NNI Research in NanoEHS

Barbara Karn, PhD

NSF Grantees Meeting
Arlington, VA

December 4, 2012

Background on NanoEHS

- 1980's Nanotechnology is enabled
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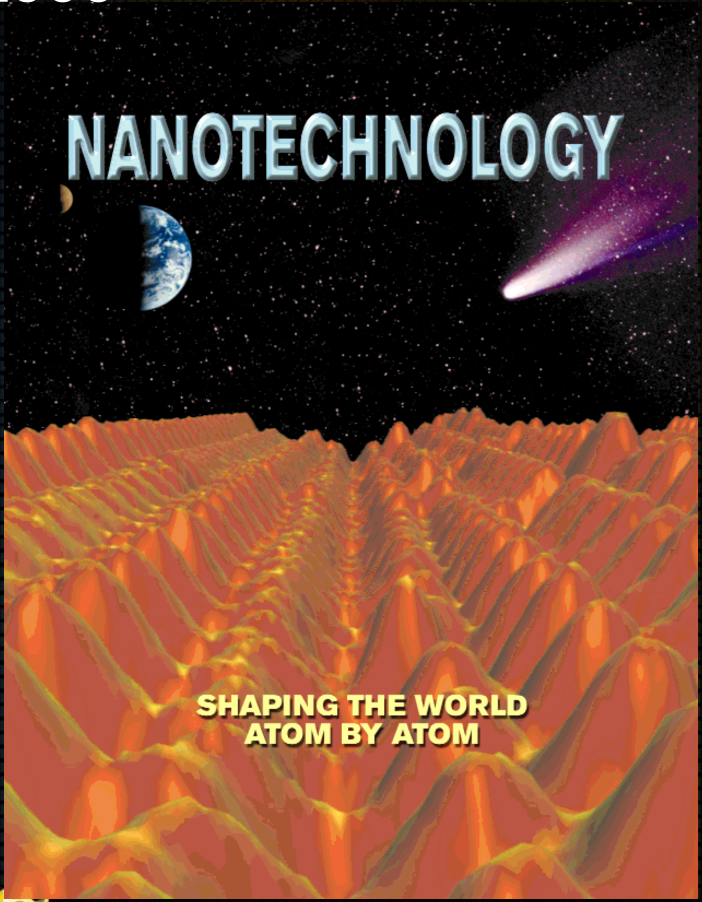
- Mid-1990's Nanotechnology is recognized

- 1999 NNI and IWGN formed

"The emerging fields of nanoscience and nanoengineering are leading to unprecedented understanding and control over the fundamental building blocks of all physical things. This is likely to change the way almost everything—from vaccines to computers to automobile tires to objects not yet imagined—is designed and made."

1999



Interagency Working Group on Nanoscience, Engineering and Technology (IWGN)
Chair: M.C. Roco, NSF.
White House IWGN Co-chair: T.A. Kalil , Special Assistant to the President, WH Economic Council.
Vice-chair: R. Trew, DOD.
Executive Secretary: J.S. Murday, NRL.
Members: K. Kirkpatrick (OSTP); J. Porter (NSTC), D. Radzanowski (OMB); P. Genther-Yoshida (DOC/TA); M.P. Casassa, R.D. Shull (DOC/NIST); G.S. Pomrenke (DOD/AFOSR); I.L. Thomas, R. Price, B.G. Volintine (DOE); R.R. John, A. Lacombe (DOT/Volpe Center); E. Murphy (DoTREAS); S. Venneri, G.H. Mucklow, M. Meyyappan, G. Krabach (NASA); J.A. Schloss, E. Kousvelari (NIH); T.A. Weber, M.P. Henkart (NSF).

2002 NSF funds CBEN

Center Vision:
Transforming Nanotechnology into a Tool to Solve Real-World Problems

CBEN's mission is to discover and develop nanomaterials that enable new medical and environmental technologies.

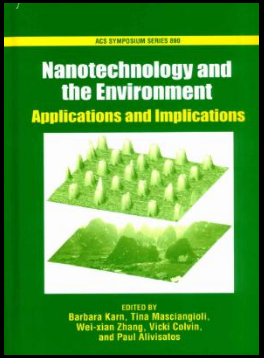
The mission is accomplished by the following:

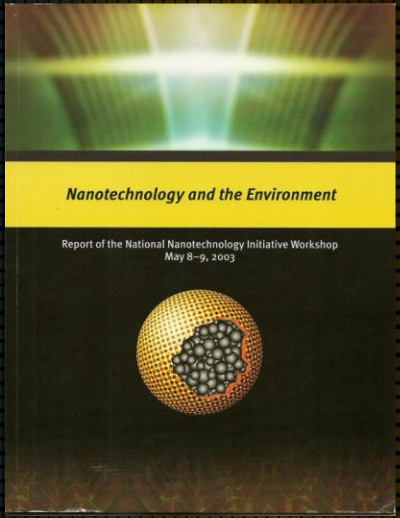
- Fundamental examination of the 'wet/dry' interface between nanomaterials, complex aqueous systems, and ultimately our environment.
- Engineering research that focuses on multifunctional nanoparticles that solve problems in environmental and biological engineering.
- Educational programs that develop teachers, students, and citizens who are well informed and enthusiastic about nanotechnology.
- Innovative knowledge transfer that recognize the importance of communicating nanotechnology research to the media, policymakers, and the general public.

This mission is inspired by the observation that because of their small size and unique properties, nanomaterials interact with and control biological systems in entirely new ways.

2003 becomes a big year for nano EHS

March-- ACS first symposium on Nanotechnology and the Environment
10 sessions, poster session, over 70 papers, both applications and implications, symposium book





May-- NNI Workshop on nanotechnology and the Environment

3 sessions on applications:
Applications for : Measurement in the environment
Sustainable materials and resources
Sustainable processes

2 sessions on Implications:
Natural/global processes
Health/environment

Preface to NNI workshop on Nanotechnology and the Environment, May 8-9, 2003

“The findings from this workshop were used in formulating the NNI Strategic Plan released in December 2004…This report also provided input to the development of programs that make up portions of the FY005-2007 NNI budgets requested for the EPA and other NNI participating agencies…The workshop was in some ways a starting point for a series of discussions within the NNI and the nanotechnology research community concerning the need to address both environmental implications and applications of nanotechnology”

Vision from the 2003 Workshop

1. Applications for Measurement in the Environment

Vision: The unique properties of nanoscale materials will enable the development of a new generation of environmental sensing systems. In addition, measurement science and technology will enable the development of a comprehensive understanding of the interaction and fate of natural and anthropogenic nanoscale and nanostructured materials in the environment.

2.Applications for Sustainable Materials and Resources

Vision: A society that uses nanotechnology to transform the way it extracts, develops, uses and dissipates materials and the flow, recovery, and recycling of valuable resources, especially in the use of energy, transportation of people and goods, availability of clean water, and supply of food.

3.Applications for Sustainable Processes

Vision: Sustainable manufacturing processes based on the use of nanoscale science and nanotechnology – integrated processes and bottom-up assembly – that can serve human needs and are compatible with the surrounding ecosystems and human population.

4.Implications in natural and global processes

Vision: The ability to understand and quantify nanoparticles in Earth system processes in order to anticipate their impacts and thus optimize and integrate environmental sustainability and nanotechnology.

5.Implications in health and environmental safety

Vision: Development of nanotechnology responsibly with a full appreciation of its health and environmental impacts.

- Develop high throughput/multi-analyte toxicological methodologies with focus on mechanism and fundamental science of particle toxicity and access to well-characterized nanomaterials for conducting risk assessment research
- Better understand the diversity of anthropogenic nanoparticles through the development of a nanomaterial inventory
- Gain information on exposure to nanomaterial resulting from medical, occupational, environmental, and accidental release of nanomaterial with regard to the concentration as well as what form(s) the nanoparticles may assume upon release into the environment
- Predict biological properties of nanomaterials through toxicological assessment of nanomaterials that includes relevant and scientifically appropriate acute and chronic toxicokinetics and pharmacokinetic studies

September--Interagency Grantees Meeting / Workshop – Nanotechnology and the Environment: Applications and Implications

Purpose: (1) To bring together environmentally-related nanotechnology research from government agencies with different missions in order to exchange scientific information, and identify areas for cooperation and coordination.
(2) To instill consideration of and for the environment into the research regardless of application.

