

Terry L. Medley, Global Director, Corporate Regulatory Affairs, DuPont University of Massachusetts Nano & Society Workshop September 24, 2010

National Nanotechnology Initiative (NNI)



- Established in fiscal year 2001 to coordinate Federal nanotechnology research and development
- Provides a vision of the long-term opportunities and benefits of nanotechnology.
- ◆ Serves as the central point of communication—cooperation and collaboration for all Federal agencies engaged in Nanotechnology research, bringing together the expertise needed to advance this broad and complex field.
- Consists of the individual and cooperative nanotechnology-related activities of 25
 Federal agencies with a range of research and regulatory roles and responsibilities.
- Creates a framework for a comprehensive nanotechnology R&D program by establishing shared goals, priorities, strategies, and provides avenues for each individual agency to leverage the resources of all participating agencies.

NNI Program Component Areas

- Fundamental Nanoscale Phenomena and Processes
- Nanomaterials
- Nanoscale Devices and Systems
- Instrumentation, Research, Metrology, and Standards for Nanotechnology
- Nanomanufacturing
- Major Research Facilities and Instrumentation Acquisition
- Environment, Health, and Safety
- Education and Societal Dimensions

NNI Nanotechnology Signature Initiatives

"To accelerate nanotechnology development in support of the President's priorities and innovation strategy, NNI member agencies have identified areas ripe for significant advances through close and targeted program-level interagency collaboration. The resulting Nanotechnology Signature Initiatives are summarized as follows:"

Nanotechnology Applications for Solar Energy

Sustainable Nanomanufacturing

Nanoelectronics for 2020 and Beyond

The National Nanotechnology Initiative Research and Development Leading to a Revolution in Technology and Industry Supplement to the President's FY 2011 Budget

NNI Expenditures

- ◆ Proposed NNI budget for Fiscal Year (FY) 2011 \$1.76 billion
- ◆ Cumulative investment since inception of NNI in FY 2001 \$14 Billion
- ◆ NNI is increasing its investments aimed at implementing the Government's strategy for nanotechnology – related environmental, health and safety (EHS) research
- ◆ Cumulative investments in EHS research since 2005 over \$480 million

President's Council of Advisors on Science and Technology (PCAST)

- ◆ An advisory group of the nation's leading scientists and engineers, appointed by President to augment the science and technology advice available to him from within the White House, cabinet departments and other Federal agencies
- ◆ Consulted about and often makes policy recommendations concerning the full range of issues where understandings from the domain of science, technology, and innovation bear potentially on the policy choices before the President
- ◆ Administered by the White House Office of Science and Technology Policy (OSTP)

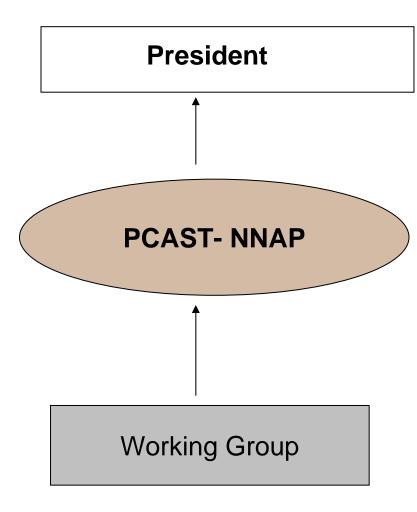
PCAST Studies

- ◆ PCAST provides advice to President on scientific and technological issues of highest importance concerning security, welfare, and health of nation
- ◆ In situations that require integrative perspective across agencies and departments, independent perspective or additional expert capacity, PCAST will:
 - Establish ad hoc working groups of experts, co-chaired by PCAST members, to provide information and advice directly to the PCAST
 - PCAST will then issue a report with its findings and recommendations based on the working group analysis
 - Goal is to complete most studies in 3-6 months or more quickly in response to Administration needs

National Nanotechnology Advisory Panel (NNAP)

- Created by U.S. Congress in the 21st Century Nanotechnology Research and Development Act which required the President to establish or designate an NNAP to review the Federal nanotechnology research and development program
- The act calls for a review of the National Nanotechnology Initiative (NNI) and report its findings to the President
- The act calls for the NNAP to report on its assessments and to make recommendations for ways to improve the program at least every two years
- In 2004, PCAST was formally designated to act as the NNAP

Role of Working Group in NNI Review



Working Group Members

- Are not members of Federal Advisory Committees
- Convened to gather information or conduct research, conduct analysis, or draft position papers
- Offer perspectives and information as individuals
- Do not work to develop consensus recommendations
- Attend teleconferences and in-person meetings
- Contribute substantively to writing of study report

Questions Mandated by Congress Under the 21st Century Nanotechnology Research and Development Act

