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SUBJECT: Public Meeting on Research Needs and Priorities Related to the Environmental, Health, and Safety Aspects of Engineered Nanoscale Materials

The Project on Emerging Nanotechnologies is an initiative launched by the Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts in 2005. It is dedicated to helping business, government and the public anticipate and manage the possible health and environmental implications of nanotechnology. As part of the Wilson Center, the Project on Emerging Nanotechnologies is a non-partisan, non-advocacy organization that collaborates with researchers, government, industry, non-governmental organizations (NGOs), and others concerned with the safe applications and utilization of nanotechnology.

Our goal is to take a long-term look at nanotechnologies; to identify gaps in the nanotechnology information, data, and oversight processes; and to develop practical strategies and approaches for closing those gaps and ensuring that the benefits of nanotechnologies will be realized. We aim to provide independent, objective information and analysis that can help inform critical decisions affecting the development, use and commercialization of responsible nanotechnologies around the globe.

Both the Wilson Center and The Pew Charitable Trusts believe there is a tremendous opportunity with nanotechnology to “get it right.” Societies have missed this chance with other new technologies and, by doing so, forfeited significant social, economic and environmental benefits.

The Project on Emerging Nanotechnologies appreciate this opportunity to submit comments to the Public Meeting on Research Needs and Priorities Related to the Environmental, Health, and Safety (EH&S) Aspects of Engineered Nanoscale Materials, held by the National Nanotechnology Coordination Office (NNCO) on behalf of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the

Project on Emerging Nanotechnologies



Committee on Technology, National Science and Technology Council (NSTC). We are encouraged that this meeting is taking place and hope that it will propel NSET and the broader National Nanotechnology Initiative (NNI) to move forward in its development and implementation of a *top-down, strategic, risk-research framework*. The Project on Emerging Nanotechnologies cannot overemphasize the need for such a coordinated and systematic risk research effort by the United States (U.S.) government specifically aimed at ensuring that potential risks posed by engineered nanomaterials to human health and to the environment are controlled and minimized.

In this regard, the Project on Emerging Nanotechnologies has been instrumental in facilitating the process of evaluating the current U.S. government EH&S risk research portfolio, identifying gaps in ongoing EH&S research, prioritizing future research needs and developing effective oversight and risk research management options for government and industry. These efforts have occurred by way of:

- Creating and maintaining the first publicly available, web-based, and fully searchable Inventory of Nanotechnology Environment, Health and Safety Research, which contains investigator, funding and categorization details on over 200 research projects from eight countries or regions around the world. According to data in the inventory, the U.S. government invested an estimated \$11 million in 2005 in highly relevant risk research dedicated to addressing the potential impacts of engineered nanomaterials. This inventory is available at <http://www.nanotechproject.org/18/esh-inventory>.
- Publishing the report, *Nanotechnology: A Research Strategy for Addressing Risk* by Dr. Andrew D. Maynard, Chief Science Advisor to the Project on Emerging Nanotechnologies, in July 2006. This report proposes detailed EH&S risk research priorities—including identifying and measuring nanomaterials exposure and environmental release, evaluating nanomaterial toxicity, controlling the release of and exposure to nanomaterials and developing “best practices” for working safely with nanomaterials—and offers short-, medium- and long-term timeframes for such investigation. The report is available at http://www.nanotechproject.org/file_download/77.
- Presenting testimony before the U.S. House Committee on Science hearing entitled “Research on Environmental and Safety Impacts of Nanotechnology: What are the Federal Agencies Doing?” on September 21, 2006, where Dr. Maynard suggested mechanisms to support a joint government-industry funded cooperative science organization, with a five-year plan to systematically address the human health impacts of engineered nanomaterials through independent, targeted risk-related research. The testimony is available at http://www.nanotechproject.org/file_download/100.
- Releasing the article “Safe handling of nanotechnology” in the November 16, 2006 edition of *Nature*, authored by 14 internationally renown scientists who have identified, prioritized and mapped Five Grand Challenges for targeted

research on nanotechnology's potential EH&S risks. The article is available at <http://www.nature.com/nature/journal/v444/n7117/full/444267a.html>. Specific recommendations include:

- Develop instruments to assess exposure to engineered nanomaterials in air and water, within the next 3-10 years;
- Develop and validate methods to evaluate the toxicity of engineered nanomaterials, within the next 5-15 years;
- Develop models for predicting the potential impact of engineered nanomaterials on the environment and human health, within the next 10 years;
- Develop robust systems for evaluating the health and environmental impact of engineered nanomaterials over their entire life, within the next 5 years; and
- Develop strategic programs that enable relevant risk-focused research, within the next 12 months.

Copies of the report, article and testimony materials mentioned above are attached and will be submitted along with these comments. It is clear that many of these efforts— together with information, analyses and critiques from other sources—move well beyond the basic listing of research needs presented in the *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials* report that was released by NEHI at the aforementioned House Committee on Science hearing. It is imperative that NSET does not further delay in developing prioritization criteria for EH&S research needs and begins to implement a workable, forward-looking, top-down risk research strategy framework. The reasons for this are many, including:

- A wide variety of products—over 380 from 17 different countries, as indicated in our Nanotechnology Consumer Product Inventory, available at <http://www.nanotechproject.org/consumerproducts>—claiming to contain and use nanomaterials are already on the market. This means that researchers, workers, consumers and ecosystems are already being exposed to these substances, despite, in many cases, uncertainty over the risks they may present.
- Many companies that manufacture or use nanomaterials in products are seeking U.S. government direction on how to establish EH&S risk assessment and management programs to develop safer nanotechnology workplaces and products, which rely on targeted and relevant U.S. government-funded risk research.
- Other national and regional governments around the world are moving forward rapidly on developing EH&S risk-research strategies, particularly the Department for Environment, Food and Rural Affairs (Defra) in the United Kingdom, the Federal Institute for Occupational Safety and Health (BAuA) in Germany and the Framework Program 7 (FP7) in the European Union.

- The public's acceptance of nanotechnology will depend in part on appropriate investment in EH&S research and the development of sound risk management practices. This requires NSET to maintain an open dialogue on risks, oversight and actions in order to increase citizen confidence in nanotechnology and trust in the U.S. government's ability to manage risks.

We hope that, taken together, these comments and the attached resources will provide useful insight into developing a strategic risk research framework, prioritizing research and enabling an effective research program to be implemented. Specifically, the attached resources provide a clear perspective on criteria for prioritization; short-, medium- and long-term research priorities; and mechanisms for implementing a strategic risk research program.

Finally, as NSET advances its activities in the future, there are a number of concrete principles that it could follow and steps that it could take to ensure that responsible and safe nanotechnologies are developed, particularly:

1. Make available information on current research that is relevant to understanding and addressing the potential EH&S risks of nanotechnology.

There is little information publicly available and easily accessible on what EH&S risk research is currently being undertaken. In the absence of an accurate and detailed account of the research that is currently being funded, it is highly unlikely that NSET will be able to identify research gaps, avoid duplicative research, prioritize new research and establish an effective strategic research framework. In addition, a lack of publicly available knowledge concerning the present and intended funding levels and areas of the U.S. government makes it difficult to develop partnerships with industry or with other countries and, ultimately, leverage federal dollars.

As mentioned earlier, the Project on Emerging Nanotechnologies has attempted to fill this gap through the creation of a publicly accessible EH&S risk research inventory. This inventory enables a sophisticated analysis of current research that has varying degrees of relevance to understanding the potential impacts of nanotechnology. However, it is only as good as the information which is provided or can be otherwise obtained. While many have argued that this is not an easy task, it is inconceivable that new research investments will be made and new research initiatives started without a good, working knowledge of what is already being done. Likewise, national and international collaboration will be delayed and, ultimately, highly ineffective without information on where critical investment is needed. *As the inventory developed by the Project on Emerging Nanotechnologies is updated—and as other organizations, such as the Organization for Economic Co-operation and Development (OECD), begin to develop similar analytic tools—we would strongly encourage NSET to provide a complete accounting of all ongoing EH&S risk research and make all relevant research information available to aforementioned resources.*