Sponsors
EPA, USDA, NSF, DOE, DOD, NIH, FDA, DOC, DOT
National Nanotechnology Coordinating Office (NNCO)

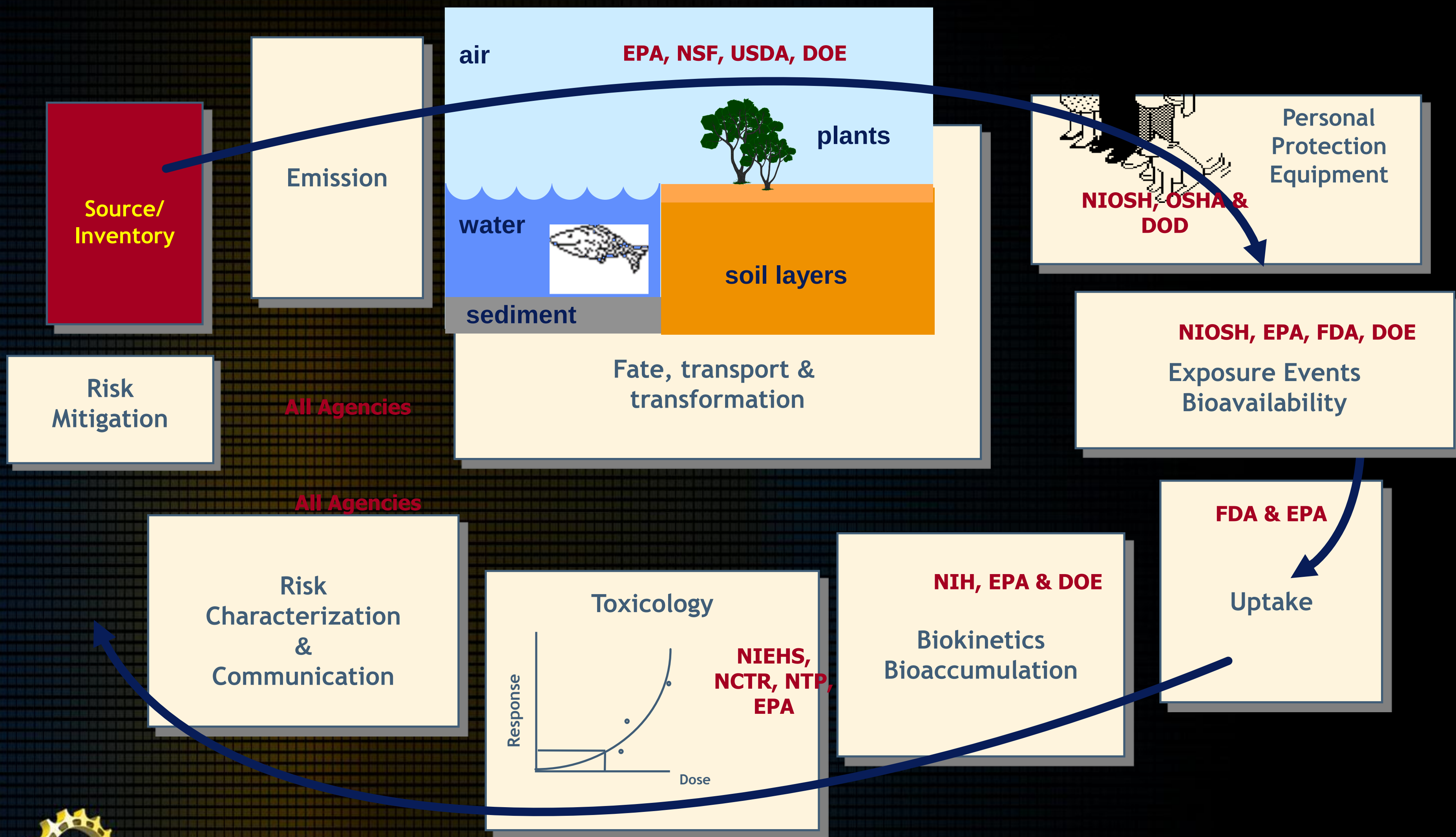
Participants
Government sponsored researchers –approximately 75 participants

Breakout topics

1. Economic benefits for the environment, e.g., use for economical cleanup impact on superfund, efficient manufacturing
2. Workplace and manufacturing issues
3. Precautions, procedures and perceptions
4. Creating a nanotech/environment community (communications, web site), continuing interactions, international links, agency cross-cutting
5. Research needs

August--NNCO convened meeting of agencies involved in Nano EHS

Regulatory and Research Topics for EHS



From Mark Alper with mods

Research Framework for Responsible nanotechnology in the environment

Applications

reactive to existing problems

or

proactive in preventing future problems.

Implications

of interactions of nanomaterials with the environment and possible risks that may be posed by the use of nanotechnology.

On December 3, 2003, the President signed into law S. 189, the 21st Century Nanotechnology Research and Development Act, PL 108-153

108TH CONGRESS
1ST SESSION

S. 189

AN ACT

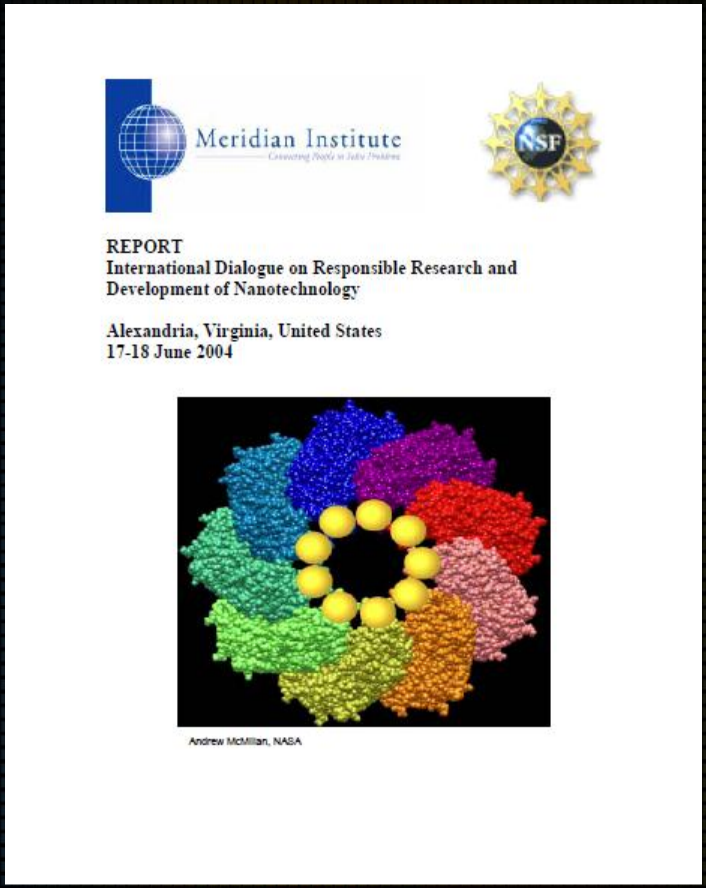
To authorize appropriations for nanoscience, nanoengineering, and nanotechnology research, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "21st Century Nanotechnology Research and Development Act".

June, 2004 International Dialogue on Responsible Research and Development of Nanotechnology


Meridian Institute

REPORT
International Dialogue on Responsible Research and Development of Nanotechnology

Alexandria, Virginia, United States
17-18 June 2004

Andrew McMillan, NASA

25 Countries plus the European Union

The four concurrent breakout group discussions focused on:

benefits and risks to the environment;
benefits and risks to human health and safety;
the socio-economic and ethical implications of nanotechnology;
the special consideration of nanotechnology in developing countries

NNI Strategic Plan II (2004) for FY 2006–2010

Goal: Support responsible development of nanotechnology (with a focus on EHS research; education; and ethical, legal, and social implications) Program component on societal dimensions:

1. Research directed at EHS impacts of nanotechnology development and risk assessment of such impacts
2. Education-related activities, such as development of materials for schools, undergraduate programs, technical training, and public outreach
3. Research directed at identifying and quantifying the broad implications of nanotechnology for society, including social, economic, workforce, educational, ethical, and legal implications

Crosscutting areas of application: Environmental improvement

1. Improved understanding of molecular processes that take place in the environment
2. Reduced pollution through the development of new “green” technologies that minimize manufacturing and transportation of waste products
3. Better environmental remediation through more efficient removal of contaminants, especially ultrafine particles, from air and water supplies, and by continuous measurement and mitigation of pollution in large geographical areas

National Nanotechnology Initiative--NSET

NIH
OSTP
OMB
NSF
DOE
NIST
NASA
NIOSH
OD
DA
USDA/NIFA
USDA/FS
EPA
NRC
DOS
DOTr
DOT
USPTO
USGS
ITIC
DOL
DOJ
DOEd
DOC BIS
DHS
CPSC
ITC

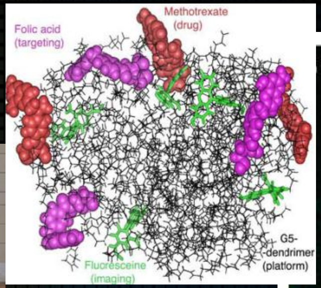
Collaborative, Multi-agency, Cross-cut Program Among 25 Federal agencies

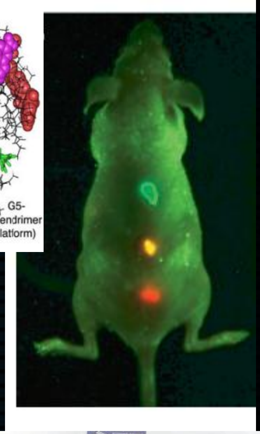
Ensures US Leadership in fundamental R&D to advance understanding and control of matter at nanoscale for:

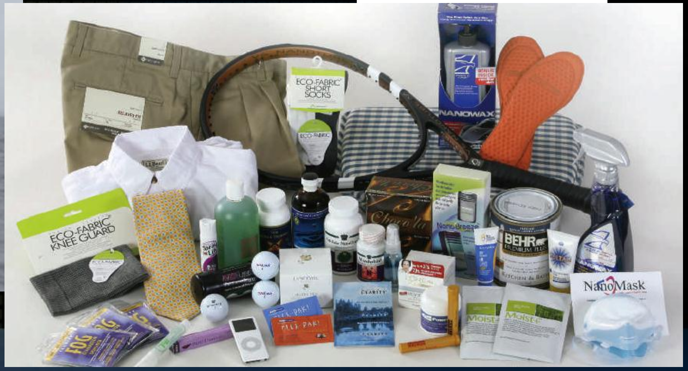
- **National economic benefit**
- **National security**
- **Improved quality of life**

National Nanotechnology Initiative (NNI) Vision

A future in which the ability to understand and control matter at the nanoscale leads to a revolution in technology and industry that benefits society.







