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From: West, Jay [Jay_West@americanchemistry.com]
Sent: Friday, April 15, 2011 2:20 PM
To: NIOSH Docket Office (CDC)
Subject: Docket NIOSH 134-A | Comments
Attachments: ACC Nano Panel NIOSH Research Strategy 20110415_FINAL.pdf

Please find attached comments from the Nanotechnology Panel of the American Chemistry Council in response to the *Request for Information: Update of NIOSH Nanotechnology Strategic Plan for Research and Guidance* (docket NIOSH 134-A) published in the March 7, 2011 *Federal Register*. The Panel appreciates this opportunity to provide its perspective on the update process. Please contact me if you have any questions.

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April 15, 2011

RE: Docket NIOSH 134-A

SUBMITTED BY ELECTRONIC MAIL TO: NIOSHDOCKET@CDC.GOV

The Nanotechnology Panel of the American Chemistry Council (ACC) welcomes the opportunity to provide our perspective on updating NIOSH's strategic plan for identifying and prioritizing nanotechnology research.¹ Research by federal agencies like NIOSH is important to answering questions about the safety of nanomaterials in the workplace—questions that are key to the acceptance of this new technology. In general, the Panel finds the current strategy to be very broad, encompassing many safety questions, including both inherent hazards and workplace concerns. The Panel feels that such an expansive program is not in the best interests of NIOSH for a number of reasons:

1. NIOSH should focus on immediate needs of the workplace;
2. The strategy unnecessarily duplicates the activities of other agencies, both inside and outside the US; and
3. The broad nature of the program dilutes NIOSH's resources (both human and financial) and thus makes completion of research initiatives more difficult.

The Panel suggests that NIOSH should include fewer areas in the updated plan and concentrate on workplace concerns. In so doing, the Panel feels that NIOSH would better position itself as the world leader in developing methods, practices, and instrumentation that are valuable for the workplace. The remainder of these comments offers the Panel's suggestions on how specific goals listed in the current strategy should be considered in the update process.

Section 4. Goals.

The Panel feels that among the four strategic goals listed in the current research strategy, Strategic Goal 3 (*Promote healthy workplaces through interventions, recommendations, and*

¹ *Strategic Plan for NIOSH Nanotechnology Research and Guidance: Filling the Gaps*. February 28, 2008 (update). http://www.cdc.gov/niosh/topics/nanotech/pdfs/NIOSH_Nanotech_Strategic_Plan.pdf.

Members of the ACC Nanotechnology Panel include 3M, Arch Chemicals, Arkema Inc., BASF Corporation, Bayer MaterialScience, Cabot Corporation, Cytec Industries, The Dow Chemical Company, DuPont, Evonik Degussa Corporation, Ferro Corporation, and Procter & Gamble.

The American Chemistry Council (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 \$674 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.



capacity building; page 20) should be the top priority (although it is not entirely clear what is meant by “capacity building”). The individual goals under Strategic Goal 3 clearly identify the areas where NIOSH can establish itself as the global leader. Such leadership is necessary because other countries have proposed addressing many of the issues listed in the individual goals (e.g., material safety data sheet format and language and managing exposure through control banding, best practices, and efficacy of personal protective equipment) in international fora such as ISO, and the absence of NIOSH guidance leads to a perceived void. Without NIOSH recommendations, other countries may set international standards that U.S. entities could be compelled to adopt without the benefit of having our own expert federal agency’s input.

Furthermore, one of the goals under Strategy Goal 3 is to “*Update occupational exposure limits (OELs) as appropriate for nanomaterials.*” The Panel feels that NIOSH should be leading a global effort to establish an OEL process for nanomaterials rather than simply updating procedures that are applicable to soluble chemicals, but may be irrelevant for nanoparticles. NIOSH could satisfy Strategic Goal 4 (*Enhance global workplace safety and health through national and international collaborations on nanotechnology research and guidance*) through such an initiative. Also, it would be helpful to explain how NIOSH intends to work with OSHA to create OELs for nanomaterials.

The Panel feels that Strategic Goals 1 and 2 in the current strategy should be removed from an updated strategy. Strategic Goal 1 (*Determine if nanoparticles and nanomaterials pose risks for work-related injuries and illness*) is focused on hazard identification research. While the Panel acknowledges the outstanding science generated by NIOSH, other agencies nationally and internationally are committed to nanomaterial hazard identification (e.g., National Toxicology Program, EPA, FDA, OECD, JRC). To have NIOSH use valuable resources in addition to these other agencies seems duplicative and unnecessary. Further, the value of Strategic Goal 2 (*Conduct research to prevent work-related injuries and illnesses by applying nanotechnology products*) is unclear because injuries associated with use of nanomaterials in the workplace have not been documented.

In summary, the Panel urges NIOSH to focus its strategic research plan on questions of exposure assessment, risk characterization, and risk management (the last 3 steps of Figure 3, page 23, in the current strategy). Hazard identification and characterization should be left to the numerous federal and international agencies already focusing on those areas. Refining NIOSH’s research focus in this way would improve the ability of NIOSH to complete the types of activities listed in the Intermediate Goals (section 4.3) in a shorter time frame than the 3-5 years envisioned in the current strategy’s performance measures.

Section 4.3. Intermediate Goals and Performance Measures.

Consistent with the comments above on reconsidering the current strategy’s Strategic Goals, the Panel offers the following comments on some of the current strategy’s Intermediate Goals:

- Section 4.3.2, Toxicity and Internal Dose, should be removed. It focuses on carbon nanotubes, a material that has very limited manufacture in the U.S., and it focuses on research areas (e.g., predictive toxicology) that are already addressed by other agencies.
- In the updated plan, activities consistent with Section 4.3.3, Epidemiology and Surveillance, in the current plan should strive for more definitive conclusions. Each Intermediate Goal in this section appears to be an evaluation rather than establishing a true guidance. NIOSH has heard from a wide variety of stakeholders on a number of issues concerning epidemiology and surveillance, and it may be time to move beyond the "Interim Guidance" stage, assuming that there is something of value to evaluate in the medical screening. The Panel also notes here an opportunity for NIOSH to partner with NIST on research related to analytical methodologies for workplace monitoring.
- The order of the two Intermediate Goals in Section 4.3.4, Risk Assessment, should be reversed. NIOSH cannot evaluate studies with the goal of completing a quantitative risk assessment without first establishing a risk assessment framework to guide the process.
- Section 4.3.5, Measurement Methods, should be a very high priority for NIOSH. The agency has acknowledged that measurement of nanomaterials in the workplace suffers from crude instrumentation, laboratory methods, or overly sophisticated methods that are not applicable to the workplace. This area would clearly benefit from NIOSH leadership.
- Intermediate Goal 6.6 (Substitute materials) should be deleted because it is outside NIOSH's scope.

Thank you for the opportunity to provide our perspective on key considerations for updating NIOSH's nanotechnology research strategy. While the Panel acknowledges NIOSH's contribution to the responsible development and, ultimately, public acceptance of nanotechnology, we believe that an updated document should focus on activities related to exposure assessment, risk characterization, and risk management, leaving hazard identification and characterization to other federal and international agencies already pursuing such work. We urge NIOSH to consider our suggestions. Please contact me if you have any questions.

Sincerely,



Jay West
Senior Director, Chemical Products and Technology Division
ACC Nanotechnology Panel