Free Executive Summary


This free executive summary is provided by the National Academies as part of our mission to educate the world on issues of science, engineering, and health. If you are interested in reading the full book, please visit us online at http://www.nap.edu/catalog/12559.html. You may browse and search the full, authoritative version for free; you may also purchase a print or electronic version of the book. If you have questions or just want more information about the books published by the National Academies Press, please contact our customer service department toll-free at 888-624-8373.

This executive summary plus thousands more available at www.nap.edu.

Copyright © National Academy of Sciences. All rights reserved. Unless otherwise indicated, all materials in this PDF file are copyrighted by the National Academy of Sciences. Distribution or copying is strictly prohibited without permission of the National Academies Press http://www.nap.edu/permissions/ Permission is granted for this material to be posted on a secure password-protected Web site. The content may not be posted on a public Web site.
Summary

The field of nanotechnology relies on the ability to engineer, manipulate, and manufacture materials at the nanoscale. Nanotechnology is already enabling the development of an industry that produces and uses engineered nanomaterials in a wide variety of industrial and consumer products, such as targeted drugs, video displays, remediation of groundwater contaminants, high performance batteries, dirt-repelling coatings on building surfaces and clothing, high-end sporting goods, and skin-care products. Over the next five to ten years, increasingly widespread use of complex engineered nanomaterials is anticipated in products as medical treatments, super-strong lightweight materials, food additives, and advanced electronics. The increasing use of engineered nanoscale materials in industrial and consumer products will result in greater exposure of workers and the general public to these materials. Responsible development of nanotechnology implies a commitment to develop and to use these materials to meet human and societal needs while making every reasonable effort to anticipate and mitigate adverse effects and unintended consequences.

The U.S. National Nanotechnology Initiative (NNI) is the government’s central locus for the coordination of federal agency investments in nanoscale research and development. NNI is responsible for supporting the missions of its member research and regulatory agencies; ensuring U.S. leadership in nanoscale science, engineering, and technology; and contributing to the nation’s economic competitiveness. Within NNI, the Nanotechnology Environmental Health Implications (NEHI) Working Group provides a forum for the NNI agencies to coordinate their activities related to understanding the potential risks posed by nanotechnology to protect public health and the environment. The NEHI’s coordination efforts have produced a series of documents that identify environmental, health, and safety (EHS) research needs related to nanomaterials (NNI 2006, 2007, 2008).

---

1Nanoscale refers to materials on the order of one billionth of a meter.
2Current members of NEHI consists of officials from the Consumer Product Safety Commission, Cooperative State Research, Education, and Extension Service, Department of Defense, Department of Energy, Department of State, Department of Transportation, Environmental Protection Agency, Food and Drug Administration, International Trade Commission, National Aeronautics and Space Administration, National Institute for Occupational Safety and Health, National Institutes of Health, National Institute of Standards and Technology, National Science Foundation, Occupational Safety and Health Administration, Office of Science and Technology Policy, Office of Management and Budget, and U.S. Geological Survey.
In 2007, the National Nanotechnology Coordination Office, which oversees the day-to-day operations of the NNI, asked the National Research Council to review independently its *Strategy for Nanotechnology-Related Environmental, Health, and Safety Research* (NNI 2008). In response, the National Research Council’s Board on Environmental Studies and Toxicology and National Materials Advisory Board oversaw the appointment of the Committee for Review of the Federal Strategy to Address Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials, which produced this report. The committee was charged to conduct a scientific and technical review of the federal strategy and to comment in general terms on how the strategy develops information needed to support EHS risk-assessment and risk-management needs with respect to nanomaterials.

Assisted by information-gathering sessions that included representatives from NNI agencies, policy experts from the European Commission, and such stakeholders as manufacturing industry, nongovernment organizations, and the insurance sector, the committee evaluated the federal strategy, asking such questions as the following:

- What are the elements of an effective nanotechnology risk-research strategy?
- Does the federal strategy have those elements?
- With respect to the federal strategy, have the appropriate research needs been identified, are the gap analysis and the selection of priorities among research needs complete, and does the research identified support risk-assessment and risk-management needs?

## WHAT ARE THE ELEMENTS OF AN EFFECTIVE NANOTECHNOLOGY RISK-RESEARCH STRATEGY?

Strategies for conducting scientific research are particularly important when resources are limited and there is a need to ensure that relevant information is being generated as efficiently and cost-effectively as possible. A strategy generally defines a set of goals, often in the context of an overarching vision; a plan of action for achieving the goals; and milestones to indicate when the goals are expected to be achieved. Because scientific research is often open-ended and serendipitous, formulating goals can be difficult.

One specific type of research strategy—a strategy for risk research—addresses challenges of broad societal significance: the reduction or prevention of harm to humans and the environment. Because of their potential influence on public-health and environmental policy and actions, it is critical that risk-research strategies be developed and implemented effectively and in a timely manner. And like any other risk-research strategy, one focused on nanotechnology-related risk research needs to be proactive—identifying possible risks and ways to mitigate risks before the technology has widespread commercial presence. It has to address nanotechnology-based products that are beginning to enter commerce as well as those under development. But it also needs to lay the scientific groundwork for addressing materials and products that potentially will arise out of new research, new tools, and cross-fertilization between distinct fields of science and technology. Therefore, a nanotechnology-related risk-research strategy must rely on both targeted research, which addresses questions that are critical for ensuring the safety of nanomaterials and products that contain them, and exploratory research, which generates new knowledge that will inform future goals and research directions.