2011 NNI Strategic Plan

Goals

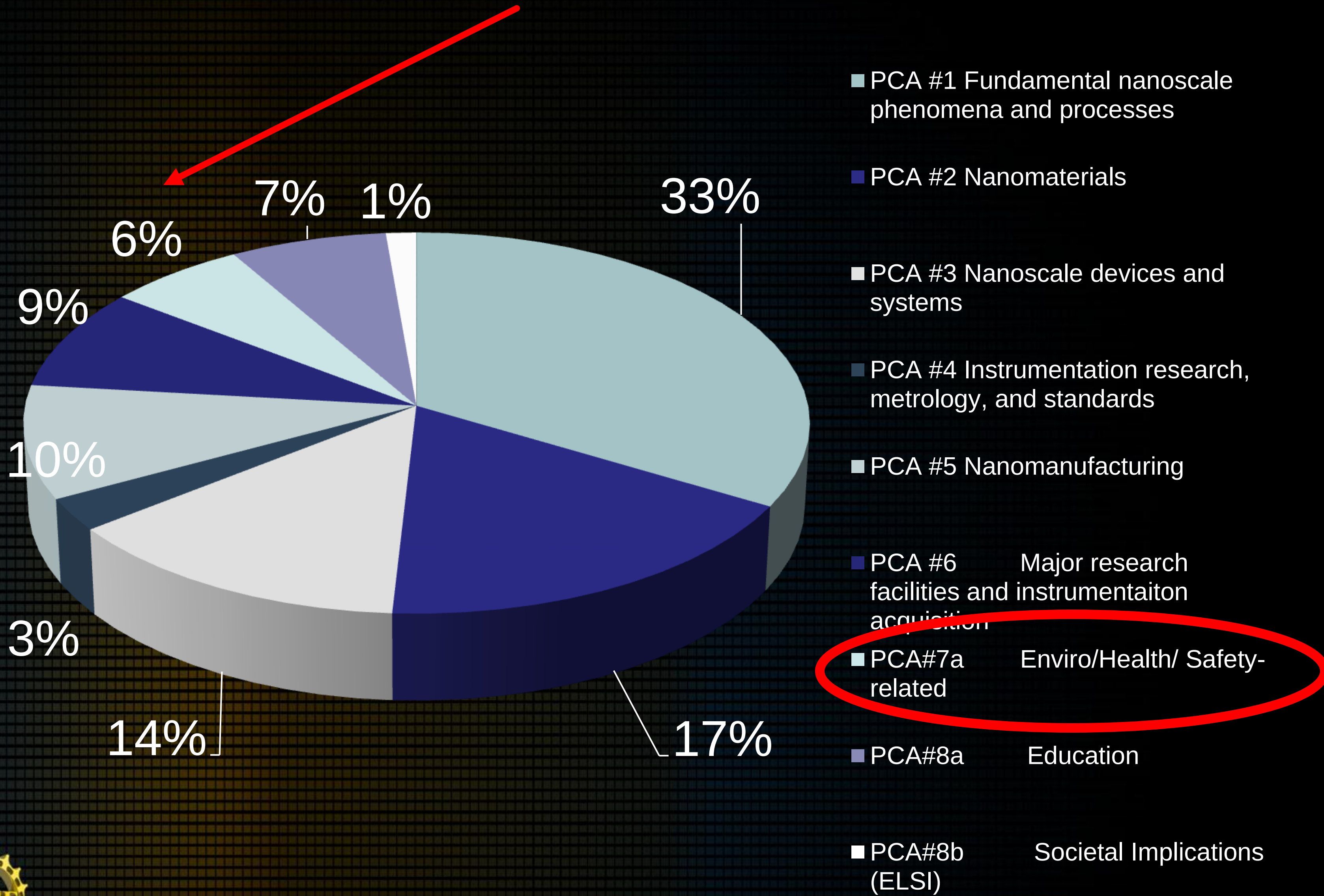
- Advance world-class nanotechnology research and development
- Foster the transfer of new technologies into products for commercial and public benefit
- Develop and sustain educational resources, a skilled workforce, and the supporting infrastructure and tools to advance nanotechnology
- Support responsible development of nanotechnology

Table 5: Proposed 2013 Agency Investments by Program Component Area
(dollars in millions)

	1. Fundamental Phenomena & Processes	2. Nanomaterials	3. Nanoscale Devices & Systems	4. Instrument Research, Metrology, & Standards	5. Nano-manufacturing	6. Major Research Facilities & Instr. Acquisition	7. Environment, Health, and Safety	8. Education & Societal Dimensions	NNI Total
DOE	117.1	146.3	39.7	11.9	9.0	118.5	0.0	0.0	442.5
NSF	146.3	81.3	53.9	12.1	52.8	28.5	29.9	30.1	434.9
HHS/NIH	74.4	83.9	191.9	22.5	1.3	11.4	20.2	3.1	408.7
DOD	138.0	32.7	95.6	1.0	6.2	15.0	1.0	0.0	289.4
DOC/NIST	20.4	7.2	17.8	14.7	15.7	16.4	9.9	0.0	102.1
NASA	0.0	9.0	10.0	0.0	3.0	0.0	0.0	0.0	22.0
EPA	0.0	0.0	0.0	0.0	0.0	0.0	19.3	0.0	19.3
HHS/FDA	0.0	0.0	0.0	0.0	0.0	0.0	11.1	0.0	11.1
HHS/NIOSH	0.0	0.0	0.0	0.0	0.0	0.0	10.0	0.0	10.0
USDA/NIFA	1.0	2.0	4.0	0.0	0.0	0.0	2.0	1.0	10.0
DHS	0.0	0.0	0.0	6.0	0.0	0.0	0.0	0.0	6.0
USDA/FS	1.0	2.0	0.0	1.0	1.0	0.0	0.0	0.0	5.0
USDA/ARS	0.0	2.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0
DOT/FHWA	0.0	2.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0
CPSC	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	2.0
TOTAL	**498.2**	**368.4**	**412.9**	**69.2**	**88.9**	**189.9**	**105.4**	**34.2**	**1767.0**

EHS = 5.69%

NSF Nano PCA Pie



NNI Signature Initiatives

Nanotechnology for Solar Energy Collection and Conversion

Use nanotechnology to help overcome current performance barriers and substantially improve the collection and conversion of solar energy.

- Improve photovoltaic solar electricity generation
- Improve solar thermal energy generation and conversion
- Improve solar-to-fuel conversions

Sustainable Nanomanufacturing—Creating the Industries of the Future

Establish manufacturing technologies for economical and sustainable integration of nanoscale building blocks into complex, large-scale systems.

- Design of scalable and sustainable nanomaterials, components, devices, and processes
- Nanomanufacturing measurement technologies

Nanoelectronics for 2020 and Beyond

Discover and use novel nanoscale fabrication processes and innovative concepts to produce revolutionary materials, devices, systems, and architectures to advance the field of electronics.

- Exploring new or alternative “state variables” for computing
- Merging nanophotonics with nanoelectronics
- Exploring carbon-based nanoelectronics
- Exploiting nanoscale processes and phenomena for quantum information science
- National nanoelectronics research and manufacturing infrastructure network (university-based infrastructure)

Nanotechnology Knowledge Infrastructure: Enabling National Leadership in Sustainable Design" (NKI)

NKI identifies four areas that will benefit from focused attention:

A diverse collaborative community of scientists, engineers, and technical staff to support research, development, and applications of nanotechnology to meet national challenges;

An agile modeling network for multidisciplinary intellectual collaboration that effectively couples experimental basic research, modeling, and applications development;

A sustainable cyber-toolbox to enable effective application of models and knowledge to nanomaterials design;

A robust digital nanotechnology data and information infrastructure to support effective data sharing, collaboration, and innovation across disciplines and applications.

