

EXECUTIVE OFFICE OF THE PRESIDENT  
PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY  
WASHINGTON, D.C. 20502

July 22, 2008

President George W. Bush  
The White House  
Washington, D.C. 20502

Dear Mr. President:

We are pleased to send you the attached letter addendum to our report, *The National Nanotechnology Initiative: Second Assessment and Recommendations of the National Nanotechnology Advisory Panel*, in which your Council of Advisors on Science and Technology (PCAST) provides a brief assessment of *The National Nanotechnology Initiative Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*. The latter document was released in February 2008, as the Council was concluding its overall assessment of the National Nanotechnology Initiative (NNI). Because of the importance of this strategy and the strong relevance to other recommendations proposed by the Council, PCAST decided to issue a letter addendum to our NNI report specifically addressing the Nanotechnology Environmental, Health, and Safety (EHS) research strategy.

The Council maintains that the NNI approach for addressing EHS research is fundamentally sound in terms of strategic priorities as well as broad collaboration across agencies, with industry, and particularly with international stakeholders. The EHS research strategy is essential to advance understanding of engineered nanomaterials in specific commercial or near-commercial applications, to enable scientifically-based risk/benefit assessments, and to facilitate balanced communication regarding nanotechnology development.

The full PCAST discussed and approved this addendum at its public meeting on April 8, 2008. We expect that the strong interagency coordination demonstrated by the NNI in producing this research strategy will provide a strong base for participating agencies to collaboratively address the identified EHS research priorities. This coordination and collaboration will be critical to ensure the responsible development of nanotechnology and to realize the profound benefits nanotechnology could offer to our Nation.

Sincerely,



John H. Marburger, III  
Co-Chair



E. Floyd Kvamme  
Co-Chair

Enclosure

Addendum to  
*The National Nanotechnology Initiative:  
 Second Assessment and Recommendations of the  
 National Nanotechnology Advisory Panel*

Assessment of the NNI Strategy for  
*Nanotechnology-Related Environmental, Health, and Safety Research*

July 2008

**Context.** In February 2008, the National Science and Technology Council Subcommittee on Nanoscale Science, Engineering, and Technology (NSET) released its *National Nanotechnology Initiative: Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*. PCAST in its role as the National Nanotechnology Advisory Panel (NNAP) at the time had essentially completed its second review of the NNI, which was released in April 2008. The NNAP determined to review and assess the NSET document (heretofore referenced as the “NNI EHS Research Strategy” or “the Strategy”) as an addendum to its broader review and assessment of the NNI environmental, health, and safety (EHS) research activities. The brief comments and recommendations that follow should thus be taken in context with the Panel’s overall findings and recommendations regarding the NNI as reported in April 2008.

As stated in that report, the NNAP maintains its view that the NNI approach for addressing EHS research is fundamentally sound in terms of strategic priorities as well as focus on and extent of collaboration across agencies, with industry, and particularly with international stakeholders. Support of fundamental nanotechnology research primarily addressing EHS under the NNI continues to grow much faster than overall NNI funding, and will double over the 5 years since EHS research was first reported in 2005:

**NNI Funding for Nanotechnology-Related EHS Research (PCA 7)**

by fiscal year, in \$ millions (FY 2008 is estimated, FY 2009 is requested)



**Rationale.** The NNI EHS Research Strategy aims to:

- Guide and accelerate progress in fundamental research relevant to safeguarding the environment and health of the public;
- Coordinate research activities across sectors regionally, nationally, and internationally (particularly in development of standards and acceptable test methodologies as the essential first step in supporting EHS research broadly); and
- Support balanced, science-driven risk versus benefit assessment of real-world applications as a sound basis for decision-making and communications.

The NNAP views these aims as critical to foster the collaboration required to advance understanding of the growing number of engineered nanomaterials in specific applications, many of which are near or in commercial use. The Panel believes this work to be absolutely essential to facilitate a balanced perception of the public and policymakers about the safety of this technology. Further, the use of nanotechnology should be viewed from a rational, scientifically-sound basis instead of obscured by misinformation and speculation, such that the full societal benefits of nanotechnology can be realized.

