Questionnaire
International Dialogue on Responsible R&D of Nanotechnology

Reply by:
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1. Nanotechnology R&D programs in USA

The National Nanotechnology Initiative (NNI) is a long-term research and development program that currently coordinates 19 federal agencies. The investment is about $960 million in the fiscal year 2004 (beginning October 1, 2003). The NNI was established in October 2000, and has been coordinated by the Nanoscale Science, Engineering and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC). The main goals of NNI are: to extend the frontiers of nanoscale science and engineering and to facilitate the development of beneficial applications of nanotechnology; to establish a balanced and flexible infrastructure, including a skilled workforce; and to address the societal implications of nanotechnology. The Federal nanotechnology investment per agency since the beginning of NNI is given in Table 1. The annual implementation plan for fiscal year (FY) 2004 is balanced between fundamental research, nine Grand Challenges, centers of excellence and networks, infrastructure, and societal and educational implications of nanotechnology.

In addition, state, local, and private organizations have regional nanotechnology investments in infrastructure and education, as well as support for business. Their contribution is estimated in fiscal year 2003 to be about half of the federal investment in NNI.

Table 1. Contribution of key Federal agencies to NNI investment in $ million/year
(each Fiscal Year (FY) begins on October 1 of the previous year and ends on September 30 of the respective year)

Federal Department or Agency	**FY 2001 Actual ($M)**	**FY 2002 Actual ($M)**	**FY 2003 Actual ($M)**	**FY 2004 Current Plan ($M)**	**FY 2005 *Request* ($M)**
National Science Foundation (NSF)	150	204	221	254	305
Department of Defense (DOD)	125	224	322	315	276
Department of Energy (DOE)	88	89	134	203	211
National Institutes of Health (NIH)	40	59	78	80	89
National Institute of Standards and technology (NIST)	33	77	64	63	35
National Aeronautics and Space Administration (NASA)	22	35	36	37	53
Environmental Protection Agency (EPA)	6	6	5	4	5
Homeland Security (TSA)	-	2	1	1	1
Department of Agriculture (USDA)	1.5	0	1	1	5
Department of Justice (DOJ)	1.4	1	1	2	1
TOTAL (% of FY 2000 investment of $270M)	**465** (172%)	**697** (258%)	**862** (319%)	**960** (356%)	**982** (364%)

The NNI definition of nanotechnology includes besides the size range between about 1 and 100 nm three other conditions: exploiting specific phenomena and functions that do not extrapolate outside of the nanoscale domain, ability to measure and change the structure at the nanoscale for a given purpose, and ability to integrate under control the nanostructures with larger structures. This definition encourages new developments in the field that were not possible without the new tools and understanding. The interagency nanotechnology group established in November 1996 organized an international benchmarking in 1997-1999. The result of that activity was the estimation that the worldwide marked for products with nanotechnology components will reach $1 trillion by 2015. The NNI was proposed in March 1999 and was funded by US Congress beginning with fiscal year 2001. The international context is illustrated in Table 2.

Table 2. Estimated government nanotechnology R&D expenditures in 1997-2004 (in $ millions/year). Explanatory notes: "W. Europe" includes countries in EU (15) and Switzerland; the rate of exchange $1 = 1.1 Euro until 2002; = 0.9 Euro in 2003, and = 0.8 Euro in 2004; Japan rate of exchange $1 = 120 yen until 2002, = 110 yen in 2003, = 105 yen in 2004; "Others" include Australia, Canada, China, Eastern Europe, FSU, Israel, Korea, Singapore, Taiwan and other countries with nanotechnology R&D; ( )* A financial year begins in USA on October 1 of the previous calendar year, six months before in most other countries. ( )** denotes the actual budget recorded at the end of the respective fiscal year; (***) – preliminary data. Estimates use the nanotechnology definition as defined in the NNI (this definition does not include MEMS, microelectronics or general research on materials), and include the publicly reported government spending.