Nanotechnology Signature Initiative in Sensors

The NSI coordinates existing and emerging efforts to explore the use of nanotechnology in two thrust areas:

Using nanotechnology and nanoscale materials to build more sensitive, specific, and adaptable sensors in order to overcome the technical barriers associated with conventional sensors

Developing new sensors to detect engineered nanomaterials across their life cycles, in order to assess the potential impact on health, safety, and the environment

EHS gets more attention

(October 26, 2010) Dr. Sally Tinkle appointed as the Deputy Director of the National Nanotechnology Coordination Office NNCO and Coordinator for Environment, Health, and Safety (EHS).

As Deputy Director, Dr. Tinkle will assist the director and all member agencies of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee to ensure effective communication and coordination of the NNI.

As Coordinator for EHS, she works with agencies to ensure effective communication and coordination of agency EHS R&D efforts and integration of these efforts with the NNI Strategy for Nanotechnology-Related EHS Research.

EHS Mission from NNI

The NNI agencies serve the public good through the development and deployment of a coordinated nanotechnology environmental, health, and safety research strategy that:

--Protects public health and the environment
--Employs science-based risk analysis and risk management
--Fosters technological advancements and benefit society.

Working Groups of NNI

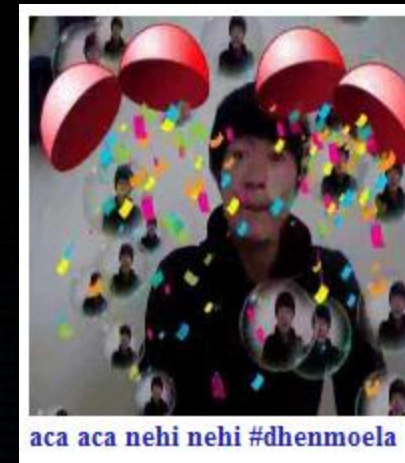
Global Issues in Nanotechnology (GIN)

Nanotechnology Environmental and Health Implications (NEHI)

Nanomanufacturing, Industry Liaison, & Innovation (NILI)

Nanotechnology Public Engagement & Communications (NPEC)


DRINK
Genuine
NEHI
in all popular flavors
WATCH FOR
THIS BOTTLE


aca aca nehi nehi #dhenmoela


Nehi
FLAVORS


Drink
NEHI


NEHI
ORANGE
SODA
CONTAINS ARTIFICIAL COLOR PRESERVED WITH 1/20 OF 1% BENZOATE OF SODA

NEHI MEMBERS

Consumer Product Safety Commission
Department of Agriculture
- Forest Service
- National Institute of Food and Agriculture

Department of Commerce
- National Institute of Standards and Technology
- International Trade Administration

Department of Defense
Department of Energy
Within the Department of Health and Human Services
- Food and Drug Administration
- National Institute of Environmental Health Sciences/National Institutes of Health
- National Institute for Occupational Safety and Health

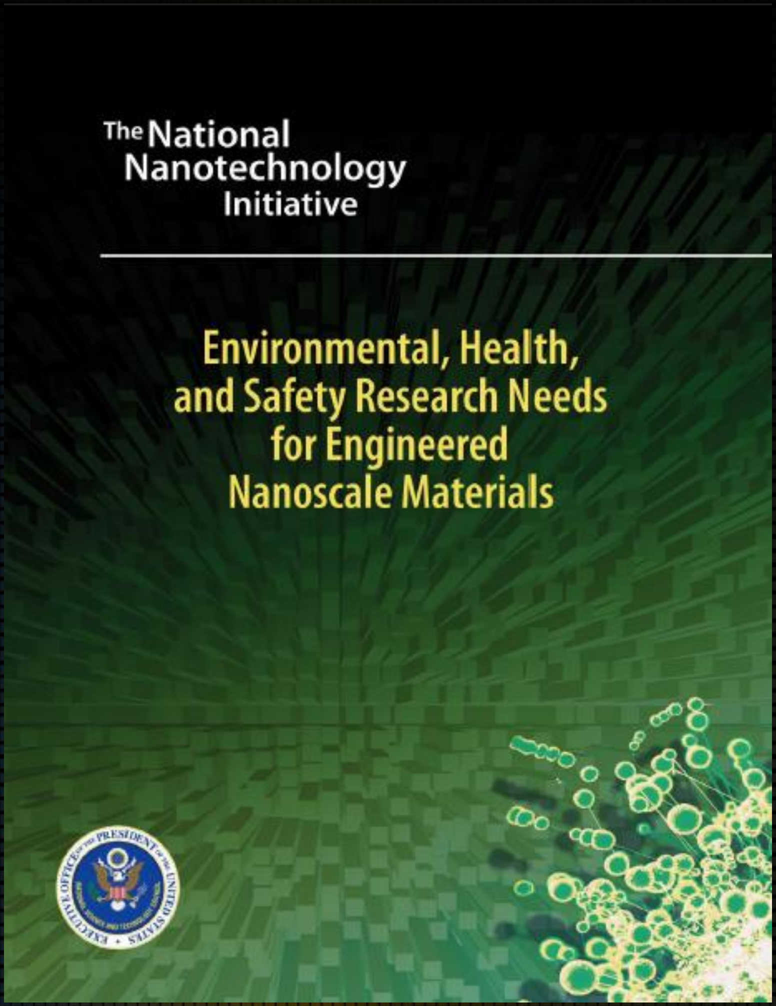
Department of the Interior/U.S. Geological Survey
Department of Labor/Occupational Safety and Health Administration
Department of State
Within the Environmental Protection Agency
- Office of Research and Development
- Office of Pollution Prevention and Toxics

National Science Foundation
National Nanotechnology Coordination Office
Office of Management and Budget
Office of Science and Technology Policy

Nanotechnology Environmental and Health Implications Working Group

NSET established the working group and charged NEHI with supporting Federal activities to protect public health and the environment by:

- Providing for information exchange among Federal agencies that support nanotechnology research and Federal agencies responsible for regulation and guidelines related to nanomaterials and products containing nanomaterials;
- Facilitating the identification, prioritization, and implementation of research and other activities required for the responsible research necessary to develop, use, and oversee nanotechnology;
- Promoting communication of information related to research on environmental, health, and safety implications of nanotechnology;
- Adaptively managing (i.e., coordinating, reviewing, and revising) the interagency EHS research strategy (EHS Strategy Document);
- Assisting in developing information and strategies as a basis for drafting guidance in the safe handling and use of nanomaterials and products;
- With input from NSET and other interagency groups, supporting the development of tools and methods to identify, prioritize, and manage strategies for specific research to enable risk analysis and regulatory decision-making for nanomaterials and products incorporating nanomaterials;
- Supporting developed of nanotechnology standards, including nomenclature and terminology, by consensus-based Nanotechnology Standards; and
- Working with international organizations and governments to share information on and to develop strategies for nanotechnology environmental, health, and safety research



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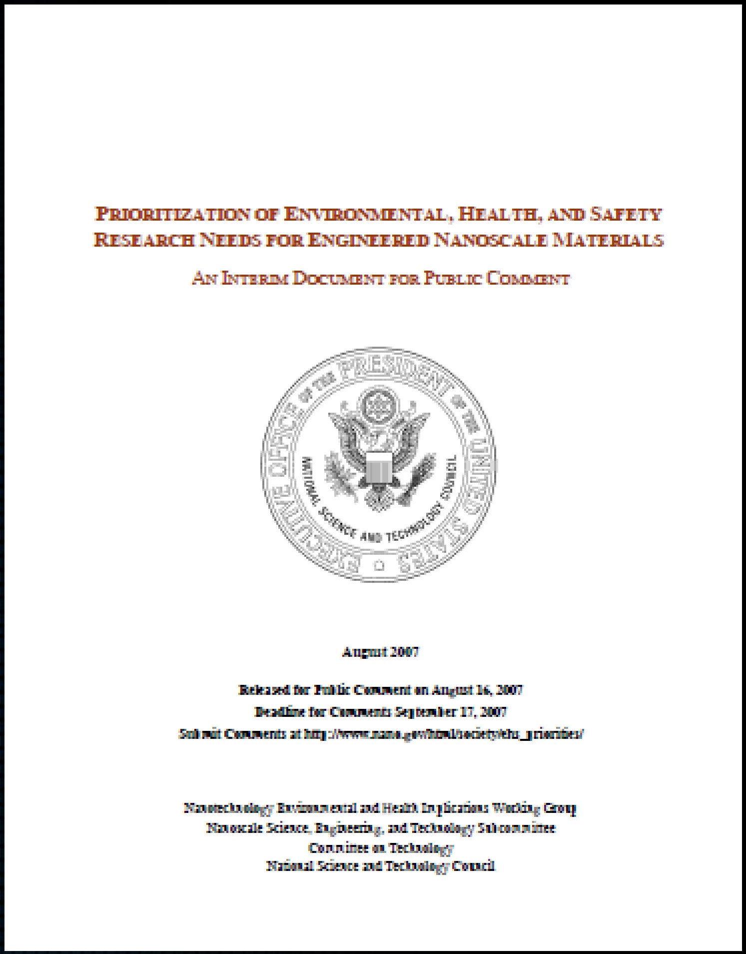