- 2. Utilize existing EH&S research prioritization efforts.** As NSET prioritizes EH&S research, it should examine and integrate strategies and recommendations that have already been developed and that are already reaching consensus within the scientific community. For example, Maynard's report, *Nanotechnology: A Research Strategy for Addressing Risk*, provides a ready-made and detailed risk research prioritization strategy, including suggested funding levels and timeframes for such research. Similarly, a number of organizations have also developed lists of research priority areas, including the Environmental Protection Agency (EPA),¹ the National Institute for Occupational Safety and Health (NIOSH),² Environmental Defense,³ the Semiconductor Research Corporation and the Chemical Industry Vision 2020 Technology Partnership,⁴ and ICF International.⁵

Finally, the *Nature* paper not only outlines an agreed-upon set of actionable recommendations, but it carries the weight of authors from different countries (including the United States, the United Kingdom and Germany), from different sectors (including government, industry, academia and non-governmental organizations), and from different disciplines (including chemistry, physics and toxicology). It has also been praised by the leaders of the House Committee on Science, Chairman Sherwood Boehlert (R-NY) and Ranking Democrat Bart Gordon (D-TN), noting that "This paper should be a landmark in the history of nanotechnology research. It lays out a clear, reasonable, prioritized, consensus-based set of priorities for examining the potential environmental and health consequences of nanotechnology over the next decade and a half. This paper should eliminate any remaining excuses for inaction in this vitally important area." Boehlert and Gordon continue by stating, "There is absolutely no reason that those same agencies and the White House should not now quickly put together a plan and a budget to implement the recommendations in the *Nature* paper as part of the fiscal 2008 budget."

¹ *External Review Draft Nanotechnology White Paper*. Washington, DC: United States Environmental Protection Agency, December 2, 2005. Available at http://www.epa.gov/osa/pdfs/EPA_nanotechnology_white_paper_external_review_draft_12-02-2005.pdf, accessed December 12, 2006.

² *Strategic Plan for NIOSH Nanotechnology Research: Filling the Knowledge Gaps*. Washington, DC: National Institute for Occupational Safety and Health, September 28, 2005. Available at http://www.cdc.gov/niosh/topics/nanotech/strat_planINTRO.html, accessed December 12, 2006.

³ Denison, Richard A. "A proposal to increase federal funding of nanotechnology risk research to at least \$100 million annually." Washington, DC: Environmental Defense, April 2005. Available at http://www.environmentaldefense.org/documents/4442_100milquestionl.pdf, accessed December 12, 2006.

⁴ Semiconductor Research Corporation and Chemical Industry Vision 2020 Technology Partnership. "Joint NNI-ChI CBAN and SRC CWG5 Nanotechnology Research Needs Recommendations." Available at <http://www.chemicalvision2020.org/pdfs/chem-semi%20ESH%20recommendations.pdf>, accessed December 12, 2006.

⁵ *Characterizing the Environmental, Health, and Safety Implications of Nanotechnology: Where Should the Federal Government Go From Here?* Fairfax, VA: ICF International, December 2006. Available at http://www.icfi.com/markets/environment/doc_files/nanotechnology.pdf, accessed December 12, 2006.

Despite the diversity of perspectives reflected in these analyses, they are generally in broad agreement on the areas requiring further research and, therefore, provide a sound basis for moving ahead rapidly with EH&S risk research prioritization. *In short, given the wide range of useful data available to NSET—and given the time the Subcommittee has already invested in preparing its plan—it seems reasonable to expect a comprehensive risk research strategy from the U.S. government within the next 3-4 months.* Such rapid turn-around is necessary, as companies continue to move full-speed ahead with product development and increasingly will seek input and answers from a well-defined U.S. government-sponsored EH&S strategy that appropriately fits their innovation timeframes. Accordingly, as one chief executive from a leading nanotechnology firm recently commented, “a year is a long time in today's product development cycle,” making evident that the U.S. government needs to move quickly in developing an EH&S plan that engages industry—or, at a minimum, prevents firms from hiding in the “regulatory sand.”⁶