In conducting this study, the committee identified nine elements that are integral to any effective risk-research strategy and that informed its evaluation of the 2008 NNI document:

- **Vision, or statement of purpose.** What is the ultimate purpose of conducting research on potential risks associated with nanotechnology?
- **Goals.** What specific research goals need to be achieved to guide the development and implementation of nanotechnologies that are as safe as possible?
Summary

• Evaluation of the state of science. What is known about the potential for the products of nanotechnology to cause harm and about how possible risks might be managed?
• Road map. What is the plan of action to achieve the stated research goals?
• Evaluation. How will research progress be measured, and who will be responsible for measuring it? Are there measurable milestones that can be evaluated against a clear timeline?
• Review. How will the strategy be revised in light of new findings, to ensure that it remains responsive to the overarching vision and goals?
• Resources. Are there sufficient resources to achieve the stated goals? If not, what are the plans to obtain new resources or to leverage other initiatives to achieve the goals?
• Mechanisms. What are the most effective approaches to achieving the stated goals?
• Accountability. How will stakeholders participate in the process of developing and evaluating a research strategy? Who will be accountable for progress toward stated goals?

DOES THE FEDERAL STRATEGY HAVE THOSE ELEMENTS?

On the basis of the information gathered at its public meetings and the professional expertise and experience of its members, the committee determined that the process of composing the government’s 2008 NNI document provided a unique and useful opportunity for coordination, planning, and consensus-building among NEHI-member federal agencies. The strategy demonstrates how the NNI and the agencies have effectively worked together to coordinate their funding and their assessment of EHS aspects of nanotechnology.

However, NNI (2008) does not have the essential elements of a research strategy—it does not present a vision, contain a clear set of goals, have a plan of action for how the goals are to be achieved, or describe mechanisms to review and evaluate funded research and assess whether progress has been achieved in the context of what we know about the potential EHS risks posed by nanotechnology.

The NNI document contains various statements of purpose, but it does not provide a clear vision as to where our understanding of the EHS implications of nanotechnology should be in 5 or 10 years. It states that “the NEHI Working Group developed this nanotechnology-related EHS research strategy to accelerate progress in research to protect public health and the environment, and to fill gaps in, and—with the growing level of effort worldwide—to avoid unnecessary duplication of, such research” (NNI 2008, p. 1). That statement of purpose is adequate for an open-ended research program with no definite objectives, but it falls short of ensuring that the results of strategic research are useful and applicable to decision-making that will reduce the potential environmental and health effects of nanotechnology.

The strategy document does not present goals for research to help ensure that the development and implementation of nanotechnology is as safe as practicable or a road map to ensure that these research goals are achieved. Although the document identifies five “research needs” for each of five research categories—“Instrumentation, Metrology, and Analytical Methods,” “Nanomaterials and Human Health,” “Nanomaterials and the Environment,” “Human and Environmental Exposure Assessment,” and “Risk Management Methods”—the needs are not articulated as clear goals that should be attained. A key element of any strategy is to identify goals and measures of progress or success before assessing what is being done. That allows a clear assessment of the value of current activities. Such an approach enables development of an action plan to leverage other efforts and address research deficiencies in a way that is transparent and measurable. Because the NNI document does not establish goals and a plan of action, there is no element of accountability, and questions are never raised as to what other research activities are needed.

The NNI document does not provide an evaluation of the state of science in each of the five research categories; rather, the research needs are evaluated against research projects that were funded in FY 2006 (see Appendix A of NNI [2008]) to provide a “snapshot” of research activities. The 2008 NNI document uses the FY 2006 data to assess the extent to which federally funded EHS research related to...
nanomaterials is supporting selected research priorities and to conduct its gap analysis of the NNI research portfolio. The committee concludes that how the FY 2006 data were used in the analysis is probably the greatest deficiency in the 2008 document, inasmuch as it is the foundation of the document’s evaluation of the strengths, weaknesses, and gaps in currently funded federal research. This is problematic because most of the listed FY 2006 research projects were focused on understanding fundamentals of nanoscience that are not explicitly associated with risk or the development of nanotechnology applications. In addition, there is no clear statement of how the FY 2006 research projects would address the identified research needs and inform an understanding of potential human health and environmental risks posed by engineered nanoscale materials.

The 2008 document does provide some information on time frame and sequencing for achieving the research needs (see Figures 3, 5, 7, 9, and 11 of NNI [2008]) but with little justification.

The NNI strategy does not identify resources necessary to address questions concerning EHS research needs for nanomaterials. Although the detailed analysis of nanotechnology-related EHS expenditures in FY 2006 provides information about what was spent during that year, there is no assessment of whether the aggregate level of spending was adequate to address EHS research needs or whether the resource expenditures by the agencies were appropriate to address EHS research needs based on their missions. An appropriate research strategy would quantify the resources needed to address research priorities and describe where the resources would come from.

