Risk Assessment: Informing the Development of Beneficial Nanotechnology

Jo Anne Shatkin, Ph.D.
The Cadmus Group, Inc.

Advancing Beneficial Nanotechnology
Foresight Institute Conference
October 24, 2005
San Francisco, California
Overview

• Why be concerned about nanoscale material impacts?
• The importance of addressing risks now
• Risk assessment: Its not just hazards
• Assessing risks of nanoscale materials
• Adaptive decision framework
Why be concerned about nanomaterial impacts?

• Novel properties
• History dictates action
• Technology advancing quickly
• Paucity of information
• Potential for wide dispersion in the environment amidst uncertainty
• No standards - yet!
GENETICALLY-MODIFIED FOODS
ARE THEY SAFE?

Safe? Compared to what?
Are any foods guaranteed safe?
I'd eat them.
Risk is always part of daily life.

I'd like to thank our distinguished panel for their informative remarks.

© 2003 Sidney Harris. Reprinted with permission from Sidney Harris. All rights reserved.

Assessing risks of nanoscale materials

- Identify and characterize hazards
- Assess exposure potential
- Evaluate toxicity
- Characterize risk
- Communicate about risks
Differentiating hazards from risks

- All materials are toxic at some concentration
- There is no risk if there is no exposure
- Risk = hazard * exposure probability
Risk assessment for beneficial nano

Risk assessment:

• Will be the basis for regulatory decision making

• Allows decision making under uncertainty

• Keeps pace with technology

• Prioritizes research directions

• Identifies areas for product innovation

• Reduces potential for unforeseen impacts
Adaptive decision framework

• A screening tool to identify and prioritize health and process issues

• Dynamic approach applies broadly to array of hazards

• Identifies key uncertainties

• Revisits early decisions with new information

• Applies to health and safety concerns
Adaptive decision framework

• Steps sequentially across processes through product lifecycle

• Evaluates risk at each step

• Focuses on exposure potential

• Transparent decision framework allows comparison of different products and processes amidst uncertainty

• Proactive approach for evaluating safety of novel materials
ID AND CHARACTERIZE HAZARDS
ASSESS EXPOSURE
EVALUATE TOXICITY
RAW MATERIALS
Process
PRODUCT
Packaging
USE
CHARACTERIZE RISK
MITIGATION MEASURES

December 14, 05
jshatkin@cadmusgroup.com
Example: SWCNT

Single Walled Carbon Nanotubes
Hazard ID: production processes (laser ablation; HiPCO) closed, but post production exposure possible during packaging.

Exposure Assessment: post production handling personal air sample concentrations ranged from 0.001 - 0.052 mg/m$^3$ (Maynard et al., 2004), particles 1-4 nm

Toxicity Evaluation: inflammatory responses in lung following intratracheal administration at doses approaching OSHA standard for graphite (5 mg/m$^3$) (Shvedova et al., 2005) particle size ~ 100-1000s nm

Risk Characterization: toxic responses possible, exposures appear low by concentration, uncertainties regarding key characteristics suggest caution and better exposure data.
“Look, I’d like to avoid overkill, but not at the risk of underkill.”

© The New Yorker Collection 2001 Robert Mankoff from cartoonbank.com. All rights reserved.