PRIORITIZATION OF ENVIRONMENTAL, HEALTH, AND SAFETY RESEARCH NEEDS FOR ENGINEERED NANOSCALE MATERIALS

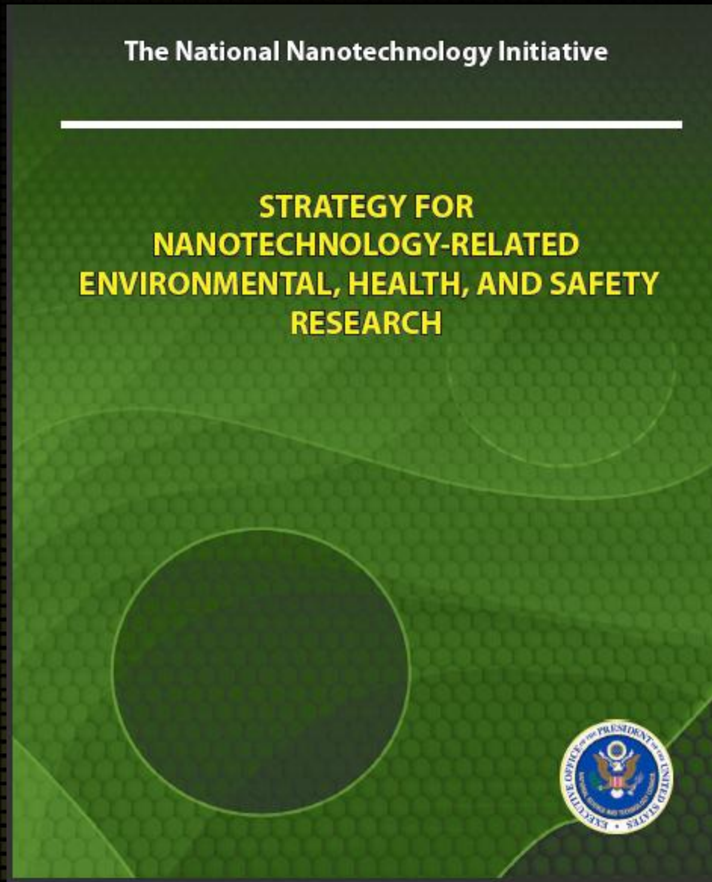
AN INTERIM DOCUMENT FOR PUBLIC COMMENT

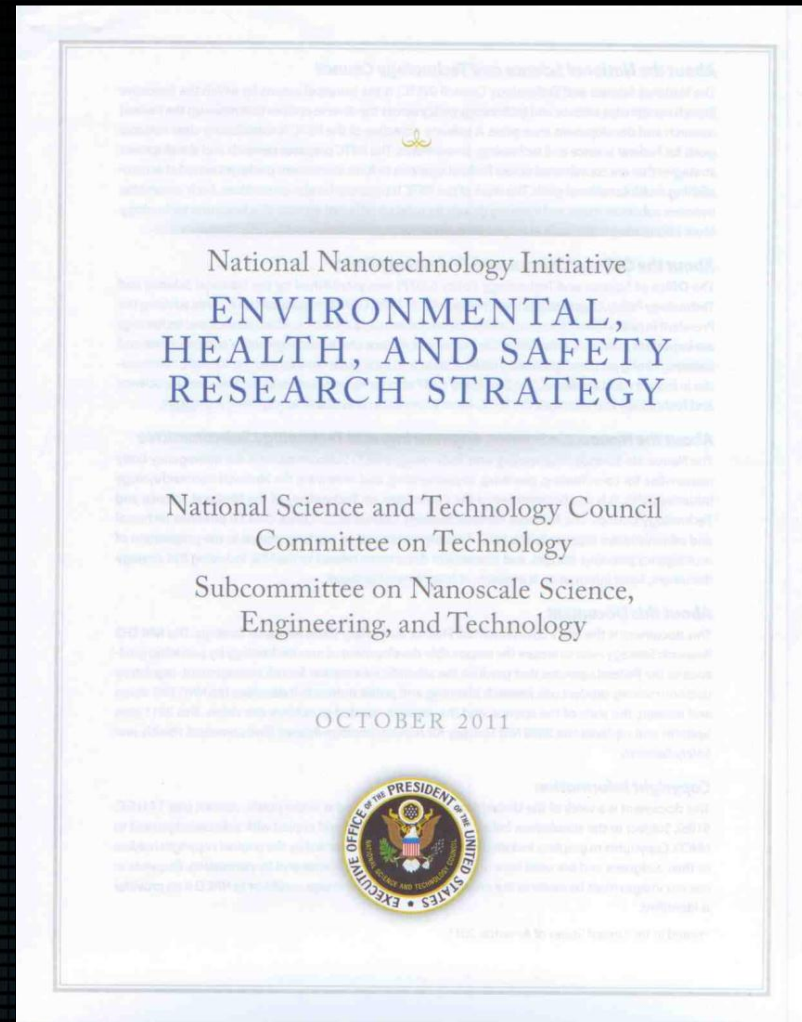
August 2007

Released for Public Comment on August 16, 2007
Deadline for Comments September 17, 2007
Submit Comments at http://www.nano.gov/html/society/ehs_priorities/

Nanotechnology Environmental and Health Implications Working Group
Nanoscale Science, Engineering, and Technology Subcommittee
Committee on Technology
National Science and Technology Council

2007


The National Nanotechnology Initiative
STRATEGY FOR NANOTECHNOLOGY-RELATED ENVIRONMENTAL, HEALTH, AND SAFETY RESEARCH


National Nanotechnology Initiative
ENVIRONMENTAL, HEALTH, AND SAFETY RESEARCH STRATEGY
National Science and Technology Council
Committee on Technology
Subcommittee on Nanoscale Science, Engineering, and Technology
OCTOBER 2011

2008

2011

2011 Nano EHS Strategy

Vision

In support of the National Nanotechnology Initiative (NNI), the vision for environmental, health, and safety research in nanotechnology is a future in which nanotechnology provides maximum benefit to the environment and to human social and economic well-being.

Mission

The NNI agencies serve the public good through the development and deployment of a coordinated nanotechnology environmental, health, and safety research strategy that:

- Protects public health and the environment
- Employs science-based risk analysis and risk management
- Fosters technological advancements that benefit society

1. Nanomaterial Measurement Infrastructure Research Needs

- Develop measurement tools to detect and identify engineered nanoscale materials in products and relevant matrices and determine their physico-chemical properties throughout all stages of their life cycles.
- Develop measurement tools for determination of biological response and to enable assessment of hazards and exposure for humans and the environment from engineered nanomaterials and nanotechnology-based products throughout all stages of their life cycles.

RN#1. Develop measurement tools for determination of physico-chemical properties of ENMs in relevant media and during the life cycles of ENMs and NEPs	§ Physical dimensions and morphology: size, size distribution, characteristic dimensions, shape § Internal structure: atomic-molecular, core-shell § Surface and interfacial properties: surface charge, zeta potential, surface structure, elemental composition, surface-bound molecular coatings and conjugates, reactivity § Bulk composition: elemental or molecular composition, crystalline phase(s) § Dispersion properties: degree and state of dispersion § Mobility and other transport properties: diffusivity, transport in biological and environmental matrices
RN#2. Develop measurement tools for detection and monitoring of ENMs in realistic exposure media and conditions during the life cycles of ENMs and NEP	§ Sampling and collection of ENMs § Detecting the presence of ENMs § Quantity of ENMs—concentration based on surface area, mass, and number concentrations § Size and size distribution of ENMs § Spatial distribution of ENMs § Discriminating ENMs from ambient NMs such as combustion products and welding fumes § Discriminating multiple types of ENMs such as metals and metal oxides

RN#3. Develop measurement tools for evaluation of transformations of ENMs in relevant media and during the life cycles of ENMs and NEPs

- Agglomeration and de-agglomeration
- Dissolution and solubility
- Adsorption of natural organic matter and bioconstituents
- Oxidation and reduction
- Deposition of ENMs on surfaces

RN#4. Develop measurement tools for evaluation of biological responses to ENMs and NEPs in relevant media and during the life cycles of ENMs and NEPs

- Adequacy of existing assays
- New assays or high-throughput, high content assays
- Correlation of biological responses with physico-chemical properties
- Surface reactivity at the interface between ENM and biological receptors
- Biomarkers of toxicological response

RN#5: Develop measurement tools for evaluation of release mechanisms of ENMs from NEPs in relevant media and during the life cycles of NEPs

- Release by fire, combustion, and incineration
- Release by mechanical degradation, such as abrasion, deformation, and impact
- Release by dissolution of matrix material
- Release by chemical reactions of the matrix material
- Release by photo-induced degradation of the matrix material
- Release by consumer interactions, such as spraying, mouthing, and swallowing
- Release by interactions with biological organisms in the environment

2. Human Exposure Assessment Research Needs

- Identify potential sources, characterize the exposure scenario, and measure actual exposures of workers, the general public, and consumers to nanomaterials.
- Characterize and identify the health outcomes among exposed populations in conjunction with information about the control strategies used and exposures to determine practices that result in safe levels of exposures.

