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# NANOTECHNOLOGY

Accuracy of Data on Federally Funded Environmental, Health, and Safety Research Could Be **Improved** 

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Highlights of GAO-08-709T, a testimony before the Subcommittee on Science, Technology, and Innovation, Committee on Commerce, Science, and Transportation, U.S. Senate

#### Why GAO Did This Study

In March 2008, GAO issued a report entitled Nanotechnology: Better Guidance Is Needed to Ensure Accurate Reporting of Federal Research Focused on Environmental, Health, and Safety Risks (GAO-08-402). In this report, GAO reviewed the National Nanotechnology Initiative (NNI), a multiagency effort administered by the Office of Science and Technology Policy (OSTP). The NNI coordinates the nanotechnology-related activities of 25 federal agencies that fund nanoscale research or have a stake in the results. A key research area funded by some agencies related to studying the potential environmental, health, and safety (EHS) risks that may result from exposure to nanoscale materials. For this testimony statement, GAO was asked to summarize the findings of its March 2008 report, focusing on (1) the extent to which selected agencies conducted EHS research in fiscal year 2006; (2) the reasonableness of the agencies' and the NNI's processes to identify and prioritize EHS research; and (3) the effectiveness of the agencies' and the NNI's process to coordinate EHS research.

#### **What GAO Recommends**

In its March 2008 report, GAO recommended better guidance to improve the accuracy of data reported by the NNI. Although OSTP asserted that it provides extensive guidance, it agreed to review how the agencies respond to the current guidance. GAO is making no new recommendations in this statement.

To view the full product, including the scope and methodology, click on GAO-08-709T. For more information, contact Ms. Anu Mittal at (202) 512-3841 or mittala@gao.gov.

### NANOTECHNOLOGY

# Accuracy of Data on Federally Funded Environmental, Health, and Safety Research Could Be Improved

#### What GAO Found

In fiscal year 2006, federal agencies devoted \$37.7 million—or 3 percent of the \$1.3 billion total nanotechnology research funding—to research that was primarily focused on the EHS risks of nanotechnology, according to the NNI. However, about 20 percent of this total cannot actually be attributed to this purpose. GAO found that 22 of the 119 projects identified as EHS in fiscal year 2006 were not primarily related to understanding the extent to which nanotechnology may pose an EHS risk. Instead, many of these projects were focused on how to use nanotechnology to remediate environmental damage or detect hazards not related to nanotechnology. GAO determined that this mischaracterization is rooted in the current reporting structure that does not allow these types of projects to be easily categorized and the lack of guidance for agencies on how to apportion research funding across multiple topics, when appropriate. In addition to the EHS funding reported by the NNI, federal agencies conduct other research that is not captured in the EHS totals. This research was not captured by the NNI because either the research was funded by an agency not considered to be a research agency or because the primary purpose of the research was not to study EHS risks.

Federal agencies and the NNI, at the time of GAO's review, were in the process of identifying and prioritizing EHS risk research needs and the overall process they were using appeared reasonable. For example, identification and prioritization of EHS research needs was being done by the agencies and the NNI collaboratively. The NNI also was engaged in an iterative prioritization effort through its Nanotechnology Environmental and Health Implications (NEHI) working group. Through this process, NEHI identified five general research categories as a priority for federally funded research. GAO found that most of the research projects that were underway in fiscal year 2006 were generally consistent with agency and NEHI priorities. NEHI released its new EHS research strategy on February 13, 2008.

Agency and NNI processes to coordinate activities related to potential EHS risks of nanotechnology have been generally effective. The NEHI working group has convened frequent meetings that have helped agencies identify opportunities to collaborate on EHS risk issues, such as joint sponsorship of research and workshops to advance knowledge and facilitate informationsharing among the agencies. NEHI also has incorporated several practices that GAO has previously identified as key to enhancing and sustaining interagency collaborative efforts, such as defining a common outcome and leveraging resources. Finally, all agency officials GAO spoke with expressed satisfaction with the coordination and collaboration on EHS risk research that has occurred through NEHI. They cited several factors they believe contribute to the group's effectiveness, including the stability of the working group membership and the expertise and dedication of its members. Furthermore, according to these officials, this stability, combined with common research needs and general excitement about the new science, has resulted in a collegial, productive working environment.

#### Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to participate in your hearing on the future direction of the National Nanotechnology Initiative (NNI). As you know, the NNI was established in 2001 as a federal, multiagency effort intended to accelerate the discovery, development, and deployment of nanoscale science, engineering, and technology to achieve economic benefits, enhance the quality of life, and promote national security. One of the key roles of the NNI is to coordinate the nanotechnology-related activities of 25 federal agencies. These agencies include both those that fund nanoscale research as well as those that have a stake in the outcome of this research, such as agencies that regulate products containing nanomaterials. While the NNI is designed to facilitate intergovernmental cooperation and identify goals and priorities for nanotechnology research, it is not a research program. It has no funding or authority to dictate the nanotechnology research agenda for participating agencies or to ensure that adequate resources are available to achieve specific goals. Instead, participating agencies develop and fund their own nanotechnology research agendas, and in fiscal year 2006, 13 of the 25 agencies participating in the NNI allocated a total of about \$1.3 billion from their appropriated budgets to nanotechnology research and development activities. Of this total in fiscal year 2006, the NNI reported that \$37.7 million (or about 3 percent of the total) was used to fund research to study the potential environmental, health, and safety (EHS) risks that might result from exposure during the manufacture, use, and disposal or recycle of nanoscale materials. As you know, while the use of nanoscale materials holds much promise, the small size and unique properties of these materials raise questions about their potential EHS risks, and research is needed to fill current gaps in scientific information about their risks.

At the request of the full committee and members of the Congressional Nanotechnology Caucus, we just completed a report that is being released today on the NNI's and federal agencies' efforts to study the potential environmental, health, and safety risks of nanotechnology. My testimony is based on the findings of this review and will cover the following three areas: (1) the extent to which selected research and regulatory agencies conducted research in fiscal year 2006 that primarily was focused on the

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<sup>&</sup>lt;sup>1</sup>GAO, Nanotechnology: Better Guidance Is Needed to Ensure Accurate Reporting of Federal Research Focused on Environmental, Health, and Safety Risks, GAO-08-402 (Washington, D.C.: Mar. 31, 2008).

potential EHS risks of nanotechnology; (2) the reasonableness of the processes that agencies and the NNI use to identify and prioritize federal research on the potential EHS risks of nanotechnology; and (3) the effectiveness of the processes that agencies and the NNI use to coordinate their research. For our review, we collected data from five federal agencies that provided 96 percent of fiscal year 2006 funding for EHS research—the Environmental Protection Agency (EPA), the National Institutes of Health (NIH), the National Institute for Occupational Safety and Health (NIOSH), the National Institute of Standards and Technology (NIST), and the National Science Foundation (NSF). We also contacted three regulatory agencies—the U.S. Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA)—that do not have specific research budgets to determine whether they conducted any research on their own relative to potential EHS risks. We conducted this performance audit from June 2007 to February 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our finding and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

#### In summary we found the following:

About 20 percent of the over \$37 million in fiscal year 2006 research expenditures that the NNI reported as being primarily focused on the EHS risks of nanotechnology cannot actually be attributed to this purpose. We found that 22 of the 119 projects identified as EHS-related by EPA, NIH, NIOSH, NIST, and NSF in fiscal year 2006 were not primarily related to understanding the extent to which nanotechnology poses an EHS risk. These 22 projects, funded by NSF and NIOSH, accounted for about \$7 million of the \$37 million that the NNI reported as being primarily focused on EHS risks. The focus of many of these projects was to explore how nanotechnology could be used to remediate environmental damage or to detect a variety of hazards unrelated to nanotechnology. We determined that this mischaracterization was the result of the current reporting structure that does not allow these types of projects to be easily categorized in another more appropriate category, and also the lack of guidance for agencies on how to apportion research funding across multiple topics, when appropriate. To address this issue, we recommended that the Office of Science and Technology Policy (OSTP), in consultation with the NNI and the Office of Management and Budget

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(OMB), provide better guidance to agencies regarding how to report research that is primarily focused on understanding or addressing the EHS risks of nanotechnology. In commenting on this report, OSTP asserted that it already provides extensive guidance, but it agreed to review the manner in which agencies respond to the current guidance.

