

UNITED STATES

Highlights

- EPA publicly released a White Paper on Nanotechnology, 15 February 2007
- NIOSH released “Progress Toward Safe Nanotechnology in the Workplace,” February 2007
- NSET/NEHI held a public meeting on an EHS research strategy, 4 January 2007
- EPA held a scientific peer consultation on risk management practices, 19-20 October 2007

1. Any national regulatory developments on human health and environmental safety including recommendations or discussions related to adapting existing regulatory systems or the drafting of laws/ regulations/ guidance materials;

The Nanoscale Science, Engineering, and Technology (NSET) Subcommittee's Nanotechnology Environmental and Health Implications (NEHI) Working Group provides for exchange of information among agencies that support nanotechnology research and those responsible for regulation of nanotechnology-related products. The Working Group also seeks to facilitate research and other activities that support responsible development of nanotechnology.

The NSET Subcommittee member agencies are active participants in national and international standards development activities, including those of ISO Technical Committee on Nanotechnologies (TC 229), American National Standards Institute- Nanotechnology Standards Panel and ASTM International's Nanotechnology Committee (E56).

The Food and Drug Administration (FDA) has initiated an internal Task Force on Nanotechnology that will, among other considerations, examine regulatory approaches to manufactured nanomaterials.

The Environmental Protection Agency (EPA) is developing guidance under the Toxic Substances Control Act (TSCA) in order for manufacturers of nanoscale materials to make the distinction between “new” and “existing” chemicals on the TSCA Inventory.

EPA has received and reviewed a number of new chemical notices for potential nanoscale materials under TSCA. EPA has permitted manufacture of these nanoscale materials under limited conditions.

2. Developments related to voluntary or stewardship schemes;

For new products using nanotechnology, USG agencies (including EPA, NIOSH, and FDA) have encouraged manufacturers to enter into discussions with the appropriate review authority early in the product development process, prior to submitting an application or notice for regulatory decision, so that potential issues of regulatory uncertainty or information needs can be identified and where possible addressed. These discussions are ongoing for a number of products that use manufactured nanomaterials.

EPA has established an Agency-wide workgroup to develop a stewardship program under TSCA that could complement EPA's regulatory authorities and to ensure the responsible development and commercial use of nanoscale materials. A key goal of the Program is to assemble and encourage the development of scientific information on hazards, exposure, risks, and risk mitigation practices to provide a sound scientific foundation to inform industry and EPA.

3. Information on any risk assessment decisions;

The National Institute for Occupational Safety and Health (NIOSH) has drafted and released for public review Current Intelligence Bulletin: Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide (<http://www.cdc.gov/niosh/review/public/tio2/>).

EPA has assessed a number of new chemical notices for potential nanoscale materials under TSCA.

4. Information on any developments related to good practice documents;

In August NIOSH released a second edition of its best practices document for working with nanomaterials “Approaches to Safe Nanotechnology: An Information Exchange with NIOSH” (<http://www.cdc.gov/niosh/topics/nanotech/safenano/>).

5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials;

The NSET Subcommittee’s NEHI Working Group has released a document entitled “Environmental, Health, and Safety Research Needs of Engineered Nanoscale Materials” that identifies EHS research needed to enable risk assessment and risk management of nanoscale materials (http://www.nano.gov/NNI_EHS_research_needs.pdf). The NEHI is performing a gap analysis and developing a prioritized research strategy to address EHS research needs.

The U.S. National Institutes of Health (NIH), U.S. Department of Health and Human Services, established a “Health Implications Working Group” to consider unintentional exposures to manufactured nanomaterials and intentional exposures to nanodiagnosics and therapeutics, as part of a larger Tran-NIH Nanotechnology Task Force. Currently, several million dollars of the NIH annual total expenditure of about \$170 million on nanotechnology research is devoted to assessing health affects of manufactured nanotechnologies (see Annex A).