RN#1. Understand processes and factors that determine exposures to nanomaterials	§ Conduct studies to understand processes and factors that determine exposure to engineered nanomaterials § Develop exposure classifications of nanomaterials and processes § Develop internationally harmonized and validated protocols for exposure surveys, sample collection and analysis, and reporting through existing and newly created international frameworks § Develop comprehensive predictive models for exposures to a broad range of engineered nanomaterials and processes § Characterize process and task-specific exposure scenarios in the workplace
RN#2. Identify population groups exposed to engineered nanomaterials	§ Systematically collect and analyze information about nanomaterial manufacture, processing, and direct use in commercial and consumer products over time to discern geographic areas where engineered nanomaterials may be emitted into the environment, consumed in the form of ingredients of products, and/or disposed of in solid waste, wastewater, etc. § Conduct population-based surveys to obtain information on use patterns for consumer products § Identify potential subpopulations that are more susceptible to exposure to engineered nanomaterials than others § Develop quantitative assessment methods appropriate for target population groups and conduct assessments of those population groups most likely to be exposed to engineered nanomaterials

RN#3. Characterize individual exposures to nanomaterials	§ Expand currently available exposure assessment techniques to facilitate more accurate exposure assessment for engineered nanomaterials at benchmark concentration levels using feasible methods § Develop new tools through national and international surveys to support effective exposure characterization of individuals § Characterize and detect nanomaterials in biological matrices and conduct studies to understand transformations of nanomaterials during transport in the environment and in human bodies § Conduct studies to examine emissions and human contact during normal use and after wear and tear have degraded a product, as well as during repeated exposures § Develop engineered nanomaterials exposure assessment models based on identified critical exposure descriptors § Develop databases to contain the collected data and information
RN#4. Conduct health surveillance of exposed populations	§ Establish a program for the epidemiological investigation of physician case reports and reports of suspicious patterns of adverse events § Establish exposure registry and medical surveillance programs for workers § Analyze injury and illness reporting in existing programs

3. Human Health Research Needs

- Understand the relationship of physico-chemical properties of engineered nanoscale materials to *in vivo* physico-chemical properties and biological response.
- Develop high-confidence predictive models of *in vivo* biological responses and causal physico-chemical properties of ENMs.

RN#1. Identify or develop appropriate, reliable, and reproducible *in vitro* and *in vivo* assays and models to predict in vivo human responses to ENMs	§ Establish a system to develop and apply reliable and reproducible *in vitro* and *in vivo* test methods § Evaluate the degree to which an *in vitro* response correlates with an *in vivo* response § Evaluate the degree to which in vitro and in vivo models predict human response § Translate structure-activity relationship and other research data into computational models to predict toxicity *in silico*
RN#2. Quantify and characterize ENMs in exposure matrices and biological matrices	§ Determine critical ENM measurands in biological and environmental matrices and ensure the development of tools to measure ENMs in appropriate matrices as needed § Determine matrix and/or weathering effects which may alter the physico-chemical characteristics of the ENM measurands § Identify key factors that may influence the detection of each measurand in a particular matrix (e.g., sample preparation, detection method, storage, temperature, solvents/solutions) § Characterize and quantify exposure for all exposure routes using *in vivo* models to identify the most likely routes of human exposure § Identify biomarkers of exposure and analytical methods for their determination

RN#3. Understand the relationship between the physico-chemical properties of ENMs and their transport, distribution, metabolism, excretion, and body burden in the human body	§ Characterize ENM physico-chemical properties and link to mechanisms of transport and distribution in the human body § Understand the relationship of the physico-chemical properties of ENMs to the mechanisms of sequestration in and translocation of ENMs out of the exposure organ and secondary organs, and to routes of excretion from the human body § Determine the metabolism or biological transformation of ENMs in the human body
RN#4. Understand the relationship between the physico-chemical properties of ENMs and uptake through the human port-of-entry tissues	§ Characterize ENMs at and in port-of-entry tissues, including nontraditional routes of entry such as the ear and eye, and identify mechanisms of ENM uptake into tissues § Determine the relationship of ENM physico-chemical properties to deposition and uptake under acute exposure conditions and under chronic exposure conditions § Translate data on ENM properties and uptake to knowledge that may be used to intentionally redesign ENMs for optimum human and environmental safety and product efficacy
RN#5. Determine the modes of action underlying the human biological response to ENMs at the molecular, cellular, tissue, organ, and whole body levels	§ Determine the dose response and time course of biological responses at the primary site of exposure and at distal organs following ENM exposure § Understand the mechanisms and molecular pathway(s) associated with ENM biology within cellular, organ, and whole organism systems § Link mechanisms of response with ENM physico-chemical properties and employ this information in the design and development of future ENMs § Develop translational alternative *in vitro* testing methods for the rapid screening of future ENMs based on mechanism(s) of response that are predictive of *in vivo* biological responses
RN#6. Determine the extent to which life stage and/or susceptibility factors modulate health effects associated with exposure to ENMs and nanotechnology-enabled products and applications	§ Determine the effect of life stage and/or gender on biological response to ENMs § Establish the role of genetic and epigenetic susceptibility on the biological response to ENMs in the context of life stage and/or susceptibility factors § Understand mechanistically the influence of preexisting disease on the biological response to ENMs in the context of life stage and other susceptibility factors § Identify exposure conditions that make susceptible individuals more vulnerable to the health effects associated with ENMs and nanotechnology-enabled applications
	§ Establish a database that contains published, peer-reviewed literature, occupational and consumer reports, and toxicological profiles that describe

4. Environment Research Needs

§ Understand the environmental fate, exposure, and ecological effects of engineered nanomaterials, with priority placed on materials with highest potential for release, exposure, and/or hazard to the environment.

RN#1. Understand environmental exposures through the identification of principal sources of exposure and exposure routes	§ Manufacturing processes and product incorporation § Life cycle of technology and exposures subsequent to product manufacturing § Analytical approaches to measure temporal changes in nanoparticle properties throughout the life cycle § Models to estimate releases § Environmental receptors for exposure assessment
RN#2. Determine factors affecting the environmental transport of nanomaterials	§ Determine key physico-chemical properties affecting transport § Determine key transport and fate processes relevant to environmental media § Develop new tools and adaptation of current predictive tools to accommodate unique properties of nanomaterials
RN#3. Understand the transformation of nanomaterials under different environmental conditions	§ Identify and evaluate nanomaterial properties and transformation processes that will reduce environmental persistence, toxicity, and production of toxic products § Determine the rate of aggregation and long-term stability of agglomeration/aggregation and the long-term stability of these aggregates and agglomerates. § Develop predictive tools to predict the transformations or degradability of nanomaterials

RN#4. Understand the effects of engineered nanomaterials on individuals of a species and the applicability of testing schemes to measure effects

RN#5. Evaluate the effects of engineered nanomaterials at the population, community, and ecosystem levels

- Test protocols
- Dose-response characterization
- Uptake/elimination kinetics, tissue / organ distribution
- Mode/mechanism of action, predictive tools
- Tiered testing schemes / environmental realism
- Population
- Community
- Other ecosystem-level effects
- Predictive tools for population-, community-, and ecosystem-level effects

5. Risk Assessment and Risk Management Research Needs

§ Increase available information for better decision making in assessing and managing risks from nanomaterials, including using comparative risk assessment and decision analysis; life cycle considerations; and additional perspectives such as ELSI considerations, stakeholders' values, and additional decision makers' considerations.

