Role of Standards in the U.S. National Nanotechnology Initiative

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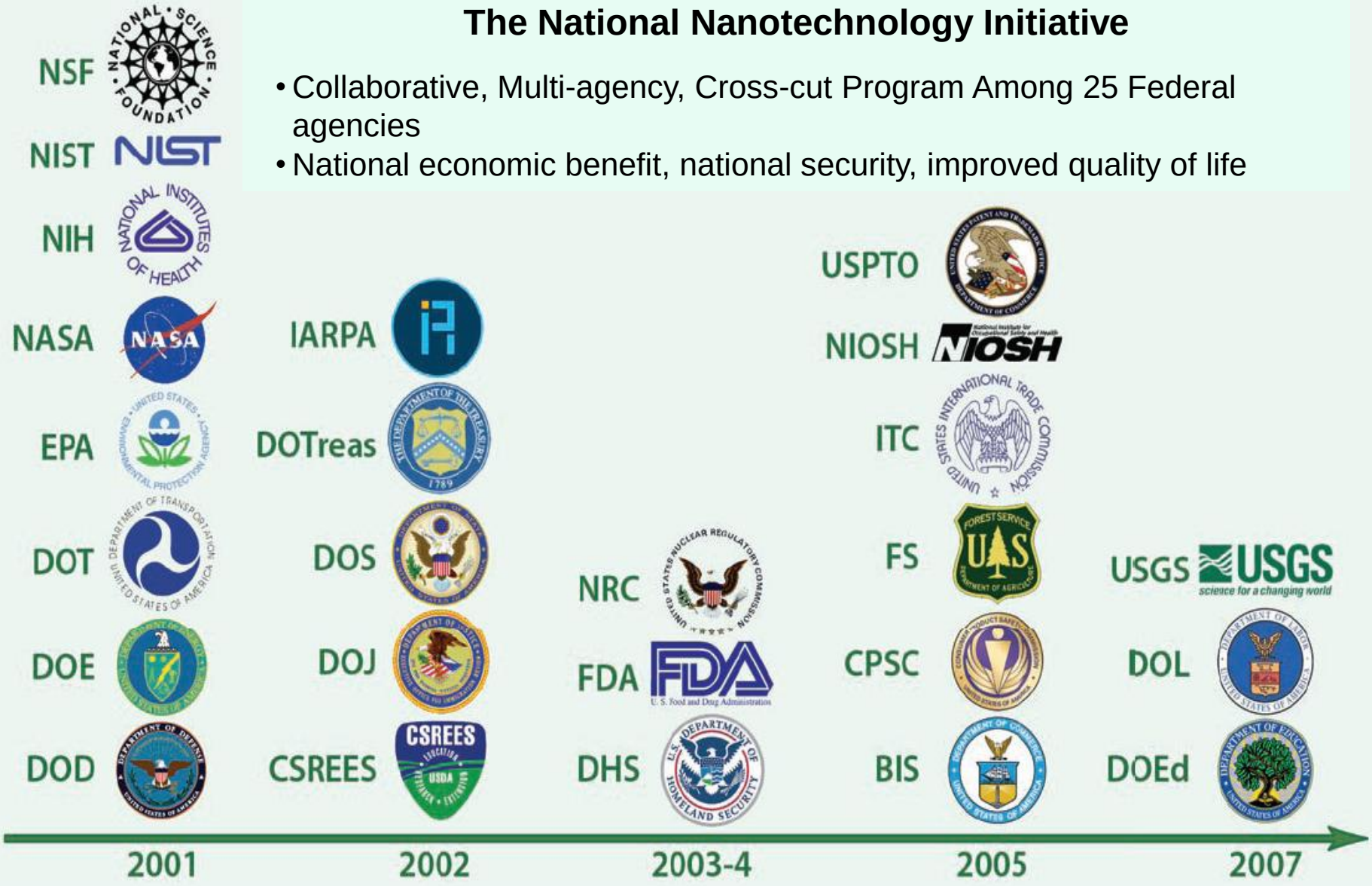
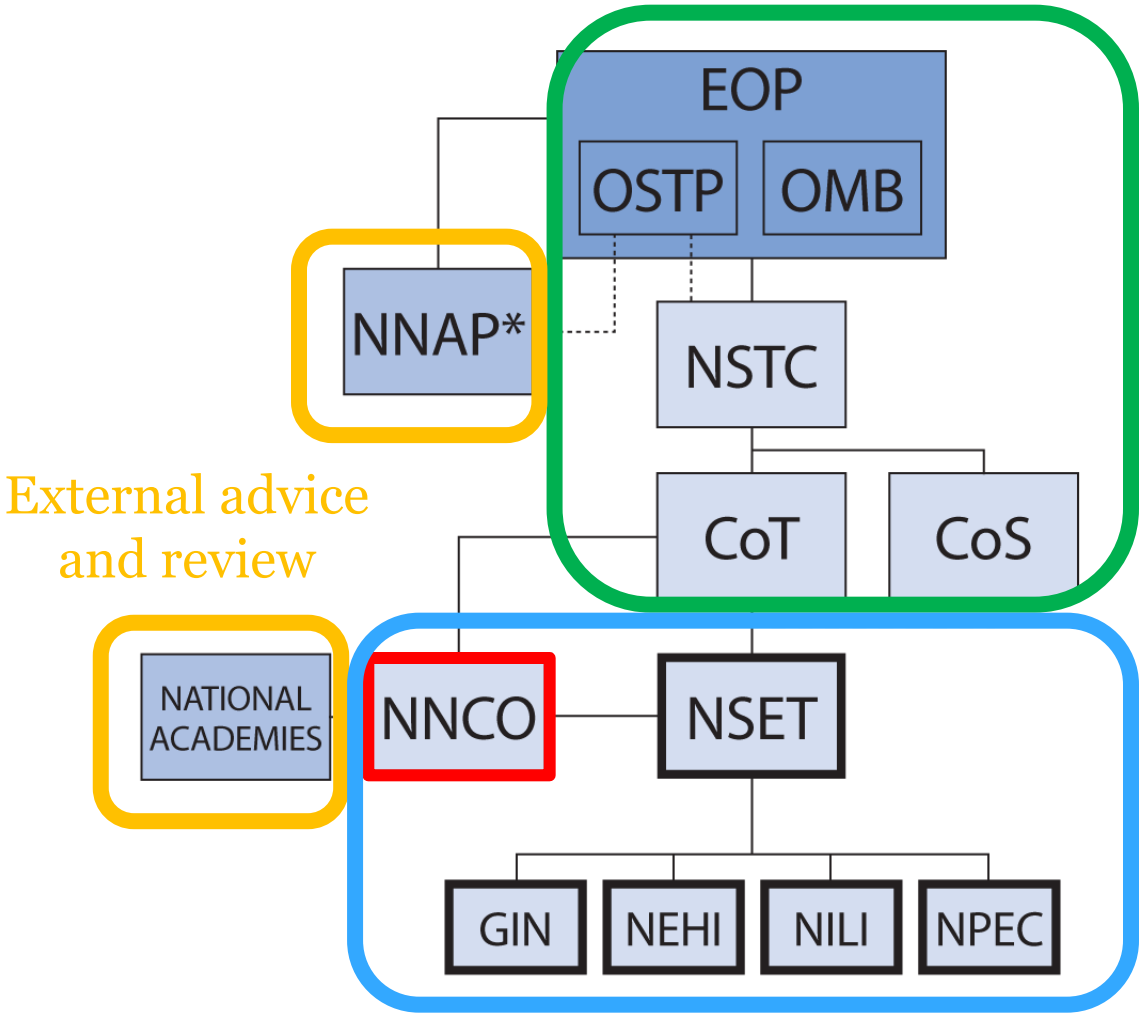
The National Nanotechnology Initiative