The U.S. National Institutes of Health (NIH), with co-sponsorship with other U.S. agencies (NIOSH and EPA), announced on 29 September 2006 a request for applications (RFA) on a research program on the physico-chemical properties of manufactured nanotechnologies. Further information on this RFA is at: <http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-06-008.html>. The research that will be supported seeks to characterize the physical and chemical properties of nanomaterials and determine the interaction of these properties with a relevant biological system at the cellular, molecular and systemic levels. NIH’s National Institute for Environmental Health Sciences (NIEHS) is leading this multi-institute/multiagency program to investigate the effects of manufactured nanotechnologies on human health. NIH intends to broadly share research results.

Also under the aegis of NIH/NIEHS, and in collaboration with the U.S. Food and Drug Administration and the Centers for Disease Control.s (CDC) National Institute for Occupational Health and Safety (NIOSH), the National Toxicology Program.s Nanotechnology Safety Initiative is undertaking toxicological evaluations of specific engineered nanoscale materials. The U.S. Consumer Product Safety Commission (CPSC), EPA and the U.S. Occupational Safety and Health Administration (OSHA) are also active participants in this initiative.

EPA.s Science Policy Council released its “Nanotechnology White Paper” (EPA/100/B-07/001, February 15, 2007) (<http://www.epa.gov/osa/nanotech.htm>) describing the science issues that EPA is addressing now, and will address in the future, regarding the potential environmental benefits and impacts of nanotechnology.

FDA has initiated research, in collaboration with NIST, to characterize certain particles used widely in commerce that are also used in drug products.

EPA is developing a nanotechnology research framework for 2007-2012. In fiscal years 2007 and 2008, EPA will focus on the following high-priority areas: environmental fate, transport, transformation, and exposure; and monitoring and detection methods. Resulting data will be used to inform and develop effects and exposure assessment methods and identify important points of releases for potential management.

NIOSH Nanotechnology Research program (<http://www.cdc.gov/niosh/topics/nanotech/research.html>) addresses health hazard and safety aspects of nanotechnology in occupational settings.

In February 2007, NIOSH's Nanotechnology Research Center (NCTR) released the nanotechnology progress report "Progress Toward Safe Nanotechnology in the Workplace" (NIOSH Publication No. 2007-123) available on-line at <http://www.cdc.gov/niosh/docs/2007-123/>. This new report details the advancements made by the NIOSH, through the NCTR, in advancing the scientific knowledge in understanding the occupational safety and health implications of engineered nanoparticles. The document also identifies 10 critical topic areas important for understanding the potential work-related health risks of nanotechnology products and developing and disseminating recommendations for mitigating these risks; it further suggests potential areas where future research could expand this knowledge.

NIOSH's Interdisciplinary Field Team of nanotechnology researchers partners with nanotechnology companies to assess exposures to nanomaterials in the workplace and the effectiveness of engineering controls and personal protective equipment in reducing such exposures.

EPA, the National Science Foundation (NSF), NIOSH, and NIH plan an expanded joint extramural research program addressing potential EHS implications of nanotechnology for human health and the environment.

NIOSH is supporting focused research on nanotechnology issues associated with worker safety and health as outlined in the NIOSH Nanotechnology Strategic Plan (available at www.cdc.gov/niosh/topics/nanotech/strat_plan.html) through intramural and extramural programs and international collaborations.

The NIH National Cancer Institute's Alliance for Nanotechnology Characterization Lab is developing a characterization cascade for use in preclinical evaluations of nanomaterials intended for cancer therapeutics.

NSF supports basic research directed at environmental, health, and safety impacts of nanotechnology development. NSF has funded hundreds of grants for such study to individual researchers, environmental centers and interdisciplinary groups.

See Annex A for a Chart summarizing research programs in the USG directed at environmental, health, and safety impacts of nanotech.