- 3. Ensure that EH&S research funding levels are adequate, that funding mechanisms are effective and that lead agencies have the necessary personnel and financial resources to get the job done.** While establishing an EH&S strategic research framework is essential, research must be adequately funded if it is to be effective. Despite claims from NSET that substantial funding is being directed toward EH&S research, an examination of highly relevant risk research projects funded in 2005 indicates that there is a significant gap between the level of investment the Project on Emerging Nanotechnologies has been able to determine and the level of investment that NSET has claimed. *To address these critical research areas, Maynard has estimated that at least \$100 million should be invested in strategic risk research over the next two years if significant progress is to be made.* These research funds must be targeted towards addressing priority research needs and must not be squandered on studies that are academically interesting but inconsequential in practice.

It is also imperative that agencies best positioned to undertake critical EH&S research are empowered to do so. For example, according to NSET, EPA and NIOSH combined accounted for only 18% of NSET's 2006 EH&S research budget estimate, while the National Science Foundation (NSF)—which is not mandated to protect human health and the environment—accounted for nearly 60% of the 2006 EH&S research budget estimate.⁷ Additionally, John Howard, Director of NIOSH, points out that the agency's \$3 million budget for nanotechnology EH&S research is not a new appropriation from Congress or

⁶ Rickert, Scott E. “Taking The Nanopulse -- Nanotechnology In 2007 -- No Ostriches Allowed: Science meets regulation. Let's look ahead.” *Industry Week*, December 6, 2006. Available at: <http://www.industryweek.com/PrintArticle.aspx?ArticleID=13166>, accessed December 12, 2006.

⁷ *The National Nanotechnology Initiative: Research and Development Leading to a Revolution in Technology and Industry, Supplement to the President's FY 2007 Budget*. Washington, DC: Office of Science and Technology Policy, July 2006. Available at http://www.nano.gov/NNI_07Budget.pdf, accessed December 12, 2006.

NSET and is a “rounding error” compared to agencies such as NSF.⁸ Yet NIOSH is responsible for research that protects what is arguably one of the most at-risk populations from nanotechnology: laboratory, production line and manufacturing plant workers. Unless it can be demonstrated clearly that agencies such as NIOSH, EPA, the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA) and the Consumer Product Safety Commission (CPSC) are getting sufficient return and value from the EH&S research investments in basic science agencies such as NSF, there needs to be a critical re-evaluation of the personnel and financial resources devoted to these mission-driven agencies in order to adequately address potential risks.

- 4. Emphasize the development of green or environmentally benign approaches to nanotechnology.** Rather than going down the traditional path of addressing risks after-the-fact, we have a unique opportunity to design and engineer risks out of both nanotechnology-based products and production processes. This requires developing approaches that reduce harmful emissions, cut energy and material inputs, and provide potential environmental benefits. So far, a small amount of funding at EPA has been directed towards advancing and concretizing this concept of Green Nanotechnology, but this area has not received the attention it deserves. *NSET should work to develop a strategy for Green Nanotechnology research and development and explore policy options that could provide incentives for industry to address risks early, rather than study them later.*

Over the past year, the Project on Emerging Nanotechnologies has spearheaded a series of public seminars and a scientific symposium on the topic of Green Nanotechnology. In the coming months, we intend to release our *Green Nanotechnology* report that will summarize the findings from these events and identify potential policy opportunities that could advance the field in the future. In doing so, the overall goal is to stress the importance of developing clean technologies to minimize potential environmental and human health risks associated with the manufacture and use of nanotechnology products and to encourage replacement of existing products with new nanotechnology products that are more environmentally friendly throughout their life cycle.