- Trends and developments in nanotechnology science and engineering
- Progress made in implementing the Program
- The need to revise the Program
- ◆ The balance among the components of the Program, including funding levels for the program component areas
- Whether the program component areas, priorities, and technical goals developed by the Council are helping to maintain United States leadership in nanotechnology
- The management, coordination, implementation, and activities of the Program
- Whether societal, ethical, legal, environmental, and workforce concerns are adequately addressed by the Program



PCAST NNI Report Findings

Report issued March 25, 2010

http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-nano-report.pdf

- Initiative is highly effective
- ◆ Calls for greater emphasis on commercialization and strategic coordination of health and safety research
- ◆ The U.S. invests more money in nanotechnology R&D than any other country but other nations are closing the gap.
- ◆ U.S. Leadership position in nanotechnology is at risk
- Better coordination of the approach to identifying EHS risks associated with nanotechnology
- Increase NNI investment in nanomanufacturing
- Strengthen the National Nanotechnology Coordinating office

PCAST NNI Report Program Management Recommendations

- Strengthen the National Nanotechnology Coordination Office (NNCO)
- ◆ Focus on Commercialization
- Signature Initiatives
- ◆ Education
- Societal Impacts

PCAST NNI Report Nanotechnology Outcome Recommendations

- Need a greater emphasis on manufacturing and commercialization while maintaining or expanding the level of basic research funding in nanotechnology
- Ensure that NNI programs increase job creation in the U.S.
- Workforce retention of scientific and engineering talent trained in the U.S.
- Moving nanotechnology to the market by clarifying the development pathway and increasing emphasis on transitioning nanotechnology to commercialization

PCAST NNI Report - Environmental, Health and Safety Recommendations

- ◆ Risk identification development of clear principles to support the identification
 - of plausible risks associated with the products of nanotechnology
- Strategic planning development and implementation of a cross-agency strategic plan that links EHS research activities with knowledge gaps and decision-making needs within government and industry
- Information resources development of information resources on crosscutting nanotechnology EHS issues that are relevant to businesses, health and safety professionals, researchers, and consumers
- ◆ Organizational changes initiate administrative changes and communication mechanisms as needed to enable the NNI to better embrace the EHS issues associated with nanotechnology research, development and commercialization

Personal Reflections on NNI EHS Considerations

- Framing the EHS issue Proactively addressing nanotech EHS
- Increased stakeholder coordination and collaboration
- Leadership and accountability
- Targeted funding
- Research to support decision making

NNI Vision for the Next Ten Years

- Basic research will remain a critical component of the research portfolio
- While basic research continues, there will be increasing focus on integration of components and processes that lead to commercialization
- The NNI will play a key role in several Signature Initiatives leveraging targeted interagency efforts to address grand challenges
- The balance of NNI programs will continue to evolve

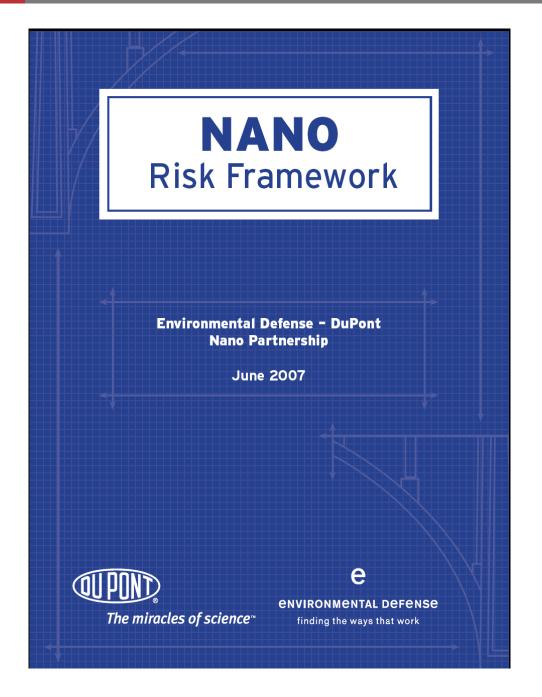
"NNI has been widely recognized as a leading model of interagency coordination and collaboration"

John Holdren, Director of OSTP February 10, 2010

"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"

National Research Council, 2009

Review of the Federal Strategy for Nanotechnology-Related Environmental, Health, and Safety Research National Academy of Sciences, Washington, D.C., Page 3



www.NanoRiskFramework.com

Nano Risk Framework

<u>Objective:</u> To develop and deliver a systematic and disciplined six-step process for identifying, managing, and reducing potential environmental safety and health risks of engineered nanomaterials across all stages of a product's lifecycle.

<u>Scope:</u> Offers guidance on the key questions an organization should consider in developing applications of nanomaterials, and on the information needed to make sound risk evaluations and risk-management decisions.

<u>Audience:</u> Primary audiences are organizations such as companies and public and private research institutions that are actively working with nanomaterials and developing associated products and other applications. Framework can also be usefut to other stakeholders, such as government officials, academia, financial institutions, and nongovernmental public-interest organizations.

