Statement of the
American Chemistry Council at the Hearing on Research On Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation Under the National Nanotechnology Initiative

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ACC Nanotechnology Panel

Before the

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Introduction

The American Chemistry Council (ACC) appreciates Chairman Gordon's invitation to address the House Committee on Science and Technology on the role of the National Nanotechnology Initiative (NNI) in planning and implementing the environmental, safety, and health research necessary for the responsible development of nanotechnology.

ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $635 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

In 2005, ACC formed its Nanotechnology Panel consisting of domestic producers that are engaged in the manufacture, distribution, and/or use of chemicals that have a business interest in the products of nanotechnology.[1] The Panel was formed to foster the responsible application of nanotechnology; to coordinate nanotechnology environmental, health, and safety research initiatives undertaken by member companies and other organizations; and to facilitate the exchange of information among member companies and other domestic and international organizations on issues related to applications and products of nanotechnology. The Panel supports nanotechnology products and applications that are consistent with ACC's Responsible Care® Program, and consistent with the Joint Statement of Principles the Panel and Environmental Defense issued on June 22, 2005 to help ensure that the commercialization of nanoscale materials proceeds in a way that protects workers, the public, and the environment.

I. Improved Federal Coordination and Support Are Essential for the Responsible Development of Nanotechnology and Its Commercial Acceptance

The federal government has a unique and critically important role to play in coordinating and adequately funding research on the environmental, health, and safety (EHS) aspects of nanotechnology. In this regard, the NNI is tasked with coordinating

1 Panel member companies include: Air Products and Chemicals, Inc., Arkema Inc., Arch Chemicals, BASF Corporation, Bayer MaterialSciences Corporation, Cytec Industries, The Dow Chemical Company, DuPont, Eka Chemicals, Elementis Specialties, Evonik Degussa Corporation, Honeywell, Oxonica, PPG Industries, Inc., Procter & Gamble, Rohm and Haas Company, and Sasol North America, Inc.,

nanotechnology research across dozens of federal agencies. This task necessarily requires a prioritized research strategy that clearly delineates the roles of the participating federal agencies. It is clear, however, from the August 2007 draft report of the Nanotechnology Environmental and Health Implications (NEHI) Working Group, *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials,* that the current priority setting process is slow and incomplete.

We applaud that part of the August 2007 NEHI Working Group's draft report that focused the EHS research priorities from 75 to a more manageable 25. However, the criteria for reducing these priorities were not fully articulated. Nor is it clear how the 25 priorities fit together into a cohesive strategy. Moreover, the draft report does not articulate the research roles of each participating federal agency.

The Panel is disappointed that there is no correlation of the 25 identified research areas to risk management or "urgently" needed research. We encourage NEHI to complete quickly the prioritization of the identified research areas, complete the final research strategy, and initiate the top priority projects. Specific projects need to be identified with annual funding requirements and realistic deliverables. At the Working Group's present pace, others will be establishing a coherent research strategy for implementation by the various federal agencies without the involvement or perspective of all NEHI members.

A high quality, comprehensive and prioritized EHS research agenda is still missing and should:

- Focus on risk assessments, and the generation and application of information on the continuum of exposure, dose and response;
- Promote new interdisciplinary partnerships that bring visionary thinking to research on nanotechnology;
- Support better understanding of the fundamental properties of nanomaterials that have an impact in the exposure-dose-response paradigm including the key properties of:
    1. Size and size distribution;
    2. Surface area of the primary particle;
    3. Shape of the primary particle;
    4. Chemical composition of the material;
    5. Agglomeration state in the medium used to treat the test system;
- Develop processes for establishing validated standard measurement protocols so that individual or categories of materials can be studied;
- Clearly delineate the responsibilities, programs, timelines, and anticipated results of funded projects for each federal agency. For example, the

National Institute for Standards and Technology (NIST) should take responsibility for identifying what reference nanoscale materials should be developed and manage their development. EPA should be responsible for developing and evaluating methods to assess exposure to and potential effects of exposure to nanoscale materials. The Food and Drug Administration (FDA) and the National Institute for Occupational Safety and Health (NIOSH) should focus their research efforts on understanding the absorption and transport of nanoscale materials in the human body, and better utilize industry's research experience prior to making final research priority recommendations. To date, industry's role has been largely restricted to passive review of decisions already made. Industry's considerable experience could be better utilized by being actively engaged earlier in the process; and

- Leverage planned and ongoing work by the Organization for Economic Cooperation and Development's (OECD) Working Party on Manufactured Nanomaterials, particularly in identifying on-going or planned research projects by other countries and interpreting the results of this research, and the testing of representative nanomaterials using standard test methods to assess potential health or environmental hazards.

In addition, the NNI should consider compiling a list of ongoing and completed EHS research or support activities already under way such as at the International Council on Nanotechnology (ICON). This list should be updated regularly and made publicly available to ensure important research is communicated timely and accurately. The public would also benefit from the NNI ensuring that databases on consumer products believed to contain nanomaterials are accurate.