6. Information on any public/ stakeholder consultation.

The NSET Subcommittee sponsored a workshop in May 2006, with support from the EPA, on Public Participation in Nanotechnology. On January 4, 2007, NSET and NEHI held a public meeting to receive comments on the document "Environmental, Health, and Safety Research Needs of Engineered Nanoscale Materials" (described in Section 5) and next steps in developing an EHS research strategy. Additional public comments were collected through the end of January. The NEHI Working group is considering this input as part of its effort to further prioritize the needs discussed in the document.

EPA's Office of Solid Waste and Emergency Response hosted a symposium on July 12 -13, 2006 about nanotechnology and its influence in waste management practices.

FDA held a public meeting October 10, 2006 to consult with the public about the kinds of new

nanotechnology material products under development and whether there are new or emerging scientific issues that should be brought to FDA's attention, including issues related to the safety of nanotechnology materials.

EPA's Office of Pollution Prevention and Toxics (OPPT) is held a scientific peer consultation October 19-20, 2007 on risk management practices pertaining to nanoscale materials to support development of the stewardship program it is considering. A second peer consultation on materials characterization is being planned for summer, 2007 in conjunction with a public meeting to receive input on the stewardship program.

OPPT is also planning a pollution prevention conference for summer 2007 to provide a forum to exchange information and ideas on the potential environmental and pollution prevention benefits of innovative nanotechnologies and nanomaterials.

NIOSH invites public comments on its nanotechnology-related documents posted on NIOSH

nanotechnology web-page (<http://www.cdc.gov/niosh/topics/nanotech/>), such as .Approaches to Safe Nanotechnology: An Information Exchange with NIOSH.

(<http://www.cdc.gov/niosh/topics/nanotech/safenano/>).

NIOSH sponsored a workshop on nanotechnology and occupational safety and health hosted by the RAND Corporation on October 17, 2005. The workshop focused on policy and planning issues (as opposed to scientific issues) that are key to understanding the options available to NIOSH in formulating and implementing its strategic objectives to protect the safety and health of workers exposed to nanoscale materials (http://www.rand.org/pubs/conf_proceedings/CF227/).

Annex A

Research programs directed at environmental, health, and safety (EHS) impacts of nanotechnology development, and risk assessment of such impacts are a growing component of the U.S. National Nanotechnology Initiative. R&D leading to a detailed understanding of the health and safety impacts of nanotechnology for researchers, workers, consumers, and the public is a strategic priority within the NNI's Societal Dimensions Program Component Area, and is reported by agency in the table below. Note that the funding indicated in this table does not include R&D within other NNI Program Component Areas that is highly relevant to EHS implications but not primarily directed at those implications, such as fundamental studies of the interactions between engineered nanoscale materials and biological systems, development of improved instrumentation for measuring the properties of engineered nanoscale materials, or applications oriented work that also produces information related to potential toxicity of nanoscale or nanostructured materials.

U.S. National Nanotechnology Initiative
 Budget for Environmental, Health, and Safety R&D, 2006-2008
 (in millions of U.S. Dollars)

	2006 Actual	2007 Estimate*	2008 Proposed
NSF	21.0	25.7	28.8
DOD	1.0	1.0	1.0
DOE	0.5	0.0	3.0
DHHS (NIH)	5.2	4.6	5.7
DOC (NIST)	2.4	1.8	5.8
NASA	0.0	0.0	0.0
EPA	3.7	8.0	9.6
USDA (CSREES)	0.1	0.1	0.1
DHHS (NIOSH)	3.8	4.6	4.6
USDA/FS	0.0	0.0	0.0
DHS	0.0	0.0	0.0
DOJ	0.0	0.0	0.0
DOT (FHWA)	0.0	0.0	0.0
TOTAL	37.7	45.8	58.6

* The 2007 Estimates reflect 2007 Budget levels, except for the Departments of Defense and Homeland Security, which are the enacted levels. Several agencies have updated their 2007 Budget levels since the release of the 2007 NNI Budget Supplement.