specific. The EPA always has the authority to assess the risk of pesticides, regardless of the use.[80]

Applicability of FIFRA to nanotechnology products was one aspect of a November 2006 EPA ruling that a device that "incorporates a substance intended to prevent, destroy or mitigate pests" is considered a pesticide and is required to be registered under FIFRA. While the ruling is not unique to nanomaterials, it came in the context of advertising claims for a washing machine containing nanoscale silver ions that kill microbes. EPA's ruling made this appliance the first nanotechnology product to be regulated under FIFRA. However, claims for the pesticidal effectiveness of the washing machine have been removed from advertisements, possibly limiting EPA's ability to regulate the device as a pesticide under FIFRA.

In a May 2010 review of EPA's role in regulating nanotechnology, the U.S. Government Accountability Office concluded that EPA was missing opportunities to collect additional information under TSCA, FIFRA, the Clean Water Act and other environmental statutes.[81]

Food and Drug Administration

A variety of current and future products that incorporate nanotechnology fall, or may fall, under the regulatory auspices of the FDA, including cosmetics, medical devices, foods, drugs, biological products, and combination products.[82] FDA anticipates that many of the nanotechnology products that the agency is likely to regulate will be combination products, such as drug-device, drug-biological, or device-biological products. According to FDA, it regulates products based on their statutory classification rather than the technology they employ, thus the agency may not provide regulatory consideration to a nanotechnology product until well after its initial development.[83] Also, some critics maintain that FDA's limited regulatory authority over certain categories of products may limit its authority to regulate nanotechnology products.

With respect to the need for unique tests or requirements for regulating nanotechnology products, FDA states that its existing requirements may be adequate for most nanotechnology products it expects to regulate. FDA asserts that nanotechnology products are in the same size-range as the cells and molecules its reviewers and scientists deal with every day. The agency says that every

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[79] "The EPA's Toxic Substances Control Act: What you must know," *Small Times*, September/October 2007.

[80] "EPA Regulates Nano Product, Not Nano Industry," *Small Times*, January 2007.

[81] Ibid.

[82] For additional information, see CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, coordinated by Judith A. Johnson.

[83] "FDA and Nanotechnology Products," Food and Drug Administration. http://www.fda.gov/nanotechnology/faqs.html

degradable medical device and injectable pharmaceutical generates particulates that pass through the nanoscale size range during the processes of their absorption and elimination by the body. FDA says that it has no knowledge of reports of adverse reactions related to the "nano" size of resorbable drug or medical device products. New tests or other requirements may be needed, according to FDA, if new risks are identified arising from new materials or manufacturing techniques. Others, in particular consumer groups, counter that FDA's resources are insufficient to adequately address the safety of emerging technologies in general, and that the agency's regulatory approach, particularly for cosmetics, dietary supplements, and other products for which pre-market review is not required, would not detect any problems until such products had been in use.[84]

FDA does not provide grants for nanotechnology research but does conduct research in several of its centers to understand the characteristics of nanomaterials and nanotechnology processes. FDA is collaborating with NIEHS on studies, as part of the interagency National Toxicology Program.

FDA says that there currently is no international regulation of nanoproducts or the underlying nanotechnology. FDA participates in multinational organizations where cooperative work on nanotechnology has been proposed, including the Organization for Economic Cooperation and Development, ASTM International, and the International Organization for Standardization.

National Institute of Environmental Health Sciences/National Toxicology Program

While not a regulatory agency, NIEHS, a part of the National Institutes of Health, is conducting nanotechnology EHS research that will support the missions of regulatory agencies. In particular, NIEHS serves as home to the interagency National Toxicology Program (NTP). The NTP's mission is to coordinate toxicological testing programs, develop and validate improved testing methods, develop approaches and generate data to strengthen scientific knowledge about potentially hazardous substances, and communicate with stakeholders.[85] In 2006, the NTP established the Nanotechnology Safety Initiative (NSI), a broad-based research program to address potential human health hazards associated with the manufacture and use of nanoscale materials. The goal of this research program is to evaluate the toxicological properties of major nanoscale materials that represent a cross-section of composition, size, surface coatings, and physical and chemical properties, and to use these as model systems to investigate fundamental questions concerning whether nanoscale materials can interact with biological systems and how they might do so.[86]

According to NTP, the NSI is focused on three areas of research with respect to specific types or groups of nanoscale materials:

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[84] See, for example, Michael Taylor, *Regulating the Products of Nanotechnology: Does FDA Have the Tools It Needs?* The Project on Emerging Nanotechnologies, October 2006, at http://www.nanotechproject.org/news/archive/is_fda_nanotech-ready. The FDA Science Board, Subcommittee on Science and Technology, designated nanotechnology as one of eight emerging technologies that are most challenging for FDA. See FDA Science Board, Subcommittee on Science and Technology, *FDA Science and Mission at Risk*, November 2007, p. 4, at http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA Report on Science and Technology.pdf. The FDA Science Board is the advisory board to the FDA Commissioner.