- In addition to the EHS funding totals reported by the NNI, we found that federal agencies conduct other EHS research that is not captured in the NNI totals. This research was not captured by the NNI because either the research was funded by an agency not generally considered to be a research agency or because the primary purpose of the research was not to study EHS risks. Because the agencies that conduct this research do not systematically track it as EHS-related research, we could not establish the exact amount of federal funding that is being devoted to this additional EHS research.
- Federal agencies and the NNI were, at the time of our review, in the process of identifying and prioritizing EHS risk research needs; overall, we believe that the process they were using was reasonable. For example, identification and prioritization of EHS research needs was being done by the agencies and the NNI collaboratively. The NNI was also engaged in an iterative prioritization effort through its Nanotechnology Environmental and Health Implications (NEHI) working group. As a result of this effort, NEHI had identified five general research categories that should be the focus of federal research efforts and five specific research priorities under each general category. Our analysis of the 97 research projects that were underway in fiscal year 2006 that were primarily related to studying EHS risks found that the focus of these projects was generally consistent with agency priorities as well as NEHI's five general research categories. However, we did find that, while agency funded research addressed each of the five general research categories, it focused on the priority needs within each category to varying degrees. As our report was in production, NEHI released a new EHS research strategy on February 13, 2008, which is intended to provide a framework to help ensure that the highest priority EHS research needs are met.
- Agency and NNI processes to coordinate activities related to potential EHS risks of nanotechnology have been generally effective. The NEHI working group has convened frequent meetings that have helped agencies identify opportunities to collaborate on EHS risk issues, such as joint sponsorship of research and workshops to advance knowledge and facilitate information-sharing among the agencies. These types of exchanges, according to most agency officials we spoke with, have helped advance knowledge and facilitated information-sharing among the

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agencies. In addition, NEHI has incorporated several practices that we have previously identified as key to enhancing and sustaining interagency collaborative efforts, such as defining a common outcome and leveraging resources, but it had not, at the time of our review, completed its overarching strategy to help better align agencies' EHS research efforts. Finally, all agency officials we spoke with expressed satisfaction with the coordination and collaboration on EHS risk research that has occurred through NEHI. They cited several factors they believe contribute to the group's effectiveness, including the stability of the working group membership and the expertise and dedication of its members. Furthermore, according to these officials, this stability, combined with common research needs and general excitement about the new science, has resulted in a collegial, productive working environment.

## Background

Nanotechnology encompasses a wide range of innovations based on the understanding and control of matter at the scale of nanometers—the equivalent of one-billionth of a meter. To illustrate, a sheet of paper is about 100,000 nanometers thick and a human hair is about 80,000 nanometers wide. At the nanoscale level, materials may exhibit electrical, biological, and other properties that differ significantly from the properties the same materials exhibit at a larger scale. Exploiting these differences in nanoscale materials has led to a range of commercial uses and holds the promise for innovations in virtually every industry from aerospace and energy to health care and agriculture. In 2006, an estimated \$50 billion in products worldwide incorporated nanotechnology and this figure has been projected to grow to \$2.6 trillion by 2014. One research institute estimates that over 500 consumer products already available to consumers may contain nanoscale materials.

