

Strategies for Assessing Nanomaterial Health Risks in Consumer Products

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Growth in Consumer Market

- Lux Research reports 148 global corporations with nanotechnology initiatives today, and projects 290 by 2008
 - \$32 billion dollars in products sold last year
 - \$1 Trillion in 5 – 20 years (Lux Research, NSF)
- Several countries such as Taiwan have growing consumer demand for products with nanotechnology
 - NanoMark Certification
 - Exports to US?

Nanotechnology Implications

- Behavior of bulk versus nanoscale materials raises several questions:
 - Are there potential health effects
 - Public acceptance of a new technology
 - Lessons from other chemicals and technologies

Federal Research Needs Document

Data gaps identified for exposure assessment

- Occupational exposures
- Consumer product use and disposal
- Environmental release
 - Exposures to humans
 - Exposures to organisms in the environment
- Life-cycle analysis

Who is CPSC?

- The U.S. Consumer Product Safety Commission is an independent regulatory agency created in 1973.
- Mission: To protect the public from unreasonable risk of injury and death associated with consumer products.
 - Approximately 420 total employees and \$62 million annual budget
- Technical expertise in the areas of Health Sciences, Engineering, Epidemiology, Human Factors, and Economics.

Regulation of Products

- Jurisdiction over 15,000 types of products used in or around the home
- Regulatory authority extends to such products as: toys, electronic equipment, appliances, clothing/textiles, household cleaners/chemicals, and building materials
- Exceptions include foods, drugs, cosmetics, medical devices, pesticides, certain radioactive materials, and automobiles

Products Containing Nanomaterials

Products claiming to contain nanomaterials

- Reported product categories under CPSC jurisdiction that may contain nanomaterials
 - Sports equipment, clothing and textiles, air deodorizers/cleaners, household chemicals, paints, appliances and building materials
 - Wide variation in potential exposures
- Wilson Center products database identifies over 500 commercial products claiming to contain nanomaterials
 - CPSC, FDA, EPA identified as primary regulatory agencies
 - Woodrow Wilson staff determined that nearly 70% of the selected products were under CPSC jurisdiction
 - Not verified by CPSC staff

Definitions of Toxicity

- CPSC regulates many chemical hazards under the Federal Hazardous Substances Act (FHSA) (15 U.S.C. §§ 1261-1278)
- Under the FHSA, the term "hazardous substance" is defined as:

“Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.”

Exposure and Toxicity

- To be considered a "hazardous substance," a substance or product must satisfy a two-part definition.

It must be "toxic", or present one of the other hazards enumerated in the statute.

It must have the potential to cause "substantial" illness or injury during or as a result of "reasonably foreseeable handling or use."

- Thus, a potential hazard depends on risk (toxicity and exposure).

Chronic Hazard Guidelines (CHG)

- In 1992, the Commission issued guidelines for assessing chronic hazards under the FHSA
- Provides guidance on
 - Assessing exposure
 - Determining toxicity (e.g., carcinogenicity, neurotoxicity, reproductive/developmental toxicity, bioavailability)
 - Acceptable Daily Intake (ADI)
 - Threshold for uptake into body
 - Risk assessment approaches and acceptable risk
- Intended to assist manufacturers in complying with the FHSA

Assessing Potential Health Risks

- **Population estimates**
 - Variation in use patterns, frequency of use, diversity of products, variation in types of housing
- **Human factors evaluation of consumer interaction**
 - Published studies
 - Other agency guidelines (e.g., EPA Exposure Factors Handbook)
 - Professional judgment
- **Best estimate (50th percentile)**
 - Upper (95th percentile) and lower bound (5th percentile) screening
- **Uncertainty** – often assume reasonable worst-case scenario
- **Reasonably foreseeable misuse**
 - Mouthing by young children
 - In the case of lead jewelry, ingestion by children

Estimating Exposure

- Three routes of exposure considered: inhalation, ingestion, dermal
- **Inhalation:** direct monitoring, modeling, surrogate data
- **Ingestion:** extraction with simulated saliva or gastric juices - assume mouthing by children
- **Dermal:** Estimating amount of substance in contact with skin
 - Experiments to quantify material leaching from product
 - Surface area of skin contacted, duration, frequency of contact, thickness of liquid interfacial layer
- **Nanomaterial considerations**
 - Bioavailability, disposition in the body (i.e., blood/brain barrier), excretion and body burden