- 5. Place increased importance on continued public dialogue and outreach.** While this public meeting is a welcome first step in setting priorities for NSET’s EH&S research agenda, it is occurring too late in the nanotechnology development process. The first Congressional hearing on this topic occurred over a year ago, and it was not until a second hearing this past fall that NSET produced its research needs document. Furthermore, by moving slowly to start such public outreach activities, the U.S. government and federal agencies have placed the risk-research communities at a disadvantage, as they are forced to catch-up with

⁸ Cable, Josh. “Official: Federal Nanotech EHS Research is a Priority.” *Occupational Hazards*, December 11, 2006. Available at http://www.occupationalhazards.com/News/Article/43564/Official_Federal_Nanotech_EHS_Research_is_a_Priority.aspx, accessed December 12, 2006.

the quick commercialization of nanotechnology products and entry in the market. In recent comments, former White House Science Advisor Neal Lane echoed these sentiments, noting there is a great need for “a deliberate effort to provide the public with balanced and easily understood information about nanotechnology’s potential benefits and its possible risks and for more public engagement”—which should be led by government, industry and the science and engineering community working together. Without such efforts, Lane noted, “A major environmental, medical or safety problem—real or bogus—with a product or application that’s labeled ‘nanotechnology’—whether it actually is nanotechnology or not—could dampen public confidence and financial investment in nanotechnology’s future, and could even lead to unwise regulation.” Lane continued by stating that:

“From the beginning, an explicit aim of the U.S. National Nanotechnology Initiative (NNI)—a \$6.5 billion federal investment in nanotechnology research launched in January 2000 under President Bill Clinton—was to excite young girls and boys about science, particularly the physical sciences and engineering. The intent was to reach millions of children using the wonders of nanotechnology to encourage them to study science and to equip them to compete successfully at the cutting-edge of a globalized economy...But so far, government-supported children’s education programs and public outreach efforts have been long on rhetoric and short on the strategy and resources necessary to achieve significant results.”⁹

Part of the problem here is that the percentage of NNI funding dedicated to public engagement is far too small to be effective. Though the NNCO was tasked with this responsibility under the 21st Century Nanotechnology Research and Development Act of 2003—which requires that the government ensure “public input and outreach...be integrated into the Program by the convening of regular and ongoing public discussions, through mechanisms such as citizens’ panels, consensus conferences, and educational events”¹⁰—there have been few resources devoted to this area and, consequently, almost no public engagement has occurred in over three years. ***It is time for the U.S. government to “step up to the plate” and invest \$4-5 million annually in nanotechnology public engagement, devoted to undertaking public programs, instituting extensive feedback mechanisms and establishing goals and performance measures.*** As is the case with EH&S research, there is a need for a comprehensive public engagement strategy with the necessary financial resources to back it up.

⁹ “Former White House Science Advisor Warns that Nanotechnology’s Potential Threatened by Weak Public Education and Outreach.” Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, December 5, 2006. Available at <http://www.nanotechproject.org/101/1252006-former-white-house-science-advisor-warns-that-nanotechnologys-potential-threatened-by-weak-public-education-and-outreach>, accessed December 12, 2006.

¹⁰ “21st Century Nanotechnology Research and Development Act.” Washington, DC: United States Congress, 108th, S. 189, 2003. Available at <http://thomas.loc.gov>, accessed December 12, 2006.

In the future, NSET must ensure that public participation moves beyond public comment sessions to include interactive dialogue and discussion. This will require the development of more novel and more creative methods for interacting with the public. For example, the Project on Emerging Nanotechnologies is planning to hold a series of web dialogues over the coming months to encourage participation by broader segments of the population and to reach out to traditionally under-represented groups, such as the elderly, women, and minorities, to contribute their ideas about nanotechnology governance. While this method may not be ideal, it does have the advantage of allowing continued interaction between expert and layperson, the ability to include many voices in the policy debate and the flexibility of addressing a range of topics that are of interest to a more diverse group of citizens, constituents and consumers.

* * *

In the end, we expect that NSET will capitalize on the ideas generated at this meeting, on the proposals submitted in this and in other documents and on the suggestions shared by various individuals and organizations to move forward without delay in prioritizing nanotechnology research that will help assure the safety of human health and the environment. The time is ripe for action, and nanotechnology's future success deserves nothing less.