**Approach.** The NNI EHS Research Strategy first establishes a baseline reference to overall nanotechnology-related EHS research funding in FY 2006. A working group of the NSET subcommittee focused on Nanotechnology Environmental and Health Implications (NEHI) worked with the White House Office of Science and Technology Policy (OSTP) and the Office of Management and Budget (OMB) to form a data call with sufficient detail to capture a detailed, program by program “snapshot” of relevant research across the NNI, including research not primarily targeted at EHS issues and thus not reported under NNI Program Component Area (PCA) 7a on EHS research. The NEHI working group worked closely with program managers and experts at the agency level in the process to scrub and analyze the data to ensure only relevant research (including partial project funding, where appropriate) was included.

Having established a baseline and having scoped the extent of EHS research activities relevant to nanotechnology, the NEHI working group conducted a thorough gap analysis to identify deficiencies and needs, assess existing research, and evaluate strengths and weaknesses in the context of a risk management framework. The working group convened as a whole and by task forces addressing the five research needs categories (instrumentation/metrology, human health, environment, exposure assessment, and risk management). The group compared the research needs and priorities previously identified in its reports on EHS research needs (September 2006) and priorities (August 2007) to the data collected on NNI EHS research as of FY 2006. The results were prioritized by research needs category and scoped for relative emphasis and sequence of work as near-term (0-5 years), mid-term (5-10 years), and long-term (10+ years). Furthermore, these strategic priorities were aligned with the risk management framework to demonstrate the proper context and impact of progress on those priorities towards informing risk assessment and future research.

The NNAP finds this process and the NNI’s overall approach to be quite thorough and robust. The interagency coordination process identified EHS research needs, mapped those needs to current activities to identify potential research opportunities, and then prioritized those opportunities to inform budget and planning activities. The Panel’s specific recommendations for future evaluation and updates of the NNI EHS Research Strategy are detailed below.

**Implementation.** As an extension of the NSET, NEHI working group members play a crucial role in assembling and implementing the NNI EHS Research Strategy. Comprised of a cross-section of experts drawn from multiple agencies with research and/or regulatory missions, the working group is ideally positioned to integrate the expertise and resources that reside in the NNI participating agencies. In so doing, the NSET is better able to facilitate intra- and interagency collaboration in a multi-disciplinary approach, and monitor the state of the science with a perspective beyond agency-specific missions. The NEHI working group provides a broad assessment of relevant research activities and helps scope the key EHS research concerns to be addressed in the strategy.

Through the NEHI working group, the agencies agreed to designate a lead coordinating agency for each research needs category and the other agencies contribute to the overall goals agreed to within the NNI:

Research Need	Instrumentation, Metrology, and Analytical Methods	Nanomaterials and Human Health	Nanomaterials and the Environment	Human & Environmental Exposure Assessment	Risk Management Methods
Agency					
NIH	○□	◆	□	□	
NIST	◆	○	○	○	○
EPA	○□	○□	◆	○□	◆
FDA	□	□	□	□	◆
NIOSH	○□	○□	○	◆	○□
NSF	○	○	○	○	○
DOD	□	□	○□	□	○□
DOE	○□	□	○□	□	□
USDA	□	○□	○□	□	□
DOT		□	□	□	□
OSHA	□	□		□	□
CPSC	○□	□	□	○□	○□
USGS	○□		○□	○□	
Projects	78	100	49	5	14
Funding	\$26.6M	\$24.1 M	\$12.7 M	\$1.1 M	\$3.3 M

- ◆ - **Coordinating Agency** – Leadership role in coordinating and communicating with other agencies
- - **Contributor** – Have funded or are planning to fund or conduct research in category
- - **User** – Have expressed a need for, or expectation to make use of, research outputs or information to support missions and responsibilities

The category of Human & Environmental Exposure Assessment clearly warrants more resources, attention and effort as noted in our Recommendations. Furthermore, due to the small average size of the projects coordination of the NEHI working group agencies is critical to ensure progress is made in a timely fashion.

These efforts do not take away from the other work within the agencies to perform their mission-oriented functions but, in our view, result in more effective activity within the lead agency (cf. examples of agency specific activity on page 27 of the PCAST report).

The NEHI working group of the NSET subcommittee remains the best locus of coordination and authoritative advisory capability for the participating agencies in implementing the government-wide nanotechnology EHS research strategy that cuts across agency and disciplinary lines. The working group will conduct ongoing evaluation and revisions to the research strategy as the science progresses and needs change. Moreover, the NNAP anticipates that the NSET subcommittee will maintain and strengthen its linkage to the growing knowledge base, best practices, and other international inputs via the Organization for Economic Cooperation and Development (OECD) and standards development organizations (for example) as recommended in the PCAST report.