Exposure and Risk

- Hazard Index (HI) calculated for non-cancer risk
- $HI = \text{average daily dose (ADD)} / \text{acceptable daily intake (ADI)}$
- When HI is greater than one
 - Exposure scenario considered to present a hazard to consumers
- Individual excess cancer risk for carcinogens (R)
 - $R = \text{unit cancer risk (Q)} \times \text{lifetime average daily dose (LADD)}$

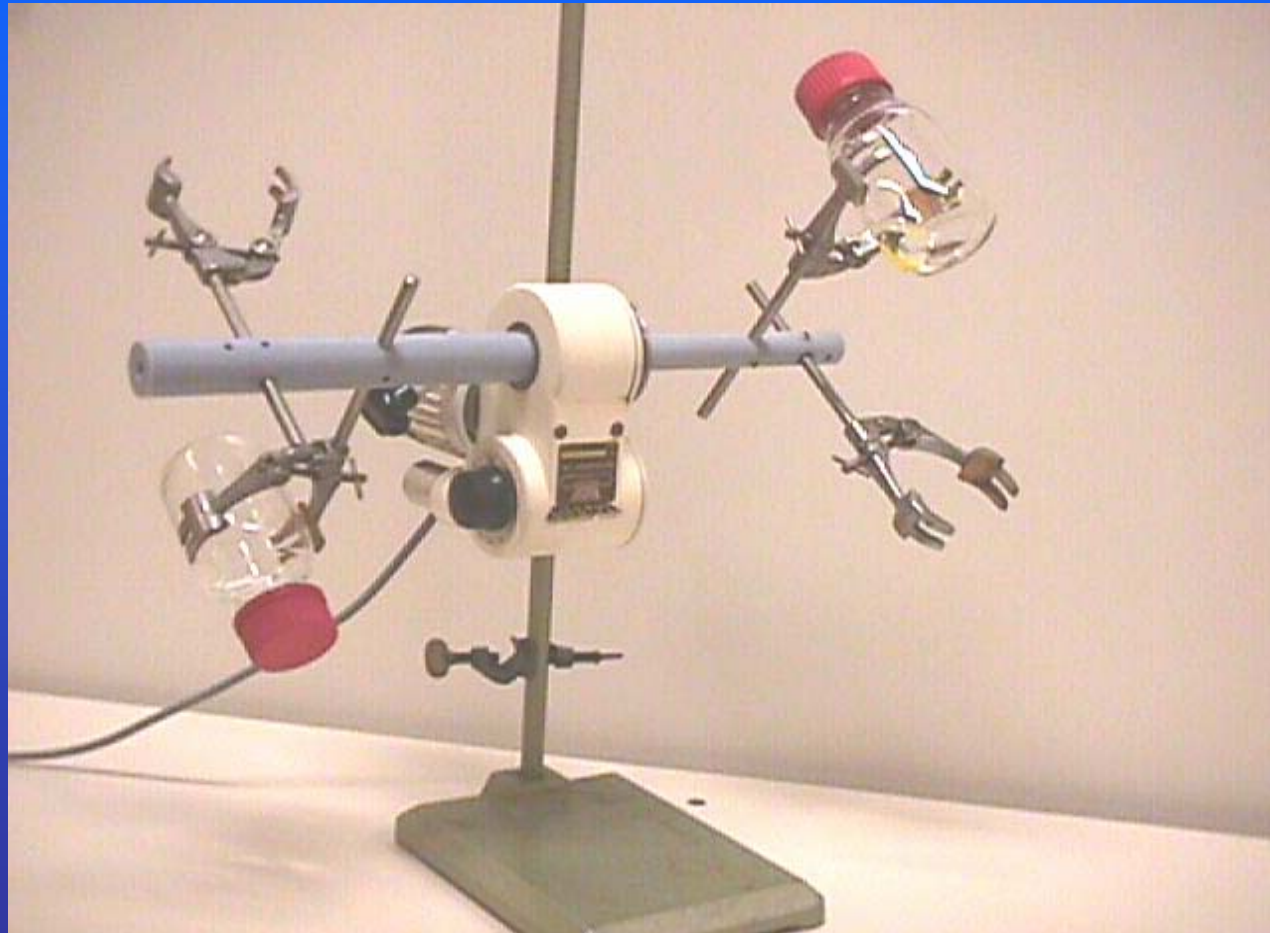
Nano FR Chemicals

- A contractor for CPSC has completed a literature review of nanomaterials that may be used as flame-retardant (FR) chemicals.
 - Physico-chemical properties
 - Exposure and health effects
- Will be posted on the CPSC website for public comment.
- CPSC signed MOU with NIST to review FRs in various products