- Collaborative, Multi-agency, Cross-cut Program Among 25 Federal agencies
- National economic benefit, national security, improved quality of life

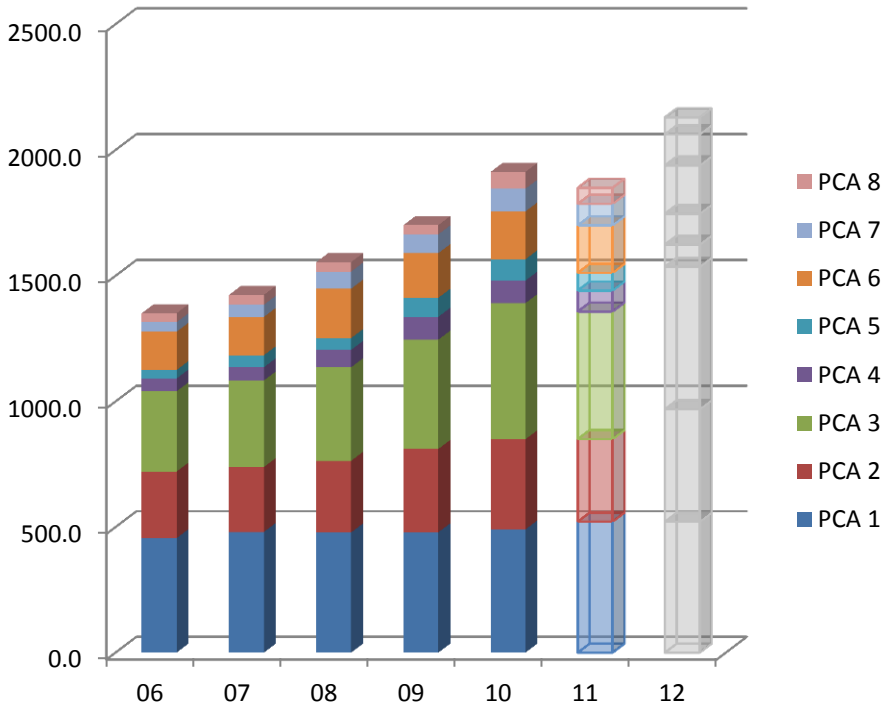


NNI Exists in a Complex Organizational Ecosystem

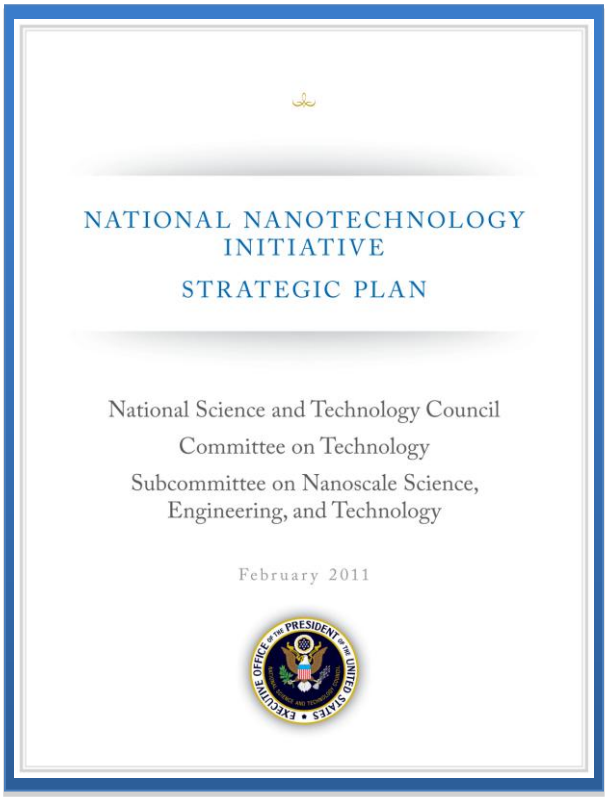


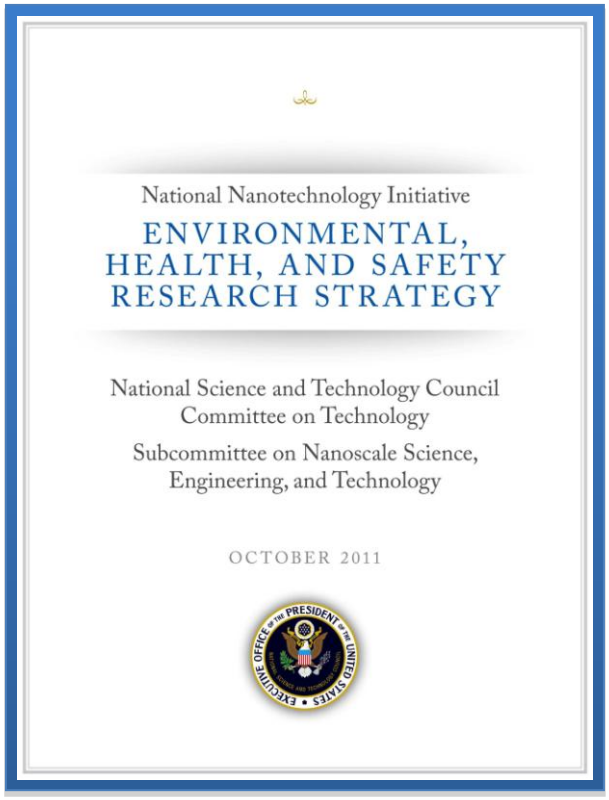
Standards: Integral to the NNI Scientific Program