Although lead agencies (for example, NIH, NIST, EPA, FDA, and NIOSH) are given roles for overseeing federal nanotechnology research, there is no accountability, that is, there is no single organization or person that will be held accountable for whether the government’s overall strategy delivers results. Accountability requires specific quantifiable objectives so that one can determine whether adequate progress is being made. The 2008 NNI document does not adequately incorporate input from other stakeholders, such as industries that produce nanomaterials and end users of nanomaterials; environmental and consumer advocacy groups; foreign interests, including substantial efforts of other countries; and local and state governments. The committee recognizes that the 2006 and 2007 NNI reports have undergone public comment, but public comment is not the same as engaging stakeholders in the process.

Without adequate input from external stakeholders, it is not possible for government agencies to develop an effective research strategy to underpin the emergence of safe nanotechnologies. Federal agencies may have a vested interest in justifying the value of current efforts rather than critically assessing what is being done and how deficiencies might be addressed. For example, when developing their own research strategies, agencies tend to ask, What research can we do within our existing capabilities? rather than the more appropriate question, What research should we be doing?

**REVIEW OF PRIORITY RESEARCH TOPICS, RESEARCH NEEDS, AND GAP ANALYSIS**

The committee reviewed the specific research categories and their designated research needs as described in the 2008 NNI document (Section II) and considered the following questions: Were the appropriate research needs identified? Were the gap analysis and priority sequencing of research needs complete? Does the identified research support risk-assessment and risk-management needs?

The NNI’s five topical categories each address research that is important for EHS risk assessment and risk management, and collectively they cover the necessary broad research topics. The listed research needs in the five categories are similarly valuable but incomplete, in some cases missing elements crucial for progress in understanding the EHS implications of nanomaterials. For example, the subject of

---

*The 246 FY 2006 research projects listed in NNI (2008) include additional research on instrumentation and metrology research and on medical-application-oriented research that is not captured in the list of 130 EHS research projects in the annual supplement to the president’s budget. The committee’s own assessment of the number of FY2006 research projects that are relevant to understanding risk of nanomaterials is discussed in Chapter 4.*
environmental exposure received insufficient emphasis in the exposure-assessment discussion, and characterization of chemical and biologic reactivity of nanoparticles was not included as a research need. That appears to have resulted from an effort to place research needs into one of the five “silo” categories with little discussion of the interrelationships and interconnections among categories.

The committee notes examples of other research needs that it judged to be insufficiently addressed in the document. For “Nanomaterials and Human Health”, a more comprehensive analysis and evaluation of absorption, distribution, metabolism, elimination, and toxicity of engineered nanomaterials at realistic exposure levels is needed. For “Human and Environmental Exposure”, exposures throughout the life cycle of nanomaterials was not sufficiently introduced or adequately integrated into this section, although a discussion was contained within “Risk Management Methods”.

The NNI’s gap analysis is not accurate in that the relevance of FY 2006 research projects to the research needs is generally overstated. The 2008 document consistently—in every research category—appears to assume that funded projects with only distant links to a research question were meeting that research need. For example, in the “Instrumentation, Metrology, and Analytical Methods” category, the development of a sub-angstrom-resolution microscope is said to fulfill the need “to detect nanomaterials in biological matrices.” In the “Nanomaterials and Human Health” category, more than 50% of the inventoried projects describe research directly relevant to developing therapeutic strategies aimed at cancer and other ailments rather than any of the research needs listed as relevant to potential EHS risks posed by nanomaterials. The committee acknowledges the value of therapeutic research but believes that it is not directly relevant to understanding potential risks associated with nanomaterials that are important in occupational, environmental, and ecologic exposure scenarios. In the category of risk-management methods, there is no coverage of management of environmental and consumer risks, including specific potential exposure scenarios, such as accidents and spills, environmental discharges, and exposure through consumer products. Uniformly, the committee agreed that many of the 246 research projects listed in Appendix A are of high scientific value, but the vast majority are of little or no direct value in reducing the uncertainty faced by stakeholders making decisions about nanotechnology and its risk-management practices. The 2008 document substantially overestimates the general nanotechnology-related research activity in environmental, health, and safety research.

In many cases, the committee concluded that the sequencing of research needs was generally appropriate but not adequately justified. In a number of cases the committee questioned the rationale for a sequence. For example, in the “Instrumentation, Metrology, and Analytical Methods” category, why put the development of materials to support exposure assessment before materials to support toxicology studies? Why delay research into alternative surface-area measurement methods for 10 years if it is identified as a critical research subject? In the “Nanomaterials and the Environment” category, the committee questioned whether resources could be used more efficiently if characterization of exposure and transformation processes occurred prior to characterization of higher-level ecosystem effects.

Although many of the NNI’s identified research needs support risk-assessment and risk-management needs, the committee concluded that failure to identify important research needs, the lack of rationale for and discussion of research priorities, and the flaws in the gap analysis undermine the ability to ensure that currently funded research adequately supports EHS risk-assessment and risk-management needs and provides critical data for the federal agencies.

