

Ensuring appropriate material characterization in nano-toxicity studies

A Workshop

October 28-29, 2008

Woodrow Wilson International Center for Scholars
1300 Pennsylvania Avenue NW
Washington, DC 20004-3027

Synopsis

Overview: Poor or inadequate material characterization is a major barrier to interpreting and comparing studies addressing the human or ecological toxicity of engineered nanomaterials.

Aims: The aims of this workshop are twofold:

- To develop minimal material characterization recommendations for nano-toxicology studies; and
- To develop a plan of action for encouraging adoption of these recommendations by researchers, research managers and research publishers.

Activities: The first day of the workshop will address the rationale for developing materials characterization requirements, the scope of the meeting, minimal material characterization requirements, and approaches to ranking the quality of characterization in nanotoxicology studies.

The second day of the workshop will address engaging relevant communities, including researchers, research managers, and journal editors.

Outcomes: The outcome will be a set of recommendations on material characterization in nanotoxicity studies, clarification of the scope and limitations of the recommendations, a plan of action for engaging relevant communities, and provisions for reviewing both the recommendations and the engagement plan. These will represent the consensus of the workshop attendees. Participation in the meeting will *not* constitute endorsement of the findings and conclusions.

Scope: The workshop will *not* develop characterization requirements for regulatory purposes. Neither will it address future information unification, collation and dissemination requirements. These are important goals that nevertheless lie outside the scope of the current workshop. However, it is intended that the outcomes of the workshop contribute to a growing awareness of the importance of appropriate characterization in nanotoxicology research that will underpin future developments.

History of the Workshop: *Characterization of nanomaterials has been on the minds of many nanotechnologists for some time. In 2004, a workshop sponsored by the National Toxicology Program (NTP), National Science Foundation, the U.S. Environmental Protection Agency, the Air Force Office of Scientific Research, and the University of Florida stressed the need for appropriate and accurate characterization of nanomaterials in toxicology studies. At a workshop held at National Institute of Standards and Technology (NIST) in 2006, a similar message from a series of speakers resonated with a number of participants from government, academia, and industry, who were thinking along the same lines. This small group took advantage of the coincidence of being in the same place and started planning how to work together and how to engage other influential nanotechnologists on how to improve characterization quality. The result is this workshop, which brings interested experts from a diverse range of backgrounds to address the central issue of raising the quality of research surrounding the potential toxicity of nanomaterials.*

Organizers: *While the meeting is being hosted by the Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies (PEN), this workshop has been initiated and organized from within the nanomaterial toxicology research and testing community. A list of individuals involved in its organization is included at the end of this document.*

Draft Agenda

(as of 9/19/08)

Day 1

9:00-9:15AM	<p>Introduction</p> <p><i>a) Why we are here, who is at the table, what the workshop will not achieve</i></p>	<p>Andrew Maynard (PEN) Shaun Clancy (Evonik)</p>
9:15-9:30AM	<p>Statement of objectives</p> <p><i>a) To develop minimal material characterization recommendations for nano-toxicology studies;</i></p> <p><i>b) To develop a plan of action for encouraging adoption of these recommendations by researchers, research managers and research publishers.</i></p>	<p>Andrew Maynard (PEN) Ray David (BASF)</p>
9:30-10:50AM (20 minutes for each)	<p>The need for minimal characterization recommendations</p> <p><i>a) Examples of poorly conducted studies</i></p> <p><i>b) Lessons from MIAME; needs of regulatory community (OECD/EPA)</i></p> <p><i>c) Conflicting results from studies in which materials were not well characterized</i></p> <p><i>d) Characteristics which may be important for predicting biological activity</i></p>	<p>Nigel Walker (NTP)</p> <p>Ray David (BASF) David Warheit (DuPont) Darrell Boverhoff (Dow) Fred Klaessig (Evonik) David Warheit (DuPont)</p>
10:50-11:00AM	Break	
11:00AM-12:00PM	<p>A minimal set of characterization parameters</p> <p><i>a) Previous recommendations: Florida meeting (need reference); Oberdorster et al, 2005; Powers et al, 2006; OECD; ISO; Warheit, 2008; others...</i></p> <p><i>b) A straw proposal – based on Warheit 2008.</i></p>	<p>Nigel Walker (NTP) Rick Canady (FDA) Shaun Clancy (Evonik) Alecks Stefaniak (NIOSH)</p>
12:00-1:00PM	Lunch	
1:00-2:00PM	<p>Breakout groups to discuss:</p> <p><i>a) Pros and cons of minimal sets/desirability</i></p> <p><i>b) Additions or deletions</i></p>	
2:00-2:45PM	Plenary Discussion	
2:45-3:00PM	Break	
3:00-4:00PM	<p>Ranking studies according to the degree of characterization</p> <p><i>a) Why is ranking necessary? (complexities of appropriate characterization, nuanced and rapid assessment of quality of research)</i></p>	<p>Fred Klaessig (Evonik) Ray David (BASF)</p>

