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National Nanotechnology Coordination Office

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Subject: ENVIRON comments on “Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials”

On behalf of ENVIRON International Corporation (ENVIRON), I am pleased to have the opportunity to provide comments to the National Nanotechnology Coordination Office (NNCO), which on behalf of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the Committee on Technology, National Science and Technology Council (NSTC), held a public meeting January 4, 2007 in Arlington, Virginia. Because ENVIRON representatives were unable to attend this meeting, we would like to submit comments regarding the prioritization of research needs, which were described in the September, 2006 document “Environmental, Health, and Safety (EHS) Research Needs for Engineered Nanoscale Materials.”

ENVIRON International Corporation (ENVIRON)

ENVIRON provides state-of-the-art strategic risk management and technical consulting services addressing a broad range of human health and environmental risk issues related to the presence of chemicals in the environment; in foods, drugs, medical devices, and consumer products; and in the workplace; as well as business issues related to the development and use of energy and environmental technologies. Practicing from a global network of offices in the Americas, Europe, Asia, and Australia, our professional staff represents a wide variety of engineering, scientific, public health, and regulatory affairs disciplines.

ENVIRON professionals in a number of areas (including epidemiology, toxicology, ecotoxicology, occupational health, industrial hygiene, environmental health) have formed a multidisciplinary team of experts to evaluate and address important health and

safety concerns surrounding the introduction of new nanotechnological products and processes. We have worked with and discussed with a number of companies, trade organizations, academic groups, law firms, government and non-governmental agencies the health, safety and environmental challenges that they face in keeping the workforce and the public safe.

From the position of decades of problem-solving experience, combined with a commitment over the last several years to remaining current on nanotechnology-related issues, developing practical approaches to environmental and human health concerns, and monitoring relevant standards and policy developments, we offer the suggestions below for a strategy to prioritize the National research agenda for EHS research needs.

Comments on the EHS Research Needs Document

“Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials” outlines a number of research needs in separate chapters – or categories, such as instrumentation and analytical methods, nanomaterials and human health, nanomaterials and the environment, surveillance, and risk management. However, the research priorities cannot be viewed as mutually exclusive categories – understanding what we know now, and what we need to know to protect workers (including technicians, maintenance workers, shippers, and handlers) and the public, should be coordinated to drive research priorities. That is, the research questions need to be tied together using an overarching approach or framework, such as the life cycle of production, use and disposal of the nanoscale materials, to fill in the knowledge gaps through focused research. Moving forward the development of the life cycle framework – including development of life cycle research methods and life cycle research applications would facilitate guidance for “real world” applications of the research findings. Above all, developing effective tools for communication is critical – and dissemination of the information needs to be part of the development process.

Within the framework of the life cycle of engineered nanoscale materials, we suggest that the research needs fall into two “high priority” categories:

- addressing the immediate concerns for the workers, public, and environment
- setting the stage now for the longer-term research agenda

Addressing immediate concerns for workers, public and environment

The research questions suggested in the report are of great interest and importance – however, within the lifecycle framework, answering the questions in logical increments will build the knowledge base. From the perspective of the stakeholders with whom we work, examples of relevant questions that need answers now, but cannot be answered by the current state of EHS research finding include:

- Why should I worry about free nanoscale materials – I receive and use them in a solution?
- Why should I worry about free nanoscale materials? All of our work with nanoscale materials is conducted in an “enclosed” environment.
- How do we know if the engineering controls currently in place are effective?
- Is personal protective equipment (PPE) necessary?
- If necessary, is the PPE currently used effective?
- What tools and equipment are most appropriate to measure “free” or unbound nanoscale materials in the workplace?
- If we measure for nanomaterials, how do we interpret what we measure?
- How are the findings from toxicological studies meaningful to my employees?
- How do I communicate to my employees whether they are at risk for any adverse health outcomes?
- How do I communicate to my employees why they should take certain precautions in the workplace, if there are no known risks?
- How do I convey to the public that there are no risks from using our products that contain nanoscale materials?
- What should I think about when disposing of nanomaterials?
- If we cannot measure nanomaterials in the workplace, how can we measure them in the environment?

- If the nanoparticles in my product are inextricably bound to each other or to another material, then why is there a concern for the public or environment?
- What are the explosive, flammability or reactivity hazards of processing and storing nanoscale materials?

Although the answers to these questions may not currently be available, there are approaches to safe handling of nanoscale materials, which have been recommended by National Institute of Occupational Health and Safety (NIOSH), including implementation of control banding approaches that are often employed in the pharmaceutical industry for handling materials with little or no information on the risks. Focused and relevant research findings that answer the questions and issues currently raised in the workplace are likely to lead to modifications that can improve and refine current guidance.

The report does not specifically address research questions that evaluate whether nanomaterials adversely affect equipment (e.g., production, containment, PPE) in ways that may impact possible exposures received by the technicians, maintenance workers, or environment. Thus, as a form of “primary prevention” research questions addressing whether engineering controls and equipment are adequate and meet expectation might be considered among the high priority recommendations.

Setting the stage now for the longer-term research agenda

One of the most critical pieces of the research agenda is setting the stage now for research on nanoscale materials that may be needed in the future. This need relates to epidemiological studies – which cannot yet be conducted, because there is no understanding of which outcomes may be important. However, research efforts focused on developing a national – or even better – an international database to define who is working with what materials, where and when, would allow for epidemiological research to be conducted in the future, with a cohort of workers defined now. While this cannot be accomplished immediately, identifying specific data elements that would become necessary in order to conduct a large, well focused epidemiological study (or even an emergency investigation after a widespread exposure or accident scenario) could be defined now and data structures and databases created. Once exposure metrics are

available for nanoscale materials, “modules” could be added to this database structure that includes exposure data, as well. The advantages of collecting such information now, for use in the future, are enormous. NIOSH has extensive experience in surveillance methods, and would be critical to the development of such an approach.

Conclusion

In the process of finalizing the research priorities, the perspective and needs of industry, the legal community, the insurers, and financiers should be considered. Research should not be conducted just for the sake of generating findings – it needs to be focused and relevant to ultimately protecting the workforce, the public, and the environment. Actively engaging the stakeholders in this prioritization is critical – as is encouraging those who work with these materials to participate in developing the knowledge-base.

Thank you for this opportunity to comment on this important document. Please do not hesitate to contact me to further clarify or discuss these suggested priorities.

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