**CONCLUSIONS AND RECOMMENDATIONS**

The NNI’s 2008 *Strategy for Nanotechnology-Related Environmental, Health, and Safety Research* could be an effective tool for communicating the breadth of federally supported research associated with developing a more complete understanding of the environmental, health, and safety implications of nanotechnology. It is the result of considerable collaboration and coordination among 18 federal agencies and is likely to eliminate unnecessary duplication of their research efforts.
However, the document does not describe a strategy for nano-risk research. It lacks input from a diverse stakeholder group, and it lacks essential elements, such as a vision and a clear set of objectives, a comprehensive assessment of the state of the science, a plan or road map that describes how research progress will be measured, and the estimated resources required to conduct such research.

There remains an urgent need for the nation to build on the current research base related to the EHS implications of nanotechnology—including the federally supported research as described in the 2008 NNI document—by developing a national strategic plan for nanotechnology-related environmental, health, and safety research.

A national strategic plan for nanotechnology-related EHS research would identify research needs clearly and estimate the financial and technical resources required to address identified research gaps. It would also provide specific, measurable objectives and a timeline for meeting them. The national strategic plan, unlike the 2008 NNI document, would consider the untapped knowledge of and input from nongovernment researchers and academics, who can contribute to understanding the potential EHS implications of nanotechnology.

Reducing the burden of uncertainty through targeted, effective research that identifies and eliminates potential environmental and health hazards of engineered nanoscale materials should have high priority for the nation. An effective national EHS strategic research plan is essential to the successful development of and public acceptance of nanotechnology-enabled products. This strategy should be informed by value-of-information thinking to determine the research that is needed to reduce the current uncertainties with respect to the potential health and environmental effects of nanomaterials. A national strategic plan would need to address nanotechnology-based products that are entering commerce as well as nanotechnologies that are under development. It would provide a path to developing the scientific knowledge to support nanotechnology-related EHS risk-based decision-making.

The committee concludes that a truly national strategy cannot be developed within the limitations of the scope of research under the umbrella of the NNI. Although the 2008 NNI document potentially represents excellent input into the national strategic plan, the NNI can produce only a strategy that is the sum of the individual agency strategies and priorities. The structure of the NNI makes the development of a visionary and authoritative research strategy extraordinarily difficult. Because the NNI is not a research program but rather a coordination mechanism, comprising the activities of 25 federal agencies, it has no central authority to make budgetary or funding decisions, and it relies on the budgets of its member agencies to gather resources or influence the shape of the overall federal nanotechnology-related EHS research activity. Because the NNI is responsible for ensuring U.S. competitiveness through the rapid development of a robust research and development program in nanotechnology while ensuring the safe and responsible development of nanotechnology, it may be perceived as having a conflict of interest. But the conflict is a false dichotomy. Strategic research on potential risks posed by nanotechnology should be an integral and fundamental part of the sustainable development of nanotechnology. Nonetheless, a clear separation of accountability for development of applications and assessment of potential implications of nanotechnology would help to ensure that the public-health mission has appropriate priority.

The committee is concerned that the actual amount of federal funding specifically addressing the EHS risks posed by nanotechnology is far less than portrayed in the NNI document and may be inadequate. The committee concludes that if no new resources are provided and the current levels of agency funding continue, the research that is generated cannot adequately evaluate the potential health and environmental risks and effects associated with engineered nanomaterials to address the uncertainties in current understanding. Such an evaluation is critical for ensuring that the future of nanotechnology is not burdened by uncertainties and innuendo about potential adverse health and environmental effects. Those concerns have been voiced recently by the nanotechnology industry and various environmental and public-health interest groups.
Having reviewed the 2008 NNI strategy document and discussed what is needed for a path forward, the committee presents the following recommendations:

A robust national strategic plan is needed for nanotechnology-related environmental, health, and safety research that builds on the five categories of research needs identified in the 2008 NNI document. The development of the plan should include input from a broad set of stakeholders across the research community and other interested parties in government, nongovernment, and industrial groups. The strategy should focus on research to support risk assessment and management, should include value-of-information considerations, and should identify

- Specific research needs for the future in such topics as potential exposures to engineered nanomaterials, toxicity, toxicokinetics, environmental fate, and standardization of testing.
- The current state of knowledge in each specific area.
- The gap between the knowledge at hand and the knowledge needed.
- Research priorities for understanding life-cycle risks to humans and the environment.
- The estimated resources that would be needed to address the gap over a specified time frame.

As part of a broader strategic plan, NNI should continue to foster the successful interagency coordination effort that led to its 2008 document with the aim of ensuring that the federal plan is an integral part of the broader national strategic plan for investments in nanotechnology-related environmental, health, and safety research. In doing so, it will need a more robust gap analysis. The federal plan should identify milestones and mechanisms to ascertain progress and identify investment strategies for each agency. Such a federal plan could feed into a national strategic plan but would not itself be a broad, multistakeholder national strategic plan. Development of a national strategic plan should begin immediately and not await further refinement of the current federal strategy.

**CONCLUDING REMARKS**

A robust national strategic plan for addressing nanotechnology-related EHS risks will need to focus on promoting research that can assist all stakeholders, including federal agencies, in planning, controlling, and optimizing the use of engineered nanomaterials while minimizing EHS effects of concern to society. Such a plan will ensure the timely development of engineered nanoscale materials that will bring about great improvements in the nation’s health, its environmental quality, its economy, and its security.
Review of the Federal Strategy for Nanotechnology-Related Environmental, Health, and Safety Research


Committee on Toxicology

Board on Environmental Studies and Toxicology

Division on Earth and Life Studies

National Materials Advisory Board

Division on Engineering and Physical Sciences

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu
The National Academy of Sciences is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of the charter granted to it by the Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters. Dr. Ralph J. Cicerone is president of the National Academy of Sciences.