	<ul style="list-style-type: none"> b) <i>Straw proposal—the ‘Clancy’ score</i> c) <i>Implementing a ranking scheme</i> 	
4:00-5:00PM	<p>Overcoming barriers to carrying out minimal materials characterization</p> <ul style="list-style-type: none"> a) <i>Methodology resources</i> b) <i>Access to instruments/techniques</i> c) <i>Partners</i> d) <i>Reference/certified materials (NIST)</i> 	<p>Anil Patri (NIH) Aleks Stefaniak (NIOSH) Sally Tinkle (NIEHS) Laurie Locascio (NIST)</p>
5:00-5:30PM	Summary of progress, and preparation for day two-engagement and dissemination	Andrew Maynard (PEN)
6:30-9:00PM	<p>Dinner – Old Ebbitt Grill (to be confirmed)</p> <p><i>(Sponsored by ACC Nanotechnology Panel and Evonik)</i></p>	All
Day 2		
9:00-9:30AM	Recap and goals for day 2	Andrew Maynard (PEN)
9:30-10:45AM	<p>Discussion: Engaging Stakeholders</p> <ul style="list-style-type: none"> 1) Academics <ul style="list-style-type: none"> a) <i>Motivating investigators – incentives and barriers</i> b) <i>Roles of overarching organizations – ICON, professional societies etc.</i> 2) Program managers/government <ul style="list-style-type: none"> a) <i>Integrating adequate characterization into study designs</i> 3) Industry <ul style="list-style-type: none"> a) <i>Issues specific to industry-funded research</i> 4) Journal editors <ul style="list-style-type: none"> a) <i>Motivating journals and editors to require adequate characterization.</i> b) <i>Ranking journals by the quality of materials characterization in nanotoxicology studies</i> c) <i>Who and how?</i> 	<p>Darrell Boverhof (Dow)</p> <p>Steve Klaine (Clemson)</p> <p>Rick Canady (FDA)</p> <p>Nigel Walker (NTP)</p>
10:45-11:00AM	Break	
11:00AM-12:00PM	<p>Developing an action plan</p> <ul style="list-style-type: none"> a) <i>Dissemination of recommendations</i> b) <i>Measures of success</i> c) <i>Decision points for future actions</i> 	<p>Andrew Maynard (PEN) Ray David (BASF)</p>

12:00-1:00PM	Working Lunch	
1:00 PM-1:30 PM	Developing an action plan (continued)	
1:30 PM-3:00 PM	<p>Future Steps</p> <p><i>a) Relevance to materials characterization for regulatory purposes</i></p> <p><i>b) Characterization information unification, collation and dissemination—relevance of the Nanoparticle Information Library, and other resources</i></p> <p><i>c) Expanding minimal characterization recommendations—where next?</i></p>	<p>Andrew Maynard (PEN)</p> <p>Ray David (BASF)</p> <p>Shaun Clancy (Evonik)</p> <p>Nigel Walker (NTP)</p>
3:30 PM	Break/Adjourn	

Organizers

D. Boverhof, The Dow Chemical Company
S. Clancy, Evonik Industries
V. Colvin, ICON
R. David, BASF Corporation
M. Hoover, NIOSH
S. Klaine, Clemson University
A. Maynard, Woodrow Wilson Institute
N. Walker, NTP/NIEHS
D. Warheit, DuPont