The National Nanotechnology Initiative (NNI) was established in 2001 as a federal, multiagency effort intended to accelerate the discovery, development, and deployment of nanoscale science, engineering, and technology to achieve economic benefits, enhance the quality of life, and promote national security. Management of the NNI falls under the purview of the National Science and Technology Council (NSTC) that coordinates science and technology policy across the federal government. The NSTC is managed by the Director of the Office of Science and Technology Policy (OSTP), who also serves as the Science Advisor to the President. The NSTC's Committee on Technology established the Nanoscale Science, Engineering, and Technology (NSET) subcommittee to help coordinate, plan, and implement the NNI's activities across participating agencies. In 2003, the NSET subcommittee further established a Nanotechnology

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Environmental and Health Implications (NEHI) working group. The purpose of the NEHI working group, composed of representatives from 16 research and regulatory agencies, is to, among other things, coordinate agency efforts related to EHS risks of nanotechnology. Similar to the NNI, the NEHI working group has no authority to mandate research priorities or to ensure that agencies adequately fund particular research.

In December 2003, Congress enacted legislation to establish a National Nanotechnology Program to coordinate federal nanotechnology research and development.<sup>3</sup> Among other things, the act directs the NSTC to establish goals and priorities for the program and to set up program component areas that reflect those goals and priorities. To implement these requirements, the NSTC has established a process to categorize research projects and activities undertaken by the various federal agencies into seven areas. Six of the seven focus on the discovery, development, and deployment of nanotechnology, while the seventh relates to the societal dimensions of nanotechnology that include issues such as the EHS risks of nanotechnology.

As part of the annual federal budget process, agencies also report their research funding for each area to OMB. The NNI's annual Supplement to the President's Budget, prepared by the NSTC, includes EHS research figures from the agencies and a general description of the research conducted by the agencies in each of the areas. For reporting purposes, the NSET subcommittee has defined EHS research as efforts whose primary purpose is to understand and address potential risks to health and to the environment posed by nanotechnology. Eight of the 13 agencies that funded nanotechnology research in fiscal year 2006 reported having devoted some of those resources to research that had a primary focus on potential EHS risks.

Under the NNI, each agency funds research and development projects that support its own mission as well as the NNI's goals. While agencies share information on their nanotechnology-related research goals with the NSET subcommittee and NEHI working group, each agency retains control over

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<sup>&</sup>lt;sup>2</sup>As of December 2007, a total of four working groups exist within the NSET subcommittee: (1) Global Issues in Nanotechnology; (2) Nanotechnology Environmental and Health Implications; (3) Nanomanufacturing, Industry Liaison, and Innovation; and (4) Nanotechnology Public Engagement and Communications.

<sup>&</sup>lt;sup>3</sup>The 21st Century Nanotechnology Research and Development Act, Pub. L. 108-153 (2003).

its decisions on the specific projects to fund. While the NNI was designed to facilitate intergovernmental cooperation and identify goals and priorities for nanotechnology research, it is not a research program. It has no funding or authority to dictate the nanotechnology research agenda for participating agencies.

The NNI used its fiscal year 2000 strategic plan and its subsequent updates to delineate a strategy to support long-term nanoscale research and development, among other things. A key component of the 2000 plan was the identification of nine specific research and development areas—known as "grand challenges"—that highlighted federal research on applications of nanotechnology with the potential to realize significant economic, governmental, and societal benefits.

In 2004, the NNI updated its strategic plan and described its goals as well as the investment strategy by which those goals were to be achieved. Consistent with the 21st Century Nanotechnology Research and Development Act, the NNI reorganized its major subject categories of research and development investment into program component areas (PCA) that cut across the interests and needs of the participating agencies. These seven areas replaced the nine grand challenges that the agencies had used to categorize their nanotechnology research. Six of the areas focus on the discovery, development, and deployment of nanotechnology. The seventh, societal dimensions, consists of two topics—research on environmental, health, and safety; and education and research on ethical, legal, and other societal aspects of nanotechnology.