The National Academy of Engineering was established in 1964, under the charter of the National Academy of Sciences, as a parallel organization of outstanding engineers. It is autonomous in its administration and in the selection of its members, sharing with the National Academy of Sciences the responsibility for advising the federal government. The National Academy of Engineering also sponsors engineering programs aimed at meeting national needs, encourages education and research, and recognizes the superior achievements of engineers. Dr. Charles M. Vest is president of the National Academy of Engineering.

The Institute of Medicine was established in 1970 by the National Academy of Sciences to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public. The Institute acts under the responsibility given to the National Academy of Sciences by its congressional charter to be an adviser to the federal government and, upon its own initiative, to identify issues of medical care, research, and education. Dr. Harvey V. Fineberg is president of the Institute of Medicine.

The National Research Council was organized by the National Academy of Sciences in 1916 to associate the broad community of science and technology with the Academy’s purposes of furthering knowledge and advising the federal government. Functioning in accordance with general policies determined by the Academy, the Council has become the principal operating agency of both the National Academy of Sciences and the National Academy of Engineering in providing services to the government, the public, and the scientific and engineering communities. The Council is administered jointly by both Academies and the Institute of Medicine. Dr. Ralph J. Cicerone and Dr. Charles M. Vest are chair and vice chair, respectively, of the National Research Council.

www.national-academies.org
COMMITTEE FOR REVIEW OF THE FEDERAL STRATEGY TO ADDRESS ENVIRONMENTAL, HEALTH, AND SAFETY RESEARCH NEEDS FOR ENGINEERED NANOSCALE MATERIALS

Members

DAVID L. EATON (Chair), University Of Washington, Seattle, WA
MARTIN A. PHILBERT (Vice Chair), University Of Michigan, Ann Arbor
GEORGE V. ALEXEEFF, California Environmental Protection Agency, Oakland
TINA BAHADORI, American Chemistry Council, Arlington, VA
JOHN M. BALBUS, Environmental Defense Fund, Washington, DC
MOUNG G. BAWENDI, Massachusetts Institute Of Technology, Cambridge
PRATIM BISWAS, Washington University In St. Louis, St. Louis, MO
VICKI L. COLVIN, Rice University, Houston, TX
STEPHEN J. KLAIN, Clemson University, Pendleton, SC
ANDREW D. MAYNARD, Woodrow Wilson International Center For Scholars, Washington, DC
NANCY A. MONTEIRO-RIVIERE, North Carolina State University, Raleigh, NC
GUNTER OBERDÖRSTER, University Of Rochester School Of Medicine And Dentistry, Rochester, NY
MARK A. RATNER, Northwestern University, Evanston, IL
JUSTIN G. TEEGUARDEN, Pacific Northwest National Laboratory, Richland, WA
MARK R. WIESNER, Duke University, Durham, NC

Staff

EILEEN N. ABT, Project Director
MICHAEL MOLONEY, Senior Program Officer
HEIDI MURRAY-SMITH, Research Associate
NORMAN GROSSBLATT, Senior Editor
MIRSADA KARALIC-LONCAREVIC, Manager, Technical Information Center
PANOLA GOLSON, Senior Program Assistant

Sponsor

 NATIONAL NANOTECHNOLOGY COORDINATION OFFICE

Prepublication Copy
BOARD ON ENVIRONMENTAL STUDIES AND TOXICOLOGY

Members

JONATHAN M. SAMET (Chair), University of Southern California, Los Angeles
RAMÓN ÁLVAREZ, Environmental Defense Fund, Austin, TX
JOHN M. BALBUS, Environmental Defense Fund, Washington, DC
DALLAS BURTRAW, Resources for the Future, Washington, DC
JAMES S. BUS, Dow Chemical Company, Midland, MI
RUTH DEFRIES, Columbia University, New York, NY
COSTEL D. DENSON, University of Delaware, Newark
E. DONALD ELLIOTT, Willkie, Farr & Gallagher LLP, Washington, DC
MARY R. ENGLISH, University of Tennessee, Knoxville
J. PAUL GILMAN, Covanta Energy Corporation, Fairfield, NJ
JUDITH A. GRAHAM (Retired), Pittsboro, NC
WILLIAM M. LEWIS, JR., University of Colorado, Boulder
JUDITH L. MEYER, University of Georgia, Athens
DENNIS D. MURPHY, University of Nevada, Reno
DANNY D. REIBLE, University of Texas, Austin
JOSEPH V. RODRICKS, ENVIRON International Corporation, Arlington, VA
ARMISTEAD G. RUSSELL, Georgia Institute of Technology, Atlanta
ROBERT F. SAWYER, University of California, Berkeley
KIMBERLY M. THOMPSON, Harvard School of Public Health, Boston, MA
MARK J. UTELL, University of Rochester Medical Center, Rochester, NY