Region	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004*** **
W. Europe	126	151	179	200	~ 225	~ 400	~ 650	~ 900
Japan	120	135	157	245	~ 465	~ 720	~ 800	~ 900
USA*	116**	190**	255**	270**	465**	697**	862**	~ 960
Others	70	83	96	110	~ 380	~ 550	~ 800	~ 900
Total (% of 1997)	**432** (100%)	**559** (129%)	**687** (159%)	**825** (191%)	**1535** (355%)	**2367** (547%)	**3112** (720%)	**3660** (847%)

More than 10% of the NNI budget addresses issues, including basic research, applications, and implications, related to environment, health, and safety. These efforts are funded by several agencies, including NSF, EPA, NIH, DOE, NIOSH (National Institute of Occupational Safety and Health), USDA, and DOD. NSF has a focus on nanoscale processes in the environment and on societal implications in its programs since August 2000. NSF will award about $16 million in 2004 for grants with primary focus on environment and nanotechnology, and additionally about the same amount for multidisciplinary projects including the environmental issues. A list of 100 grants, including abstracts, is available on http://www.nsf.gov/home/crssprgm/nano/nni01_03_env.htm. The support for social, ethical and economic implications is an area of growing interest. Information on two grants of over $1 million each with a focus on the interaction with the public and the creation of databases is available on http://www.nsf.gov/od/lpa/news/03/pr0389.htm. NSF's Nanoscale Science and Engineering Centers (NSEC) and the National Nanotechnology Infrastructure Network (NNIN) are required to have research and education components addressing the environmental and societal implications. Three federal agencies now have focused efforts to study the potential risks of exposure to nanomaterials: the National Toxicology Program (NTP) - a multiagency effort established in the Department of Health and Human Services, NIOSH, and EPA. The NTP studies will focus on the potential toxicity of nanomaterials, beginning with titanium dioxide, several types of quantum dots, and fullerenes. The first studies will be of the distribution

and uptake by the skin of titanium dioxide, fullerenes and quantum dots. The NTP is also considering conducting inhalation studies of fullerenes, and is exploring ways to assist NIOSH in the development of inhalation exposure capability for carbon nanotubes. The NIOSH provides research, information, education and training in the field of occupational safety and health. In 2004, NIOSH initiated several research projects focused on nanotechnology, including a five-year program to assess the toxicity of ultrafine and nanoparticles. EPA is funding research at universities to examine the toxicity of manufactured nanomaterials such as quantum dots, carbon nanotubes, and titanium dioxide. In addition, current and past work in ultrafine particulates at EPA labs and funded through the extramural program at EPA can help inform the effects of nanoparticles on human health. Scientists funded by the NIH also are studying the chemistry, biology, and physics of nanoscale material interactions at the molecular and cellular level addressed in vitro experiments and models. This research is creating a significant body of knowledge of nanoscale materials reactions with biological materials.

2. Laws and regulations that apply to nanotechnology development

On December 3, 2003, the President signed into law the 21st Century Nanotechnology Research and Development Act (Public Law 108-153). A section of that Law is dedicated to societal implications.

Congress issues authorization laws and funding appropriations for nanotechnology R&D by federal agencies participating in NNI each year. The number of participating agencies has increased from 6 agencies in FY 2001 to 10 agencies in FY 2002 and 19 agencies in FY 2004.

Organizations with primary responsibility for implementing regulations and guidance in areas relevant to nanotechnology materials and products are:

- Environmental and Protection Agency (EPA)
- Food and Drug Administration (FDA)
- National Institute of Occupational Safety and Health (NIOSH)
- Occupational Safety and Health Administration (OSHA)
- US Department of Agriculture (USDA)
- Consumer Product Safety Commission (CPSC)
- US Patent and Trade Office (USPTO)

Research to establish the knowledge base that is used by regulatory agencies to inform their decision-making process may be performed by federal agencies, such as NSF, NIH, NIST, EPA, FDA, NIOSH, OSHA, USDA, DOE, and DOD, or may be performed by industry or other private sector research institutions.

NSET/NSTC has established the National Nanotechnology Coordinating Office (NNCO) in 2001 as its secretariat with one of its role to monitor potential unexpected consequences of nanotechnology; the NNCO has certain responsibilities pursuant to PL 108-153. The Nanomaterial Environmental and Health Implications (NEHI) working group was established in 2003 to address environment, health and safety (EHS) issues, including risk assessment, identification and prioritization of EHS research needs, and communication of information pertaining the EHS of nanomaterials to researchers and others who handle and use nanomaterials.