PCAs are intended to provide a means by which the NSET subcommittee, OSTP, OMB, Congress, and others may be informed of the relative federal investment in these key areas. PCAs also provide a structure by which the agencies that fund research can better direct and coordinate their activities. In response to increased concerns about the potential EHS risks of nanotechnology, the NSET subcommittee and the agencies agreed in fiscal year 2005 to separately report their research funding for each of the two components of the societal dimensions PCA. The December 2007 update of the NNI's strategic plan reaffirmed the program's goals, identified steps to accomplish those goals, and formally divided the societal dimensions PCA into two PCAs—"environment, health, and safety" and "education and societal dimensions."

Beginning with the development of the fiscal year 2005 federal budget, agencies have worked with OMB to identify funding for nanoscale research that would be reflected in the NNI's annual Supplement to the

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President's Budget. OMB analysts reviewed aggregated, rather than project-level, data on research funding for each PCA to help ensure consistent reporting across the agencies. Agencies also relied on definitions of the PCAs developed by the NSET subcommittee to determine the appropriate area in which to report research funding. Neither NSET nor OMB provided guidance on whether or how to apportion funding for a single research project to more than one PCA, if appropriate. However, representatives from both NSET and OMB stressed that the agencies were not to report each research dollar more than once.

Almost One-Fifth of Reported EHS Research Projects Were Not Primarily Focused on Studying the EHS Risks of Nanotechnology

About 18 percent of the total research dollars reported by the agencies as being primarily focused on the study of nanotechnology-related EHS risks in fiscal year 2006 cannot actually be attributed to this purpose. Specifically, we found that 22 of the 119 projects funded by five federal agencies were not primarily related to studying EHS risks. These 22 projects accounted for about \$7 million of the total that the NNI reported as supporting research primarily focused on EHS risks. Almost all of these projects—20 out of 22—were funded by NSF, with the two additional projects funded by NIOSH. We found that the primary purpose of many of these 22 projects was to explore ways to use nanotechnology to remediate environmental damage or to identify environmental, chemical, or biological hazards not related to nanotechnology. For example, some NSFfunded research explored the use of nanotechnology to improve water or gaseous filtration systems. Table 1 shows our analysis of the nanotechnology research projects reported as being primarily focused on EHS risks.

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Table 1: GAO Analysis of the Number and Dollar Value of Nanotechnology Research Projects Reported by Selected Agencies as Being Primarily Focused on Environmental, Health, and Safety Risks, Fiscal Year 2006

(Dollars in millions)							
Projects reported by agencies as being primarily focused on EHS		Projects determined by GAO to be primarily focused on EHS		Projects determined by GAO not to be primarily focused on EHS			
Agency	Number	Dollar Value <sup>a</sup>	Number	Dollar Value	Number	Dollar value	
EPA	10	\$3.6	10	\$3.6	0	\$0	
NIH	18	\$5.6	18	\$5.6	0	\$0	
NIOSH	23	\$4.3	21	\$4.2	2	\$0.1	
NIST	2	\$2.4	2	\$2.4	0	\$0	
NSF	66	\$21.1	46	\$14.7	20	\$6.4	
Total	119	\$37	97	\$30.5	22	\$6.5	

Source: GAO analysis of agency obligations data.

<sup>a</sup>Figures differ slightly from those reported by the NNI in the Supplement to the President's FY2008 Budget due to rounding error or modifications made to the project-level data after they were reported by agencies to the NNI.

We found that the miscategorization of these 22 projects resulted largely from a reporting structure for nanotechnology research that does not easily allow agencies to recognize projects that use nanotechnology to improve the environment or enhance the detection of environmental contaminants, and from the limited guidance available to the agencies on how to consistently report EHS research. From fiscal years 2001 to 2004, the NSET subcommittee categorized federal research and development activities into nine categories, known as "grand challenges," that included one focused on "nanoscale processes for environmental improvement." Agencies initiated work on many of these 22 projects under the grand challenges categorization scheme. Starting in fiscal year 2005, NSET adopted a new categorization scheme, based on PCAs, for agencies to report their nanotechnology research. The new scheme eliminated the research category of environmental improvement applications and asked agencies to report research designed to address or understand the risks associated with nanotechnology as part of the societal dimensions PCA.