RN#1. Incorporate relevant risk characterization information, hazard identification, exposure science, and risk modeling and methods into the safety evaluation of nanomaterials	§ Characterization, fate, and release of nanoparticles throughout the life cycles of nanotechnology-enabled products § Development of predictive models on accumulation, migration, and release of nanoparticles throughout the life cycles of nanotehcnology-enabled products § Safety of nanoparticles throughout the life cycles of the nanotechnology-enabled products § Comprehensive and predictive models to assess the potential risks of nanoparticles during the manufacturing and life cycle of nanoproducts, with inputs from human and environment exposures and material properties
RN#2. Understand, characterize, and control workplace exposures to nanomaterials	§ Dissemination and implementation of effective techniques and protocols to measure exposures in the workplace § Identification and demonstration of effective containment and control technologies including for accidents and spills § Development of an effective industry surveillance system § Design and deployment of a prospective epidemiological framework relevant to exposure science § Systematic approaches for occupational risk modeling
RN#3. Integrate life cycle considerations into risk assessment and risk management	§ Establishment of nano-specific taxonomy for life cycle stages § Integration of risk assessment, life cycle analyses, and decision-making approaches into regulatory decision making processes § Application of adaptive management tools based on monitoring/implementation to evaluate life cycle analysis implementation § Development of case studies, e.g., green chemistry, nanomaterials selection, nanomaterials acquisition process, illustrating application of these risk management methods

RN#4. Integrate risk assessment into decision-making frameworks for risk management	§ Development of comparative risk assessment and formal decision-analytical methods operating across multiple metrics as opposed to "absolute" risk assessment strategies § Use of formal decision-analytical methods (e.g., multi-criteria decision analysis) to prioritize risk management alternatives § Gap analyses and value of information analysis to identify research needs and focus investments in the areas of highest uncertainty § Integration of stakeholder values and risk perceptions into risk management processes and illustrate application of integrated decision framework through case studies in risk management decision making
RN#5. Integrate and standardize risk communication within the risk management framework	§ Development and use of standardized terminology in risk communications § Early information-sharing on hazards and risk among federal agencies § Development of appropriate risk communication approaches for agency-specific needs

Informatics Infrastructure Research Needs

RN#1. Develop computational models of ENM structure–property-activity relationships to support the design and development of ENM with maximum benefit and minimum risk to humans and the environment

- Validate the predictive capability of *in vitro* and *in vivo* assays and employ that subset of assays in data generation to establish computational models to predict ENM behavior in humans and the environment.
- Establish a standard set of physical and chemical characterization parameters, dose metrics, and biological response metrics.
- Design and establish structures and ontologies for methods development, data capture, sharing, and analysis.
- Evaluate and adapt as necessary existing computational models by beginning with existing models for exposure and dosimetry and using data generated from validated assays.
- Use ENM exposure and dosimetry models to develop ENM structure-activity models to predict ENM behavior in humans and the environment.
- Establish training sets and beta test sites to refine and validate ENM structure–activity models.
- Disseminate ENM structure-activity models through publicly accessible nanotechnology websites.

PCAST REPORT TO THE PRESIDENT AND CONGRESS ON THE FOURTH ASSESSMENT OF THE NATIONAL NANOTECHNOLOGY INITIATIVE (2012)

Environmental, Health, and Safety (EHS)

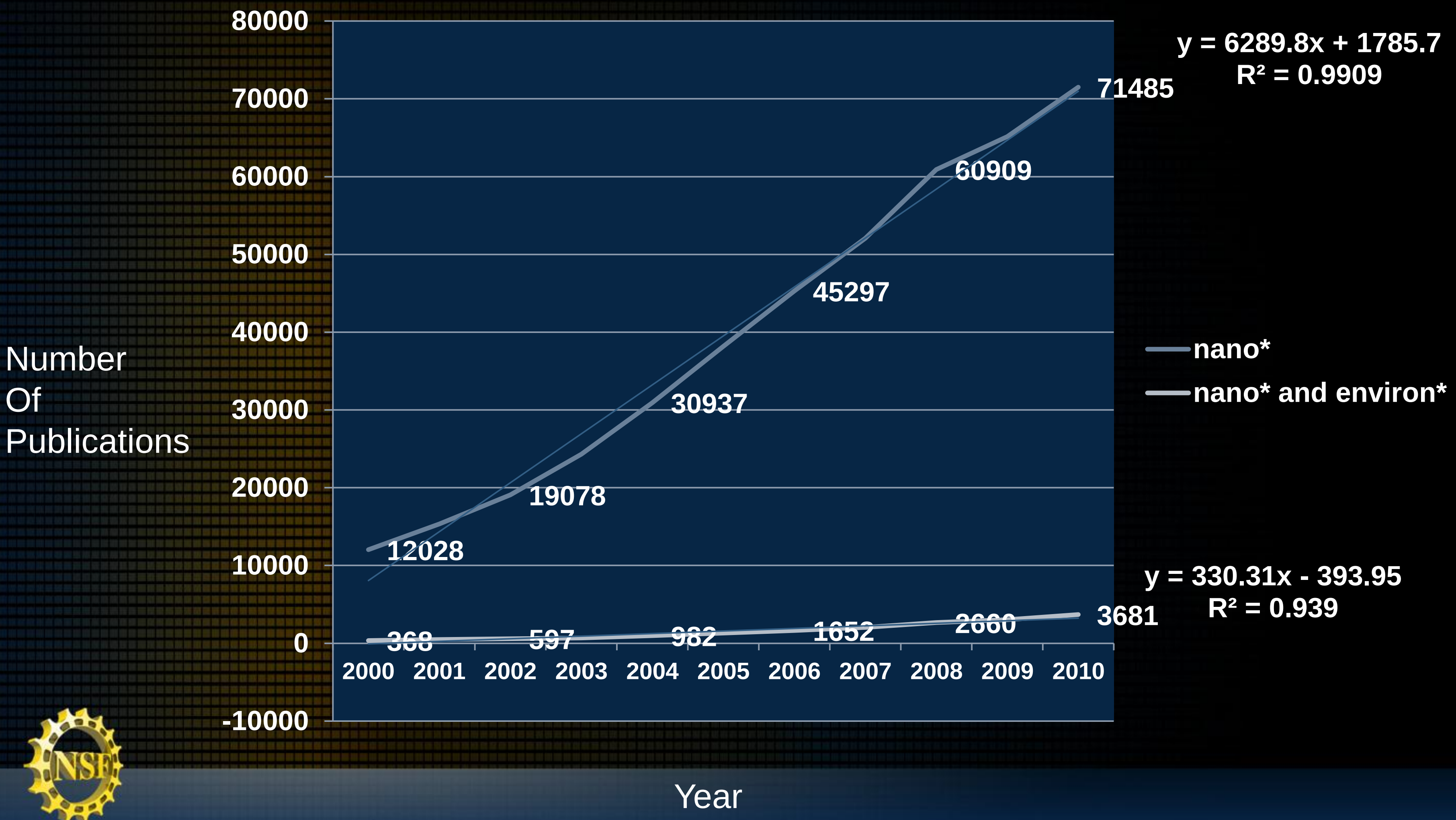
The NSET should:

• Establish high-level, cross-agency authoritative and accountable governance of Federal nanotechnology-related EHS research so that the knowledge created as a result of Federal investments can better inform policy makers.

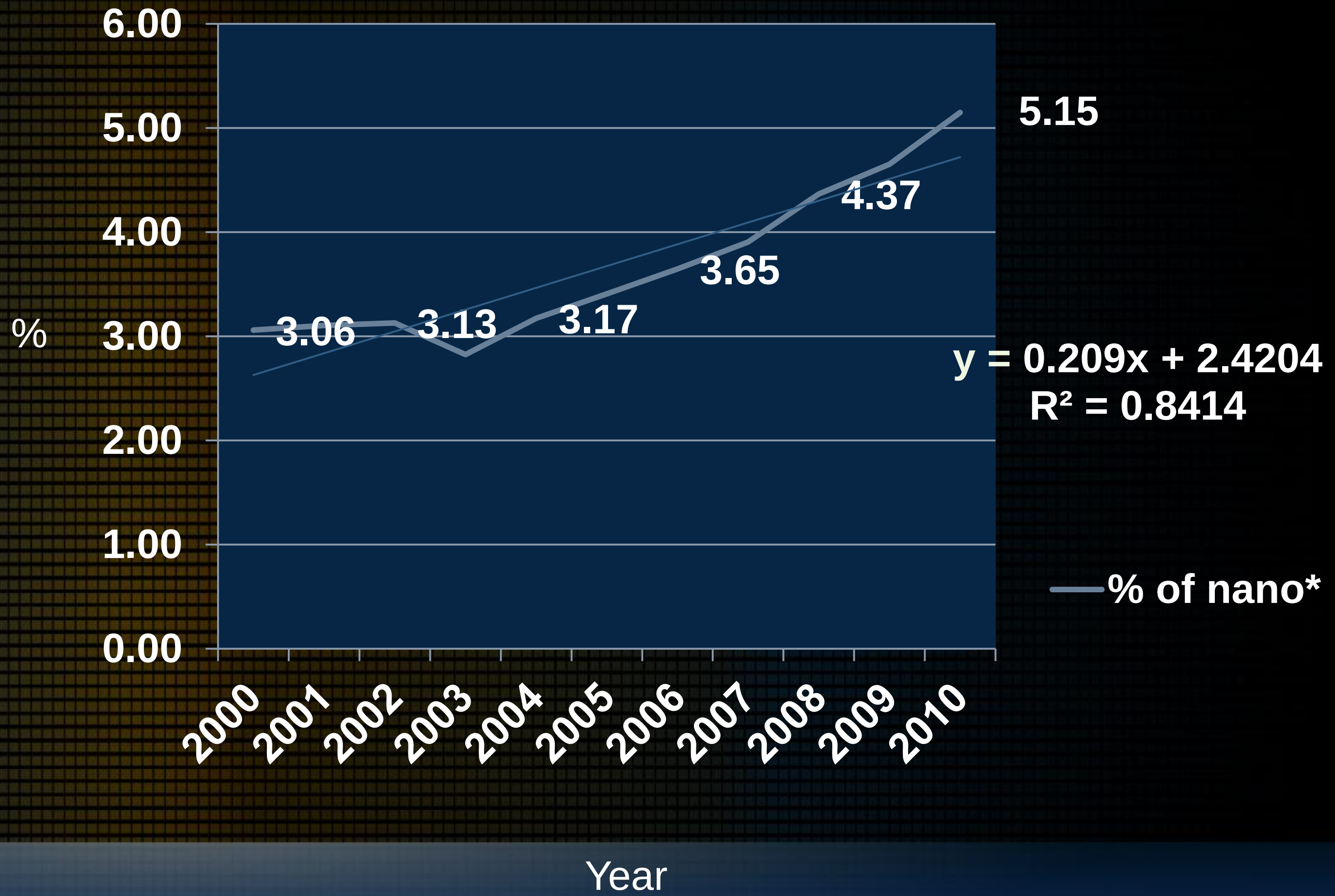
• Increase investment in cross-cutting areas of EHS that promote knowledge transfer such as informatics, partnerships, and instrumentation development.

