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HESI Nanomaterial Environmental, Health and Safety Project Committee

<u>Chair</u>: Raymond M. David, PhD, DABT (BASF Corporation)

Vice-Chair:

Hon-Wing Leung, PhD, DABT, CIH (Arkema Inc.)

January 19, 2009, Assembly of Members Meeting HESI Annual Meeting Tucson, AZ



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2008 Participation

INDUSTRY

Arkema BASF Coca-Cola Dow Chemical L'Oreal Procter & Gamble

PUBLIC

CDC National Institute of Occupational Safety and Health (NIOSH) East Carolina University NIH National Institute of Environmental Health Sciences (NIEHS) North Carolina State University University of Rochester US Consumer Product Safety Commission (CPSC) US Environmental Protection Agency US Food and Drug Administration



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Project Goals

- Determine the current knowledge-base and research needs for toxicology and safety evaluations of engineered nanomaterials.
- Identify unresolved scientific issues, research needs, and/or data gaps that would facilitate the development of a comprehensive risk assessment for nanomaterials.
- Develop a better understanding of the fundamental behavior of nanomaterials.



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Eight-Part Series in Toxicological Sciences (2005-2006)

Research strategies for safety evaluation of nanomaterials:

- **1.** Human health implications of exposure
- 2. Toxicological and safety evaluation
- **3.** Nanoscale technologies
- 4. Risk assessment of nanoparticles
- 5. Role of dissolution in biological fate and effects of nanoscale particles
- 6. Characterization of nanoscale particles
- 7. Consumer exposure
- 8. International efforts to develop risk-based safety evaluations



Research Objectives

- Explore human health effects associated with pulmonary exposure to the same wellcharacterized materials in *in vivo* and *in vitro* test systems.
- Evaluate the distribution and fate of nanomaterials in biological systems.
- Multi-sector consortium established to conduct research.



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Pulmonary Toxicity Studies: In Vivo

Materials

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- Titanium dioxide (TiO₂)
- > multi-walled carbon nanotubes (MWCNT)
- carbon black

Routes of Administration (rat)

- Nose-only inhalation chamber (BASF)
- Pharyngeal aspiration (NIOSH)
- Exposure levels were consistent from test system to test system.

Results

Slight differences were observed in responses to different nanoparticles.



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Fate Studies (Tissue Distribution) Following Systemic or Lung Exposure (Procter & Gamble)

Material

Nanoscale polystyrene fluorescent beads

Routes of Administration (rat)

- > pharyngeal aspiration
- iv injection (systemic exposure)

Results

- Small particles (20 nm) distribute differently from larger ones (100-1000 nm).
- Smaller particles are not as persistent.
- Distribution is route-specific.



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In Vitro Evaluations (East Carolina University)

Material

- ≻ TiO₂
- > MWCNT

Methodology

- Incubation of rat, human lung cells, rat alveolar macrophages, and CHO cells with nanomaterials
- Cytotoxicity and cell proliferation evaluated.

Results

- Differences were observed in response sensitivity between rat and human cell lines.
- There may be differences in response to TiO₂ and MWCNT.



2009 Project Committee Activity

HESI.

Webinar

- February 2009
- "Genotoxicity of Nanomaterials"
- ~ 50 invited participants
- Speakers from BASF and University of Copenhagen



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Project Committee Sunset

- Project Committee has elected to disband, effective March 31, 2009.
- Interested parties are encouraged to submit targeted proposals on nanomaterial safety and toxicity to HESI for consideration via the Emerging Issues process.