Senior Staff

JAMES J. REISA, Director
DAVID J. POLICANSKY, Scholar
RAYMOND A. WASSEL, Senior Program Officer for Environmental Studies
EILEEN N. ABT, Senior Program Officer for Risk Analysis
SUSAN N.J. MARTEL, Senior Program Officer for Toxicology
KULBIR BAKSHI, Senior Program Officer
ELLEN K. MARTUS, Senior Program Officer
RUTH E. CROSSGROVE, Senior Editor

1This study was planned, overseen, and supported by the Board on Environmental Studies and Toxicology.
NATIONAL MATERIALS ADVISORY BOARD

Members

KATHARINE G. FRASE (Chair), IBM
LYLE H. SCHWARTZ (Vice Chair), University Of Maryland
PAUL BECHER, Oak Ridge National Laboratory (Retired)
EVERETT E. BLOOM, Oak Ridge National Laboratory (Retired)
BARBARA D. BOYAN, Georgia Institute of Technology
PETER R. BRIDENBAUGH, Alcoa, Inc. (Retired)
L. CATHERINE BRINSON, Northwestern University
JOHN W. CAHN, University Of Washington
DIANNE CHONG, The Boeing Company
PAUL CITRON, Medtronic, Inc. (Retired)
GEORGE T. GRAY, III, Los Alamos National Laboratory
SOSSINA M. HAILE, California Institute of Technology
CAROL A. HANDWERKER, Purdue University
ELIZABETH HOLM, Sandia National Laboratories
DAVID W. JOHNSON, JR., Stevens Institute of Technology
ROBERT H. LATIFF, SAIC, Alexandria, Virginia
KENNETH H. SANDHAGE, Georgia Institute of Technology
LINDA SCHADLER, Rensselaer Polytechnic Institute
ROBERT E. SCHAFFRIK, GE Aircraft Engines
JAMES C. SEFERIS, Glocal Network Corporation, Seattle, Washington
STEVEN WAX, Strategic Analysis, Inc

Staff

GARY FISCHMAN, Director
MICHAEL H. MOLONEY, Senior Program Officer
EMILY ANN MEYER, Program Officer
ERIK SVEDBERG, Program Officer
TERI G. THOROWGOOD, Administrative Coordinator
LAURA TOTH, Program Assistant
HEATHER LOZOWSKI, Financial Associate
OTHER REPORTS OF THE
BOARD ON ENVIRONMENTAL STUDIES AND TOXICOLOGY

Respiratory Diseases Research at NIOSH (2008)
Evaluating Research Efficiency in the U.S. Environmental Protection Agency (2008)
Hydrology, Ecology, and Fishes of the Klamath River Basin (2008)
Applications of Toxicogenomic Technologies to Predictive Toxicology and Risk Assessment (2007)
Models in Environmental Regulatory Decision Making (2007)
Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues (2006)
New Source Review for Stationary Sources of Air Pollution (2006)
Human Biomonitoring for Environmental Chemicals (2006)
Health Risks from Dioxin and Related Compounds: Evaluation of the EPA Reassessment (2006)
Superfund and Mining Megasites—Lessons from the Coeur d’Alene River Basin (2005)
Health Implications of Perchlorate Ingestion (2005)
Endangered and Threatened Species of the Platte River (2004)
Atlantic Salmon in Maine (2004)
Cumulative Environmental Effects of Alaska North Slope Oil and Gas Development (2003)
Arsenic in Drinking Water: 2001 Update (2001)
Evaluating Vehicle Emissions Inspection and Maintenance Programs (2001)
Compensating for Wetland Losses Under the Clean Water Act (2001)
Acute Exposure Guideline Levels for Selected Airborne Chemicals (six volumes, 2000-2008)
Toxicological Effects of Methylmercury (2000)
Strengthening Science at the U.S. Environmental Protection Agency (2000)
Scientific Frontiers in Developmental Toxicology and Risk Assessment (2000)
Ecological Indicators for the Nation (2000)
Hormonally Active Agents in the Environment (1999)
Research Priorities for Airborne Particulate Matter (four volumes, 1998-2004)
The National Research Council’s Committee on Toxicology: The First 50 Years (1997)
Carcinogens and Anticarcinogens in the Human Diet (1996)
Upstream: Salmon and Society in the Pacific Northwest (1996)
Wetlands: Characteristics and Boundaries (1995)
Biologic Markers (five volumes, 1989-1995)
Science and Judgment in Risk Assessment (1994)
Pesticides in the Diets of Infants and Children (1993)
Dolphins and the Tuna Industry (1992)
Science and the National Parks (1992)
Human Exposure Assessment for Airborne Pollutants (1991)
Rethinking the Ozone Problem in Urban and Regional Air Pollution (1991)
Decline of the Sea Turtles (1990)

Copies of these reports may be ordered from the National Academies Press
(800) 624-6242 or (202) 334-3313
www.nap.edu
OTHER REPORTS OF THE NATIONAL MATERIALS ADVISORY BOARD