[85] "Toxicology in the 21st Century: The Role of the National Toxicology Program," Update, National Toxicology Program, January 2004. http://ntp.niehs.nih.gov/ntp/htdocs/Liaison/2004JanLO_News.pdf

[86] *Toxicology in the 21st Century: The Role of the National Toxicology Program*, Department of Health and Human Services, February 2004. http://ntp.niehs.nih.gov/ntp/main_pages/NTPVision.pdf

- non-medical, commercially relevant and available nanoscale materials to which humans are intentionally being exposed, such as cosmetics and sunscreens;
- nanoscale materials representing specific classes (e.g., fullerenes and metal oxides) so that information can be extrapolated to other members of those classes; and
- subsets of nanomaterials to test specific hypotheses about a key characteristic (such as size, composition, shape, or surface chemistry) that might be related to biological activity.[87]

NSI research activities are focused on metal oxides, fluorescent crystalline semiconductors (also known as quantum dots), fullerenes, carbon nanotubes, nanoscale silver, and nanoscale gold.

Occupational Safety and Health Administration/National Institute for Occupational Safety and Health

The mission of the Occupational Safety and Health Administration (OSHA), an agency of the Department of Labor, is to ensure the safety and health of America's workers by setting and enforcing standards; providing training, outreach, and education; establishing partnerships; and encouraging continual improvement in workplace safety and health. OSHA has not yet taken any regulatory actions with respect to nanotechnology.

The National Institute for Occupational Safety and Health (NIOSH), a part of the Centers for Disease Control, is the lead federal agency conducting research and providing guidance on the occupational safety and health implications and applications of nanotechnology. NIOSH co-chairs the NSET's NEHI working group together with EPA. NIOSH is not a regulatory agency, but its work directly supports OSHA and other regulatory agencies. NIOSH and OSHA are considering new risk management approaches that seek to maximize flexibility for innovation while ensuring the health and safety of workers.[88]

NIOSH states that its nanotechnology efforts are building on its experience in defining the characteristics, properties, and effects of ultrafine particles—such as welding fumes and diesel particulates—as well as its experience in conducting advanced health effects laboratory studies and in fostering industrial hygiene policies and practices.

NIOSH has developed interim guidelines for working with nanomaterials. The agency asserts that these guidelines are consistent with the best scientific knowledge of nanoparticle toxicity and control. NIOSH also maintains a Nanoparticle Information Library with information on the health and associated properties of nanomaterials as an online resource for occupational health professionals, industrial users, worker groups, and researchers.[89]

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[87] National Toxicology Program website, available at http://ntp.niehs.nih.gov/?objectid=30302D16-F1F6-975E-7B315D93D4A1246F

[88] *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*, Nanoscale Science, Engineering, and Technology Subcommittee, National Science and Technology Council, The White House, September 2006.

[89] "Nanotechnology at NIOSH," National Institute for Occupational Safety and Health. http://www.cdc.gov/niosh/topics/nanotech/

Consumer Product Safety Commission

The Consumer Product Safety Commission (CPSC) is charged with protecting the public from unreasonable risks of serious injury or death from certain types of consumer products.[90] CPSC has asserted that potential safety and health risks of nanomaterials can be assessed under existing CPSC statutes, regulations and guidelines. Since the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and the Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) do not require pre-market registration or approval of products, CPSC does not evaluate a product's risk to the public until it has been distributed in commerce.

In August 2005, CPSC commissioners approved a nanotechnology statement which notes that nanotechnology presents challenges that "may require unique exposure and risk assessment strategies." The CPSC statement identified regulatory challenges, including identification of the specific nanomaterial in a product; the need to characterize the materials to which a consumer is exposed during product use, including an assessment of the size distribution of the materials released; and the application of toxicological data of appropriate particle sizes to assess health risks. The CPSC takes the position that it is unable to make any general statements about potential consumer exposure to nanomaterials or the health effects that may result from exposure to nanomaterials during consumer use and disposal due to the wide variation in potential health effects and the dearth of exposure and toxicity data for specific nanomaterials.[91]

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[90] CPSC's regulatory authorities are provided by the Consumer Product Safety Act; Federal Hazardous Substances Act of 1960, as amended by the Toy Safety Acts of 1969 and 1984 and the Child Protection Amendments of 1966; Poison Prevention Packaging Act of 1970; Flammable Fabrics Act of 1953; and Refrigerator Safety Act of 1956.

[91] "CPSC Nanomaterial Statement," Consumer Product Safety Commission, August 2005. http://www.cpsc.gov/library/cpscnanostatement.pdf