ACC has communicated at length with EPA, NIOSH, and other parties on information that could be assisted by EHS research projects and would be useful in the near term. These research issues include the following items:

- Information on the handling of nanomaterials in dry forms and potential exposures to users incorporating nanomaterials into product applications;
- Information on environmental releases related to the production or use of nanomaterials- air, water, and solid waste potential exposures unique to nanomaterials and risk management methods;
- Information on the fate and transport mechanisms for nanomaterials in the environment;
- Information on hazards of nanomaterials- basic and acute data supplemented as appropriate by a tiered decision-making structure for further testing;
- Information leading to the development of workplace practice guidelines; and

- Information on the explosion hazard potential that has been alleged with some nanomaterials.

Within the most recent NEHI report, ACC agrees with the 25 identified research areas within the five research categories identified by the Working Group. Within Category #1, the Panel specifically believes that Projects 1, 2, and 5 are high priority research areas. The Panel notes that all the projects in Category #2 were considered by the Working Group to be equal in priority. The Panel agrees with this assessment since these research areas are likely to be inter-related.

The Working Group identified five priorities for Category #3-Nanomaterials and the Environment. In its January, 2007 comments, the Panel noted the importance of research on environmental transport and fate of nanomaterials. The Panel recommends that projects 4 and 5 dealing with transport and fate receive the highest priority. Category #4 covers health and environmental exposure assessment and includes research projects currently underway. The Panel encourages the Working Group to consider the pilot studies underway by NIOSH that are designed to characterize worker exposure and better understand workplace processes and factors that determine occupational exposure to nanomaterials. Risk management methods are addressed in Category #5, and the Panel notes that the Working Group established priorities for each of the five identified areas. The Panel believes that all five areas are important research priorities, but notes that accurately communicating information on the hazards from and potential exposure to nanomaterials should remain a top priority.

II. The Panel Urges as an Appropriate Next Step the Funding of An Independent Review by the National Research Council Board of Environmental Studies and Toxicology (BEST) to Establish EHS Research Priorities for Manufactured Nanomaterials and a Substantial Increase In Federal Funding of EHS Programs for Manufactured Nanomaterials

The Panel believes that the National Academy of Sciences' Board of Environmental Studies and Toxicology (BEST) has an important role to play in completing the "next steps" articulated in the NEHI Working Group's report. On February 22, 2007, ACC, along with 18 organizations requested that Congress appropriate $1 million for BEST to develop a roadmap for federal EHS research projects and set priorities suitable for federal funding (letter appended to this statement). This funding would enable BEST to develop a roadmap and strategy for the federal government for environmental, health, and safety research needed to help support the safe development and use of nanoscale materials and nanotechnologies.

At current funding levels, only a small percentage of the NNI funds have been directed to environmental, health, and safety research. Moreover, the federal budget at other agencies with a significant interest in nanotechnology, such as EPA and NIOSH, is inadequate in light of the enormity of the task at hand. The Panel believes that a more appropriate balance is needed between the funding of potential health effects studies and environmental studies. In general, the Panel believes that approximately 5-10% of the overall NNI budget should be focused on EHS research projects on an annual basis. This range is consistent with the range of funding private industry devotes to research and development. Additionally, more funds should be directed to environmental exposure research.

Until appropriate metrics are developed (as part of a comprehensive research strategy) to measure the results of the EHS research funding, a specific multi-year timetable for funding is premature. The research strategy should be sufficiently flexible to take into account results from completed research, address information gaps that may arise, and be adjusted so that projects are not continually funded.

III. Identifying and Minimizing Potential Health and Environmental Risks is Consistent with the Responsible Development of Nanotechnology

ACC's Nanotechnology Panel member companies are committed to support and actively promote the safe manufacture and use of the products of nanotechnology, consistent with the ACC's Responsible Care® program – a set of ethical principles and management systems, now nearing its 20th year, designed to improve continuously its member companies' safety, health and environmental performance. This long-established program helps guide the Panel members' approach to the development of nanotechnology, just as it does for more conventional and better understood industrial chemicals and processes.

ACC and the member companies of its Nanotechnology Panel strongly support EPA's planned Nanomaterials Stewardship Program (NMSP). Information gained under the NMSP, along with occupational exposure information gained by NIOSH, supporting research of other federal agencies, and information from international bodies such as OECD, will assist in prioritizing EHS research projects for the foreseeable future.

IV. Conclusion

In closing, ACC would like to emphasize the importance of significant and sustained federal support for developing and implementing a comprehensive nanotechnology research strategy, particularly in areas of worker safety, human health, and the environment. Federal government support for a comprehensive EHS research agenda is essential to the sustained and responsible development of nanotechnology.

ACC urges that the prioritization process for EHS research be completed expeditiously and that BEST be funded to complete a research roadmap and strategy.

While the foundation for this important process has been established, NNI must complete its task with a renewed sense of urgency.