1. Fundamental nanoscale phenomena and processes
2. Nanomaterials
3. Nanoscale devices and systems
4. ***Instrumentation research, metrology, and standards for nanotechnology***
5. Nanomanufacturing
6. Major research facilities and instrumentation acquisition
7. Environment, health, and safety
8. Education and societal dimensions



Standards: Integral to the NNI Strategic Vision





Standards: Identified as a Recurring Theme in the 2011 NNI Strategic Plan

Goal 2: Technology Transfer

Objectives

2.1 Develop robust, scalable nanomanufacturing methods necessary to facilitate commercialization...

Nanomanufacturing R&D involves a fundamental understanding of the manufacturing process, including the development and application of measurement and characterization techniques, reference materials, and *standards.*

2.5.2. Enhancing interagency communication and collaboration towards *assuring safe nanotechnology-enabled products* for domestic and international consumers, through activities such as developing documentary standards.

For example, ongoing interagency support of development of U.S. and international documentary standards will facilitate such innovation and product development.

Standards: A Recurring Theme in the 2011 NNI Strategic Plan

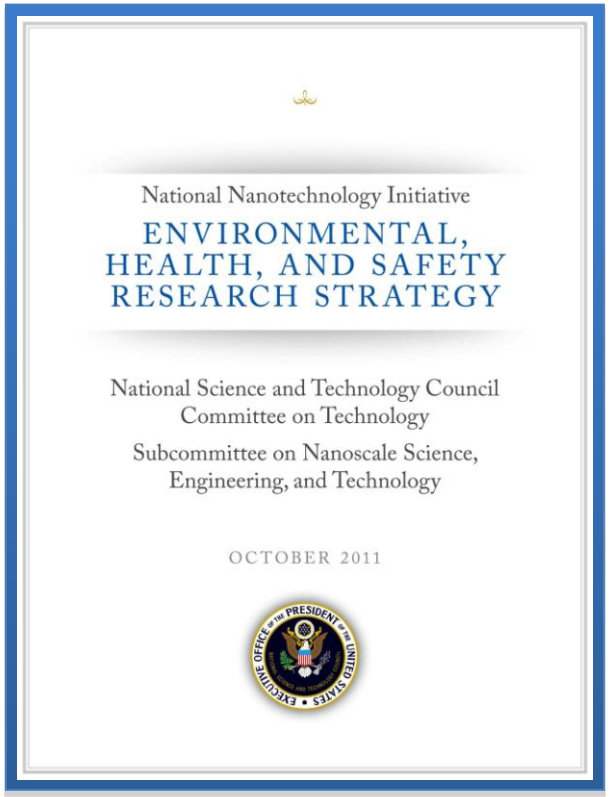
Goal 4: Responsible Development of Nanotechnology

Objectives

4.1 Incorporate safety evaluation of nanomaterials into the product life cycle by:

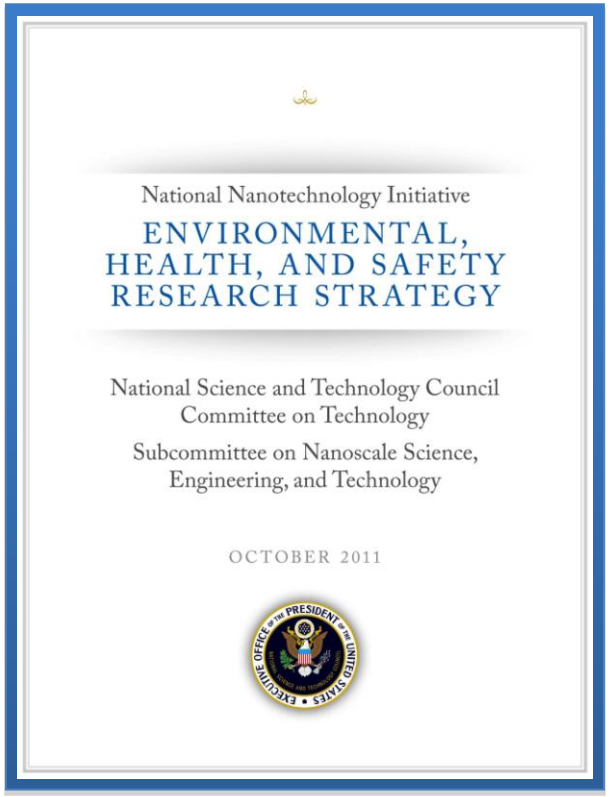
- Developing and applying:
  - *Measurement and screening tools (defined as protocols, standards*, models, data, and instruments) to assess the physico-chemical properties of nanomaterials and their biological effects in the environment and on human health and to quantify exposure across the nanotechnology product life cycle.
  - Establishing guidance, *standards*, or other methods to *formulate nanotechnology-related regulatory approaches* for domestic and global researchers, manufacturers, distributors, and users of nanotechnology-enabled products to ensure the protection of public health and the environment.