Ballistic Imaging (2008)
Managing Materials for a Twenty-First Century Military (2007)
Fusion of Security System Data to Improve Airport Security (2007)
Fusion of Security System Data to Improve Airport Security (2007)
Defending the U.S. Air Transportation System Against Chemical and Biological Threats (2006)
Going to Extremes: Meeting the Emerging Demand for Durable Polymer Matrix Composites (2005)
High-Performance Structural Fibers for Advanced Polymer Matrix Composites (2005)
Nanotechnology for the Intelligence Community (2005)
Summary of the Power Systems Workshop on Nanotechnology for the Intelligence Community (2004)
Summary of the Sensing and Positioning Technology Workshop of the Committee on Nanotechnology for the Intelligence Community (2004)
Opportunities to Improve Airport Passenger Screening with Mass Spectrometry (2004)
Science-Based Assessment: Accelerating Product Development of Combination Medical Devices (2004)
Summary of the Workshop on Structural Nanomaterials (2001)

Copies of these reports may be ordered from the National Academies Press
(800) 624-6242 or (202) 334-3313
www.nap.edu
Preface

Nanotechnology relies on the ability to engineer, manipulate, and manufacture materials at the nanoscale. Nanotechnology is already enabling the development of an industry that produces and uses engineered nanomaterials in a wide variety of industrial and consumer products. The increasing use of nanomaterials in industrial and consumer products will result in greater exposure of workers and the general public to engineered nanoscale materials.

The U.S. National Nanotechnology Initiative (NNI) is the central locus for the coordination of federal agency investments in nanoscale research and development. In 2007, the National Nanotechnology Coordination Office, which oversees the operation of NNI, asked the National Research Council to review its publication *Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*. The National Research Council’s Board on Environmental Studies and Toxicology and National Materials Advisory Board convened the Committee for Review of the Federal Strategy to Address Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials, which produced this report. The committee was composed of members with expertise in nanotechnology, nanomaterials, metrology, toxicology, risk assessment, exposure assessment, ecotoxicology, occupational and public health, and risk management.

The committee was asked to conduct a scientific and technical review of the federal strategy. The committee considered the elements of an effective nanotechnology risk-research strategy, evaluated whether the federal strategy has these elements, and assessed how the research identified in the strategy will support risk-assessment and risk-management needs. To assist its task, the committee held two workshops at which it heard from representatives of NNI agencies, policy experts from the European Commission, and such stakeholders as manufacturing industry, nongovernment organizations, and the insurance sector.

This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council’s Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following for their review of this report: David E. Aspnes, North Carolina State University; Christopher G. Whipple, ENVIRON International Corporation; Richard A. Denison, Environmental Defense Fund; William H. Farland, Colorado State University; Richard A.L. Jones, University of Sheffield; Gregory V. Lowry, Carnegie Mellon University; David Y. Pui, University of Minnesota; Ronald F. Turco, Purdue University; Mark J. Utell, University of Rochester School of Medicine and Dentistry; David B. Warheit, DuPont Haskell Laboratory.

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of the report was overseen by the review coordinator, Richard
Preface

Schlesinger, Pace University, and the review monitor, Elsa Garmire, Dartmouth College. Appointed by the National Research Council, they were responsible for making certain that an independent examination of the report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of the report rests entirely with the committee and the institution.

The committee gratefully acknowledges the following for their presentations: Pilar Aguar, European Commission; Norris Alderson, U.S. Food and Drug Administration; Carolyn Cairns, Consumers Union; Richard Canady, U.S. Food and Drug Administration; Altaf Carim, U.S. Department of Energy; Thomas Epprecht, Swiss Re; William Gulledge, American Chemistry Council; Michael Holman, Lux Research; William Kojola, AFL-CIO; Philippe Martin, European Commission; Terry Medley, DuPont; Jeffrey Morris, U.S. Environmental Protection Agency; Vladimir Murashov, National Institute for Occupational Safety and Health; Dianne Poster, National Institute of Standards and Technology; William Rees, U.S. Department of Defense; Mihail Roco, National Science Foundation; Jennifer Sass, National Resources Defense Council; Phillip Sayre, U.S. Environmental Protection Agency; Paul Schulte, National Institute for Occupational Safety and Health; Clayton Teague, National Nanotechnology Coordination Office; and Sally Tinkle, National Institute of Environmental Health Sciences.

The committee is also grateful for the assistance of the National Research Council staff in preparing this report. Staff members who contributed to the effort are Eileen Abt, project director; Michael Moloney, senior program officer; James Reisa, director of the Board on Environmental Studies and Toxicology; Heidi Murray-Smith, research associate; Norman Grossblatt, senior editor; Mirsada Karalic-Loncarevic, manager, technical information center; and Panola Golson, senior program assistant.

We would especially like to thank the committee members for their efforts throughout the development of this report.