The new scheme shifted the focus from applications-oriented research to research focused on the EHS implications of nanotechnology. However, the new scheme had no way for agencies to categorize environmentally focused research that was underway. As a result, NSF and NIOSH characterized these projects as EHS focused for lack of a more closely related category to place them in, according to program managers. Furthermore, neither NSET nor OMB provided agencies guidance on how to apportion the dollars for a single project to more than one program

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component area, when appropriate. This is especially significant for broad, multiphase research projects, such as NSF's support to develop networks of research facilities. Of the five agencies we reviewed, only NSF apportioned funds for a single project to more than one PCA.

In addition to research reported to the NNI as being primarily focused on the EHS risks of nanotechnology, some agencies conduct research that is not reflected in the EHS totals provided by the NNI either because they are not considered federal research agencies or because the primary purpose of the research was not to study EHS risks. For example, some agencies conduct research that results in information highly relevant to EHS risks but that was not primarily directed at understanding or addressing those risks and therefore is not captured in the EHS total. This type of research provides information that is needed to understand and measure nanomaterials to ensure safe handling and protection against potential health or environmental hazards; however, such research is captured under other PCAs, such as instrumentation, metrology, and standards. Because the agencies that conduct this research do not systematically track it as EHS-related, we could not establish the exact amount of federal funding that is being devoted to this additional EHS research.

Processes to Identify and Prioritize Needed EHS Research Appear Reasonable and Are Ongoing but a Comprehensive Research Strategy Has Not Yet Been Developed All eight agencies in our review have processes in place to identify and prioritize the research they need related to the potential EHS risks of nanotechnology. Most agencies have developed task forces or designated individuals to specifically consider nanotechnology issues and identify priorities, although the scope and exact purpose of these activities differ by agency. Once identified, agencies communicate their EHS research priorities to the public and to the research community in a variety of ways, including publication in agency documents that specifically address nanotechnology issues, agency strategic plans or budget documents, agency Web sites, and presentations at public conferences or workshops. We determined that each agency's nanotechnology research priorities generally reflected its mission. For example, the priorities identified by FDA and CPSC are largely focused on the detection and safety of nanoparticles in the commercial products they regulate. On the other hand, EHS research priorities identified by NSF reflect its broader mission to advance science in general, and include a more diverse range of priorities, such as the safety and transport of nanomaterials in the environment, and the safety of nanomaterials in the workplace.

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In addition to the efforts of individual agencies, the NSET subcommittee has engaged in an iterative prioritization process through its NEHI working group. Beginning in 2006, NEHI identified but did not prioritize five broad research categories and 75 more specific subcategories of needs where additional information was considered necessary to further evaluate the potential EHS risks of nanotechnology. NEHI obtained public input on its 2006 report and released another report in August 2007, in which it distilled the previous list of 75 unprioritized specific research needs into a set of five prioritized needs for each of the five general research categories. The NEHI working group has used these initial steps to identify the gaps between the needs and priorities it has identified and the research that agencies have underway. NEHI issued a report summarizing the results of this analysis in February 2008.

Although a comprehensive research strategy for EHS research had not been finalized at the time of our review, the prioritization processes taking place within individual agencies and the NNI appeared to be reasonable. Numerous agency officials said their agency's EHS research priorities were generally reflected both in the NEHI working group's 2006 research needs and 2007 research prioritization reports. Our comparison of agency nanotechnology priorities to the NNI's priorities corroborated these statements. Specifically, we found that all but one of the research priorities identified by individual agencies could be linked to one or more of the five general research categories. According to agency officials, the alignment of agency priorities with the general research categories is particularly beneficial to the regulatory agencies, such as CPSC and OSHA, which do not conduct their own research, but rely instead on research agencies for data to inform their regulatory decisions.

In addition, we found that the primary purposes of agency projects underway in fiscal year 2006 were generally consistent with both agency priorities and the NEHI working group's research categories. Of these 97 projects, 43 were focused on Nanomaterials and Human Health, including all 18 of the projects funded by NIH. EPA and NSF funded all 25 projects related to Nanomaterials and the Environment. These two general research categories accounted for 70 percent of all projects focused on EHS risks.