Standards: Integral to the NNI Environmental, Health, and Safety Research Strategy



Standards as used in this document refers to internationally recognized reference materials and certified reference materials, developed by organizations such as the National Institute for Standards and Technology (NIST), and *consensus-based documentary standards published by national and international standards development organizations such as the International Standards Organization (ISO) and ASTM International*.

Standards: Integral to the NNI Environmental, Health, and Safety Research



Six Core Research Areas

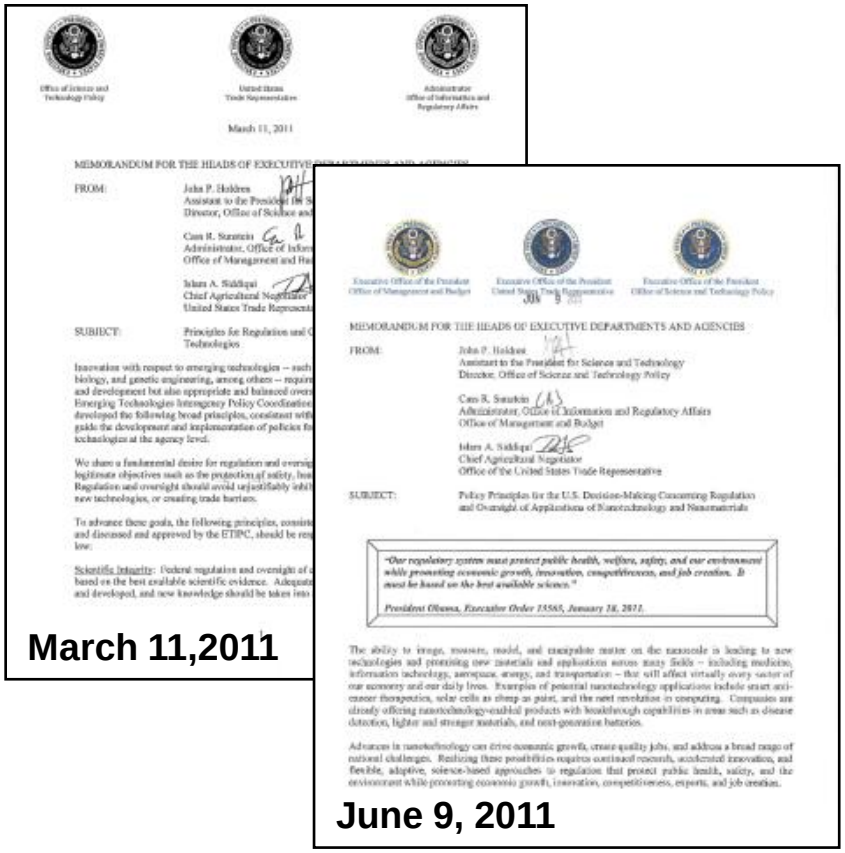
- ***Nanomaterial Measurement Infrastructure***
- Human Exposure Assessment
- Human Health
- Environment
- Risk Assessment and Risk Management Methods
- Informatics and Modeling for NanoEHS Research

Targeting and Accelerating Research

Critical Elements:

- Prioritize nanomaterials for study
- ***Establish standard measurements, terminology, nomenclature, assay methods***
- Develop informatics and predictive modeling tools
- Stratify knowledge for risk assessment
- Partner to achieve the NNI EHS research goals, including globally

Emerging Technologies Interagency Policy Coordination Committee (ETIPC)



March 11,2011

June 9, 2011

- **Broad principles:** guide development and implementation of policies for oversight across the US government
- **Two memos**: Affirm that rulemaking should be evidence-based, and commensurate with risk; nanomaterials should not as a class be presumed either benign or harmful

Standards: A Recurring Theme in the 2011 NNI Strategic Vision and Implementation Plans

Standards are critical for

- Establishing the common vocabulary and intellectual structure for scientific, commercial, and regulatory purposes
- Increasing certainty for governments and in the global marketplace

Implementing the 2011 Strategic Plan: The Path Forward

"Furthermore, NNI member agencies will *continue to participate in international* ***standards organizations and multilateral fora*** *to address policy-relevant nanotechnology issues and to promote international cooperation in aspects of nanotechnology that might affect human health and environmental safety."*

Thank you!