**Recommendations.** The NNAP made four recommendations with respect to EHS implications in its April 2008 report on the NNI. These include continuing to strengthen EHS research with industry and international stakeholders. The NNCO has done well to implement many avenues of such cooperation since the first NNAP report in May 2005, but much remains to be done to establish clear risk/reward profiles for the engineered nanomaterials finding their way into industrial products. Further, to date, the U.S. is funding and performing the majority of this research; thus, every effort should be made to encourage international participation. This will also facilitate development of consensus-based international standards. As discussed in our recent report, we suggest that a focus on the substantive characterization of the 14 nanomaterials selected through the OECD collaboration would be an important goal over the near term. Further, we suggest that segregating implications research from applications research would be a mistake. As an example, some nanomaterials may be found to have some deleterious effects on humans and yet be important ingredients in life-saving pharmaceuticals – just as chemotherapy while hard on many body functions is a valuable tool in cancer eradication. Linking application to implication assures that risk/reward is put into perspective. Similarly, our report recommendations recognize that expertise to conduct thorough risk/benefit analyses may require cross-agency joint programs. These should ensure that the expertise available at each of the participating agencies is both available and best utilized.

Having reviewed the NNI EHS Research Strategy, the NNAP posits the following recommendations in addition to those in its recently completed review of the NNI:

1. **Assess Federal nanotechnology EHS portfolio and update gap analysis against research priorities triennially.** The baseline reference in the appendix of the NNI EHS Research Strategy makes an important contribution to understanding the range of EHS activities occurring across the participating agencies. The report suggests that such baselining should occur on 3-5 year intervals. We recommend implementing a three year interval and that the report discussing the new baseline be available in time for the triennial review of the NNI by the National Academies and the NNAP. With this schedule the next baseline update would occur for projects funded in FY 2009 and be available for the 2011 NNAP report.
2. **Leverage opportunities to bootstrap identified gap areas and to encourage increased investments elsewhere through collaboration with industry and other countries; encourage broad and ongoing agency participation in such efforts.** International and industry collaboration in EHS research would greatly expedite knowledge discovery. The gap analysis outlined in the NEHI working group report should be communicated

broadly so as to encourage international and industry research in the gap areas. Specifically, the gap approach should inform researchers working with the 14 commercial or near-commercial nanomaterials identified by the OECD Working Party on Manufactured Nanomaterials project as they seek to identify and work on materials where characterization is lacking.

3. **Encourage supported researchers to report on the development of analytical methodologies used in their research so that a series of best practices can evolve for risk assessment and characterization.** In addition to timely communication of the results of research projects, researchers should be encouraged to report on the development of analytical methodologies used in their research so that a series of best practices can evolve for risk assessment and characterization (e.g., sponsor international symposia for presentation and sharing of data, debate of best practices and continuous gap analyses).
4. **Promote broad and practical use of EHS findings in defining responsible use of nanotechnology in research, manufacturing and commercial application.** By “responsible use,” the NNAP means use that fully accounts for both risks and benefits, known and anticipated, in a manner consistent with the intended application and expected lifecycle.
5. **Increase exposure assessment funding.** The funding profile of FY 2006 shows NIOSH funding of \$1.1 M for 5 projects. In the assessment of the NNAP, this spending level should increase substantially. The FY 2009 projection from Appendix C of the April 2008 NNAP report shows that NIOSH is budgeting \$6 M in the coming fiscal year. In light of the onset of manufacturing for nanotechnology-based products, and the Panel’s expressed concern that worker safety should be paramount, the NNAP encourages a continuing acceleration of NIOSH funding, particularly for exposure assessment in the context of manufacturing and disposal of nanomaterials and products incorporating relevant quantities of nanomaterials.
6. **Maintain and strengthen agency support and coordination efforts through the NSET subcommittee and NEHI working group.** The NNI EHS Research Strategy clearly demonstrates the value and importance of cross agency coordination through the NSET subcommittee as exemplified by the NEHI working group. Appropriate and informed support for EHS research within the NNI is an important responsibility that demands the kind of strong coordination enabled by the NEHI working group. We recommend that all agencies that fund or conduct research on nanomaterials along with those whose charters specifically include EHS-related activities directly support the NSET/NEHI data gathering and communications functions.