Furthermore, we determined that, while agency-funded research addressed each of the five general research categories, it focused on the priority needs within each category to varying degrees. Specifically, we found that the two highest-priority needs in each category were addressed only slightly more frequently than the two lowest-priority needs.

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Moreover, although the NEHI working group considered the five specific research priorities related to human health equally important, 19 of the 43 projects focused on a single priority—"research to determine the mechanisms of interaction between nanomaterials and the body at the molecular, cellular, and tissular levels." Table 2 shows a summary of projects by agency and specific NEHI research priority.

Table 2: Research Primarily Focused on the Environmental, Health, and Safety Risks of Nanotechnology by Agency and Specific Nanotechnology Environmental and Health Implications Working Group Research Priority

	EPA	NIH	NIOSH	NIST	NSF	Total
Instrumentation, Metrology, and Analytical Methods		0	1	2	8	11
Develop methods to detect nanomaterials in biological matrices, the environment, and the workplace				1	7	8
Understand how chemical and physical modifications affect the properties of nanomaterials						0
3. Develop methods for standardizing assessment of particle size, size distribution, shape, structure, and surface area			1	1		2
4. Develop certified reference materials for chemical and physical characterization of nanomaterials						0
5. Develop methods to characterize a nanomaterial's spatio-chemical composition, purity, and heterogeneity					1	1
Nanomaterials and Human Health	4	18	10	0	11	43
Develop methods to quantify and characterize exposure to nanomaterials and characterize nanomaterials in biological matrices <sup>a</sup>	1	1	4		2	8
2. Understand the absorption and transport of nanomaterials throughout the human body <sup>a</sup>	1	1			2	4
3. Establish the relationship between the properties of nanomaterials and uptake via the respiratory or digestive tracts or through the eyes or skin, and assess body burden <sup>a</sup>		5	3		1	9
4. Determine the mechanisms of interaction between nanomaterials and the body at the molecular, cellular, and tissular levels <sup>a</sup>	1	10	3		5	19
5. Identify or develop appropriate in vitro and in vivo assays/models to predict in vivo human responses to nanomaterials exposure <sup>a</sup>	1	1			1	3
Nanomaterials and the Environment	5	0	0	0	20	25
1. Understand the effects of engineered nanomaterials in individuals of a species and the applicability of testing schemes to measure effects	1				2	3
2. Understand environmental exposures through identification of principle sources of exposure and exposure routes					1	1
3. Evaluate abiotic and ecosystem-wide effects					6	6
4. Determine factors affecting the environmental transport of nanomaterials	2				9	11
Understand the transformation of nanomaterials under different environmental conditions	2				2	4

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	EPA	NIH	NIOSH	NIST	NSF	Total
Health and Environmental Exposure Assessment		0	3	0	2	5
Characterize exposures among workers			2		1	3
Identify population groups and environments exposed to engineered nanoscale materials						0
Characterize exposure to the general population from industrial processes and industrial and consumer products containing nanomaterials						0
4. Characterize health of exposed populations and environments						0
<ol> <li>Understand workplace processes and factors that determine exposure to nanomaterials</li> </ol>			1		1	2
Risk Management Methods	1	0	7	0	5	13
Understand and develop best workplace practices, processes, and environmental exposure controls			4		2	6
2. Examine product or material life cycle to inform risk reduction decisions	1				1	2
3. Develop risk characterization information to determine and classify nanomaterials based on physical or chemical properties			1		2	3
Develop nanomaterial-use and safety-incident trend information to help focus risk management efforts						0
5. Develop specific risk communication approaches and materials			2			2
Total	10	18	21	2	46	97

Source: GAO analysis of agency data.