State of Research

Number of publications: nano and nano/environment



Nano/environment as % of nano



A Simplistic View of Nano EHS

1. Nanoscale materials can be used to improve the environment

For example, zeolite catalysts, nano-scaled metal oxides, zero valent iron

2. There could be harmful effects for humans from manufactured nanoscale materials

For example, pulmonary effects in rats and mice, skin penetration of nanomaterials

3. There could be toxic effects for organisms in the environment

For example, daphnia response, plant root response, fish enzymes

4. The full life cycle must be considered

For example, automobiles, electronic equipment

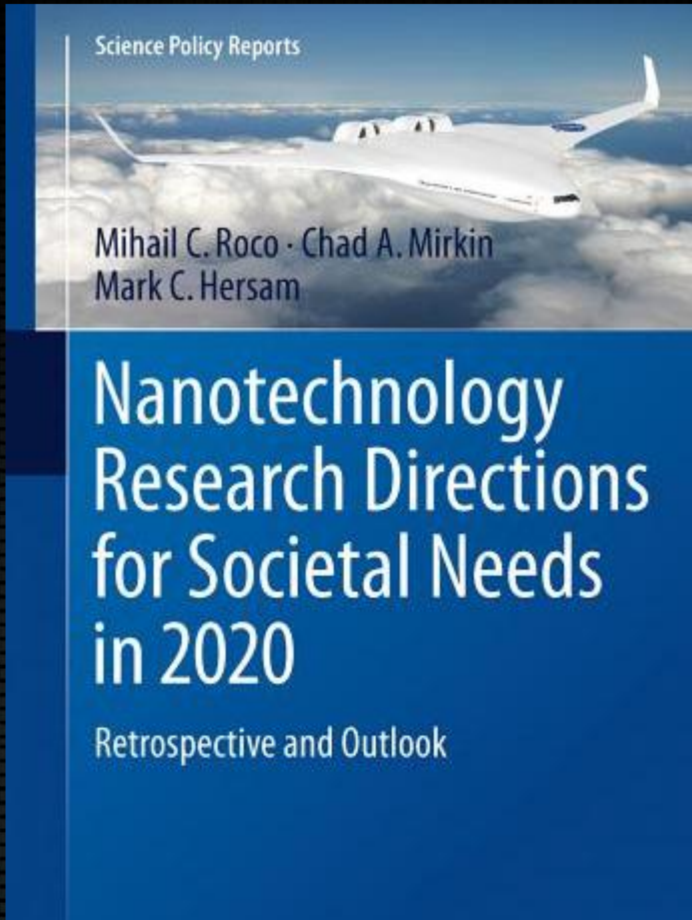
5. There may be ways to design out toxic effects and prevent pollution

Green nano

There is a need to go beyond nano EHS to <u>sustainability</u>

Social and economic aspects, in addition to the environment, are considered in <u>sustainability</u>

<u>Nanotechnology</u> can aid in reaching <u>sustainability</u>



Nanotechnology research moves to sustainability

Safe and sustainable development of nanotechnology for responsible and effective management of its potential; this includes environmental, health, and safety (EHS) aspects and support for a sustainable environment in terms of energy, water, food, raw materials, and climate

Thoughts for the Nano EHS program

1. The engineered nanoparticles of the present and future are complex and heterogeneous. These cutting edge nanomaterials need to be examined as they are extracted, produced, used, and disposed of or recycled sustainably

2 . Detailed materials characterization is necessary to get meaningful results in nano EHS studies.

3. Prevention of adverse impacts is an important and necessary research area.

This includes both applying environmentally benign synthesis methods in engineering and manufacturing nanomaterials as well using nanotechnology in preventing adverse impacts in current non-nano synthesis and manufacturing processes.

4.Research must take a systems approach.

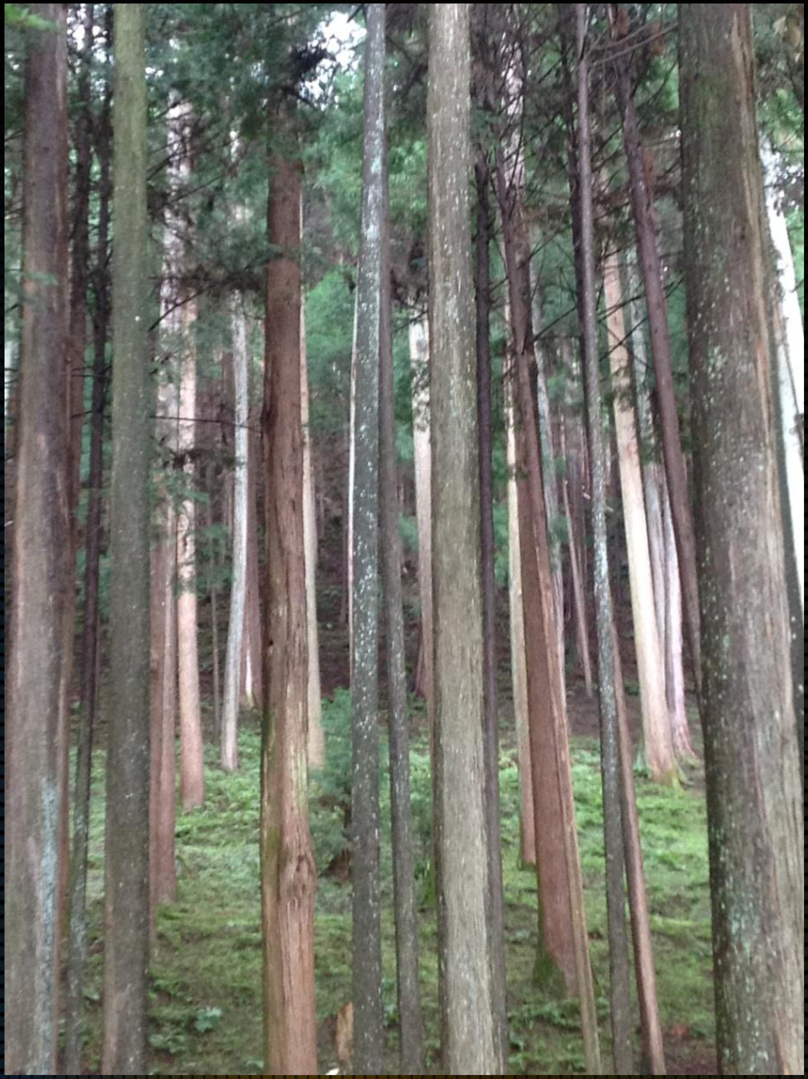
Whether the impacted system is a natural system or an industrial system, the EHS research must start from a systems view to justify how and where adverse impacts could occur. Models and statistical techniques are used to identify priorities for study within systems.

5. Fundamental tools need to be developed.

Monitoring instrumentation, sensors, models, and metrology are but a few of the necessary tools for measuring nanomaterials' impact on the environment, health or safety. Fundamental works on standards for measurements are also needed.

6. Nano EHS research informs and enables responsible development and sustainability.

There is a great opportunity for partnership with sustainability programs in the nano EHS area, particularly in applications that improve EHS. For example, nanomaterials and membranes can enhance water treatment or contribute to efficient energy technologies and slow down greenhouse gas production and resource depletion.



Questions?

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“When you fully understand the situation, it is worse than you think”

Barry Commoner

Don’t forget the basics

Commoner’s Laws of Ecology

- You can’t throw anything away. Nothing ever goes away
- Everything is connected to everything else. You can’t do just one thing. No action is without side effects.
- Nature knows best
- There is no such thing as a free lunch.
- If you don’t put something in the ecology, it’s not there

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.

RAMM 1: Incorporate relevant risk characterization information, hazard identification, exposure science, and risk modeling and methods into the safety evaluation of nanomaterials

RAMM 2: Understand, characterize, and control workplace exposures to nanomaterials

RAMM 3: Integrate life cycle considerations into risk assessment and risk management

RAMM 4 Integrate risk assessment into decision-making frameworks for risk management

RAMM 5 Integrate and standardize risk communication within the risk management framework