David L. Eaton, Chair
Martin A. Philbert, Vice Chair
Abbreviations

ADME absorption, distribution, metabolism, elimination
AEC Atomic Energy Commission
CSREES Cooperative State Research, Education, and Extension Service
CST UK Council for Science and Technology
DHS Department of Homeland Security
DHHS Department of Health and Human Services
DOC Department of Commerce
DOD Department of Defense
DOE Department of Energy
DOJ Department of Justice
DOT Department of Transportation
EC European Commission
EHS environmental, health, and safety
EPA U.S. Environmental Protection Agency
EU European Union
FDA Food and Drug Administration
FHWA Federal Highway Administration
FS Forest Service
FY fiscal year
GIN Global Issues in Nanotechnology Working Group
ICON International Council on Nanotechnology
IWGN Interagency Working Group on Nanotechnology
NASA National Aeronautics and Space Administration
NEHI Nanotechnology Environmental Health Implications
NIH National Institutes of Health
NILI Nanomanufacturing Industry Liaison and Innovation Working Group
NIOSH National Institute of Occupational Safety and Health
NIST National Institute of Standards and Technology
NNCO National Nanotechnology Coordination Office
NNI U.S. National Nanotechnology Initiative
NORA National Occupational Research Agenda
NPEC National Public Engagement and Communications Working Group
NRC National Research Council
NRC Nuclear Regulatory Commission
NSET Nanoscale Science, Engineering, and Technology subcommittee
NSF National Science Foundation
NSTC National Science and Technology Council
OECD Organization for Economic Co-operation and Development
OMB Office of Management and Budget
OSTP Office of Science and Technology Policy
PART Program Assessment Rating Tool
PCA program component area
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCAST</td>
<td>President’s Council of Advisors on Science and Technology</td>
</tr>
<tr>
<td>QSAR</td>
<td>quantitative structure – activity relationship</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>research and development</td>
</tr>
<tr>
<td>SCENIHR</td>
<td>Scientific Committee on Emerging and Newly-Identified Health Risks</td>
</tr>
<tr>
<td>USDA</td>
<td>U.S. Department of Agriculture</td>
</tr>
<tr>
<td>VOI</td>
<td>Value of Information</td>
</tr>
<tr>
<td>WPMN</td>
<td>Working Party on Manufactured Nanomaterials</td>
</tr>
</tbody>
</table>
# Contents

ABBREVIATIONS................................................................................................. xiii

SUMMARY............................................................................................................. 1

1. **THE NATIONAL NANOTECHNOLOGY INITIATIVE AND THE GENESIS OF THE ENVIRONMENTAL, HEALTH, AND SAFETY STRATEGY** ................................................................. 8
   Environment, Health, and Safety, 11
   Structure of this Report, 15
   References, 15

2. **ELEMENTS OF AN EFFECTIVE NANOTECHNOLOGY RISK-RESEARCH STRATEGY** .......... 18
   Overview, 18
   Developing Effective Research Strategies, 18
   Developing Effective Risk-Research Strategies, 20
   Developing Nanotechnology-Specific Risk-Research Strategies, 21
   Elements of a Risk-Research Strategy, 25
   References, 26

3. **EVALUATION OF THE FEDERAL STRATEGY** ................................................... 28
   Is There an Evaluation of the Existing State of Science? 28
   Does the Strategy Have a Vision or Stated Purpose? 29
   Does the Strategy Have Goals to Ensure the Safe Development of Nanotechnologies and is There a Road Map for Achieving Stated Goals, 31
   Does the Strategy Provide for Evaluation of Research Priorities and an Assessment of Research Progress? 32
   Does the Strategy Identify the Resources Needed to Achieve Stated Goals? 32
   Does the Strategy Provide Accountability for Achieving Stated Goals? 33
   Conclusions, 34
   Reference, 35

4. **REVIEW OF PRIORITY RESEARCH TOPICS, RESEARCH NEEDS, AND GAP ANALYSIS** .............. 37
   Cross-Cutting Conclusions on Analysis of Specific Research Categories, 38
   Analysis of Specific Research Categories, 41
   Committee’s Assessment of Current Distribution of Federal Investment in Nanotechnology-Related Environmental, Health, and Safety Research, 61
   Conclusions, 63
   References, 64

5. **CONCLUSIONS AND RECOMMENDATIONS** ...................................................................... 66
Appendices

A. Biographic Information on the Committee for Review of the Federal Strategy to Address Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials ................................................................. 70

B. Statement of Task ............................................................................................................................ 75

C. Workshop Agendas .......................................................................................................................... 76

D. National Nanotechnology Initiative Strategy for Nanotechnology-Related Environmental, Health, and Safety Research .................................................................................................................. 78

Boxes, Figures, and Tables

Boxes

1-1 A Brief History of the National Nanotechnology Initiative, 9
2-1 Elements of a Research Strategy, 19
4-1 Questions that Structured the Committee’s Analysis, 37
4-2 Environmental, Health, and Safety Research Categories Identified by the National Nanotechnology Initiative, 38
4-3 Research Needs for the Instrumentation, Metrology, and Analytical Methods, 43
4-4 Research Needs for Nanomaterials and Human Health, 47
4-5 Research Needs for Nanomaterials and the Environment, 52
4-6 Research Needs for Human and Environmental Exposure Assessment, 56
4-7 Research Needs for Risk Management Methods, 58

Figures

1-1 Organization of NNI, 10
1-2 NNI Research Funding by Program Component Area for FY 2006, 13

Tables

1-1 Estimated FY 2008 Agency NNI-Related Investments by Program Component Area (in $ millions), 12
4-1 NNI Evaluation of Federal Grant Awards in FY 2006 That Are Directly Relevant to EHS Issues, 62
4-2 NRC Committee’s Estimate of the Percentage of FY 2006 Projects That Are Aimed Primarily at Understanding Potential Risks Posed by Engineered Nanomaterials, 63
Review of the Federal Strategy for Nanotechnology-Related Environmental, Health, and Safety Research