Coordination Processes Have Fostered Interagency Collaboration and Information-Sharing Agency and NNI processes to coordinate research and other activities related to the potential EHS risks of nanotechnology have been generally effective, and have resulted in numerous interagency collaborations. All eight agencies in our review have collaborated on multiple occasions with other NEHI-member agencies on activities related to the EHS risks of nanotechnology. These EHS-related activities are consistent with the expressed goals of the larger NNI—to promote the integration of federal efforts through communication, coordination, and collaboration. The NEHI working group is at the center of this effort.

We found that regular NEHI working group meetings, augmented by informal discussions, have provided a venue for agencies to exchange information on a variety of topics associated with EHS risks, including their respective research needs and opportunities for collaborations. Interagency collaboration has taken many forms, including joint sponsorship of EHS-related research and workshops, the detailing of staff to other NEHI working group agencies, and various other general collaborations or memoranda of understanding.

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<sup>&</sup>lt;sup>a</sup>Priorities given equal weight.

Furthermore, the NEHI working group has adopted a number of practices GAO has previously identified as essential to helping enhance and sustain collaboration among federal agencies. For example, in 2005 NEHI clearly defined its purpose and objectives and delineated roles and responsibilities for group members. Furthermore, collaboration through multiagency grant announcements and jointly sponsored workshops has served as a mechanism to leverage limited resources to achieve increased knowledge about potential EHS risks.

Finally, all agency officials we spoke with expressed satisfaction with their agency's participation in the NEHI working group, specifically, the coordination and collaboration on EHS risk research and other activities that have occurred as a result of their participation. Many officials described NEHI as unique among interagency efforts in terms of its effectiveness. Given limited resources, the development of ongoing relationships between agencies with different missions, but compatible nanotechnology research goals, is particularly important. NIH officials commented that their agency's collaboration with NIST to develop standard reference materials for nanoparticles may not have occurred as readily had it not been for regular NEHI meetings and workshops. In addition, NEHI has effectively brought together research and regulatory agencies, which has enhanced planning and coordination. Many officials noted that participation in NEHI has frequently given regulators the opportunity to become aware of and involved with research projects at a very early point in their development, which has resulted in research that better suits the needs of regulatory agencies.

Many officials also cited the dedication of individual NEHI working group representatives, who participate in the working group in addition to their regular agency duties, as critical to the group's overall effectiveness. A number of the members have served on the body for several years, providing stability and continuity that contributes to a collegial and productive working atmosphere. In addition, because nanotechnology is relatively new with many unknowns, these officials said the agencies are excited about advancing knowledge about nanomaterials and contributing to the informational needs of both regulatory and research agencies. Furthermore, according to some officials, there is a shared sense among NEHI representatives of the need to apply lessons learned from the

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<sup>&</sup>lt;sup>4</sup>GAO, Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies, GAO-06-15 (Washington, D.C.: Oct. 21, 2005).

development of past technologies, such as genetically modified organisms, to help ensure the safe development and application of nanotechnology.

In closing, Mr. Chairman, while nanotechnology is likely to affect many aspects of our daily lives in the future as novel drug delivery systems, improved energy storage capability, and stronger, lightweight materials are developed and made available, it is essential to consider the potential risks of this technology in concert with its potential benefits. Federal funding for studying the potential EHS risks of nanotechnology is critical to enhancing our understanding of these new materials, and we must have consistent, accurate, and complete information on the amount of agency funding that is being dedicated to this effort. However, this information is not currently available because the totals reported by the NNI include research that is more focused on uses for nanotechnology, rather than the risks it may pose. Furthermore, agencies currently have limited guidance on how to report projects with more than one research focus across program component areas, when appropriate. As a result, the inventory of projects designed to address these risks is inaccurate and cannot ensure that the highest-priority research needs are met.

Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions that you and other Members may have.

# GAO Contact and Staff Acknowledgment

Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. For further information about this testimony, please contact Ms. Anu Mittal, at (202) 512-3841 or at mittala@gao.gov. Individuals who contributed to this statement include Nancy Crothers, Elizabeth Erdmann, David Lutter, Rebecca Shea, and Cheryl Williams.

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