Goal: Comprehensive, flexible, practical

Comprehensive, Flexible and Practical

Comprehensive

Lifecycle Approach

Base Sets (Properties, Hazards, Exposure)

Cross-Functional Review

Review and Adapt

Flexible

Appropriate to Stage of Development

Data Generation

Conservative Assumptions

Appropriate Bridging

Expert Judgment

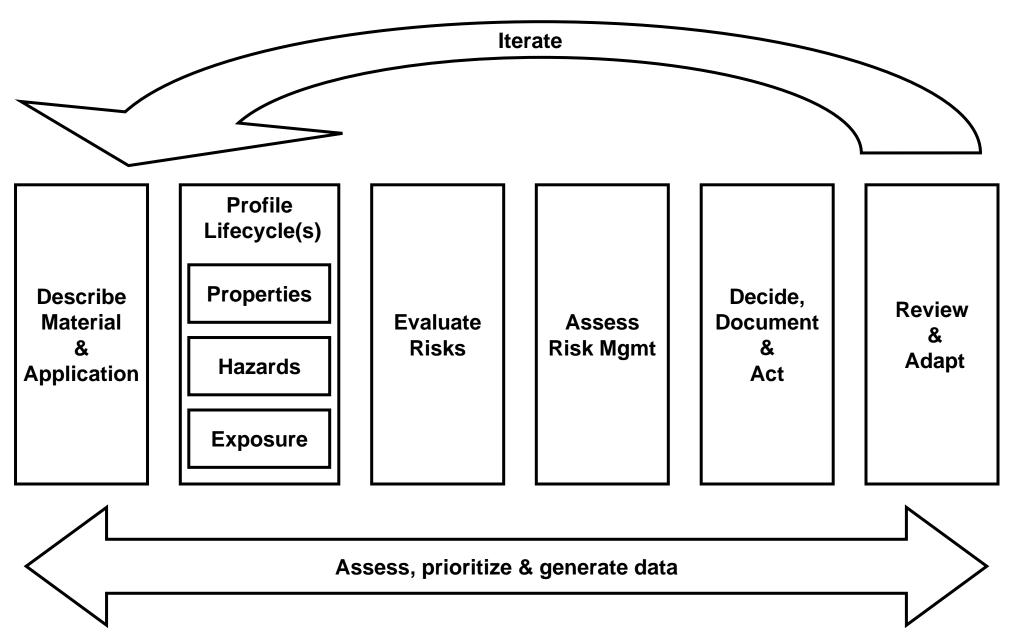
Practical

Familiar risk assessment paradigm

Typical development process

Complements product stewardship

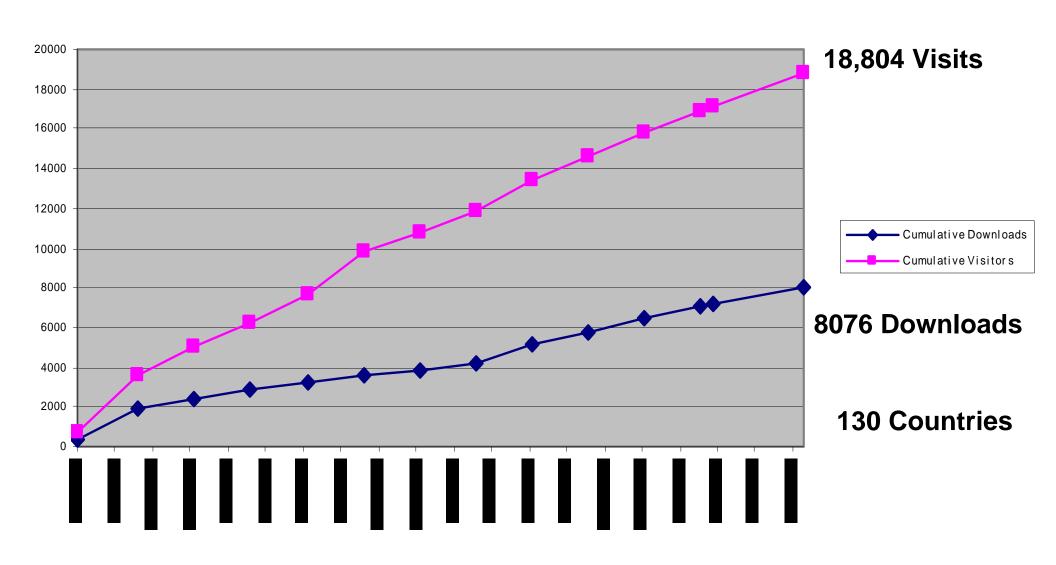
Environmental Defense – DuPont Nano Risk Framework



www.NanoRiskFramework.com

Nano Risk Framework – Site Visitors and Downloads

(As of September 9, 2010)



Conclusion

Broad scale collaborative efforts are needed to advance science and risk-based policy for responsible nanotechnology development.