The materials and products based on nanotechnology are regulated today within the existing network of statutes, regulations, rules, guidelines, and other voluntary activities. Nanostructures are

generally evaluated as "chemicals with new uses" or as "new chemicals". In some cases, pre-market review and approval is required (e.g. drugs, food packaging, and new chemical compounds). In other cases, post-market surveillance and monitoring applies (e.g., cosmetics and most consumer products). The existing regulatory network will be modified, if necessary. Examples of regulatory laws and standards applicable to nanoparticles and other nanostructures include:

- In the environments (in air, water, soils):
  - Toxic Substance Control Act (TSCA), administered by EPA.
  - Clear Air Act for ultrafine particles, administered by EPA
  - Waste disposal acts, administered by EPA
- In the work place (aerosol-based standards based on existing health risk data)
  - Permissible Exposure Limits (PELs), established by Occupational Safety and Health Administration (OSHA)
  - Recommended Exposure Limits (RELs), established by National Institute of Occupational Safety and Health (NIOSH)
  - Threshold Limit Values (TLVs), established by the American Conference of Government Industrial Hygienists (ACGIH)
  - Personal Protective Equipment to reduce exposure, established by OSHA and ASTM (American Society for Testing and Materials)
- Nanoparticles for drugs to be metabolized in human body, to be used as diagnostics or therapeutic medical devices (such as quantum dots); Regulated by FDA
- Nanostructured "particles/substances" to be incorporated into food; FDA and USDA share the regulations (such as food additives, food coloring)
- Substances incorporated into consumer products; regulated by Consumer Product Safety Commission (CPSC) under the Federal Hazardous Substances Act. A focus is on protection of children, who are more susceptible and who sometimes put objects in their mouth that were not intended for that purpose.

Under NSET coordination, the EPA, FDA, CPSC, OSHA, NIOSH, NIST, USDA and other agencies are reviewing existing rules and procedures to determine how to use the existing statutes and regulations to review products of nanotechnology, as these products are developed. Where new nanotechnology products differ from existing products and present unique concerns for the environment or public health, modification or extension of rules will be considered.

3. Key issues that need to be addressed in order to ensure the responsible development of nanotechnology

- Proper selection of R&D priorities for a balanced and equitable development of nanotechnology that includes research into its potential economic, social and legal implications
- Environmental, health and safety implications associated with nanostructured materials. While natural nanostructured materials and nanostructured process-by-products are of high concern, the unique characteristics of engineered nanoparticles and nanostructured surfaces present particular challenges to understanding and controlling environmental and health implications
- Avoiding possible adverse EHS (environment/health/safety) aspects of nanotechnology by practicing "green chemistry" (clean processes and processing) and "environmentally benign manufacturing"

- Using nanotechnology to understand, measure, and reduce/control pollution from our current processes
- Ethical aspects related to the distribution of the benefits of nanotechnology
- Best mechanisms for communicating with the public
- Issues related to individual rights, such as privacy, have access to healthcare, and various topics at the confluence of nanotechnology, biotechnology, information technology, and cognitive sciences.

4. Suggested measures to ensure the responsible development of nanotechnology (at national, regional, and global levels)

- Develop better understanding on environment, health and societal implications of nanotechnology through continued support of R&D programs
- Promote exchange of information on the results of R&D on environment, health, and societal implications of nanotechnology. For illustration, NSF sponsored the first workshop on Societal Implications of Nanoscience and Nanotechnology in 2000, and a joint EC-NSF workshop on the same topic was held in 2001. Follow-on to the 2000 workshop was held in December 2003, and several NNI grantees and research direction meetings were held in 2003-2004
- Prepare "Best practices" statements for handling and use of engineered nanomaterials, particularly in industrial or manufacturing environments and research laboratories
- Prepare "Best Practices" statements for protection and handling natural and process-by-product nanomaterials, such as those from combustion engines or welding
- Disseminate precompetitive research results and develop collaborative activities in order to advance broader goals such as water purification; energy conversion, storage, and transmission; and treatment of chronic illnesses
- Evaluate various issues in the broader societal context and from an international perspective
- Promote two-way interactions with the public at the local, national, and international levels.