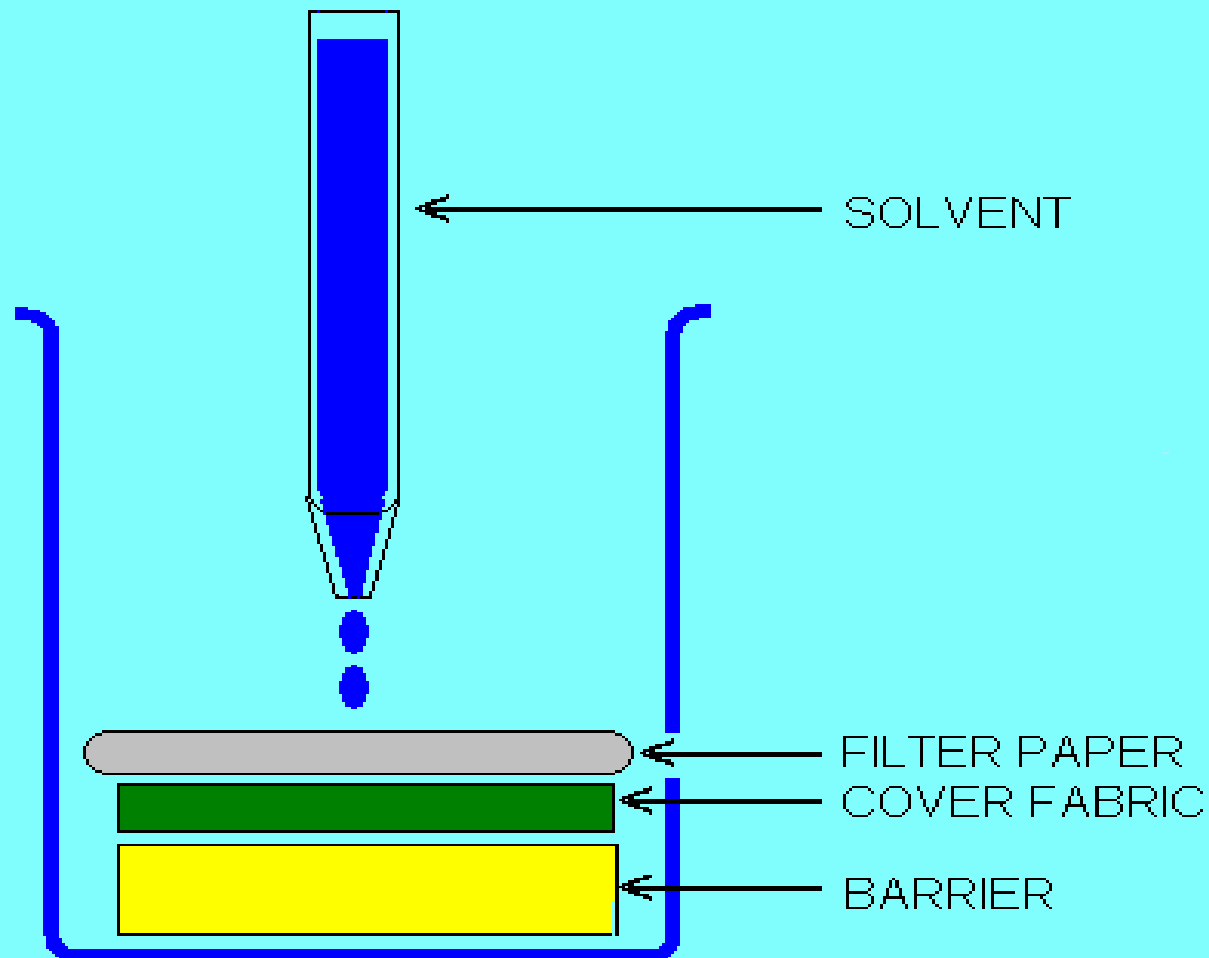
Examples of Exposure Studies

- Mattress flammability standard
 - Concerns over fire-retardant chemical exposure
 - Potential routes of exposure identified (inhalation, ingestion, dermal absorption)
 - Experimental studies to estimate route-specific exposures
 - Calculation of average daily dose (ADD)

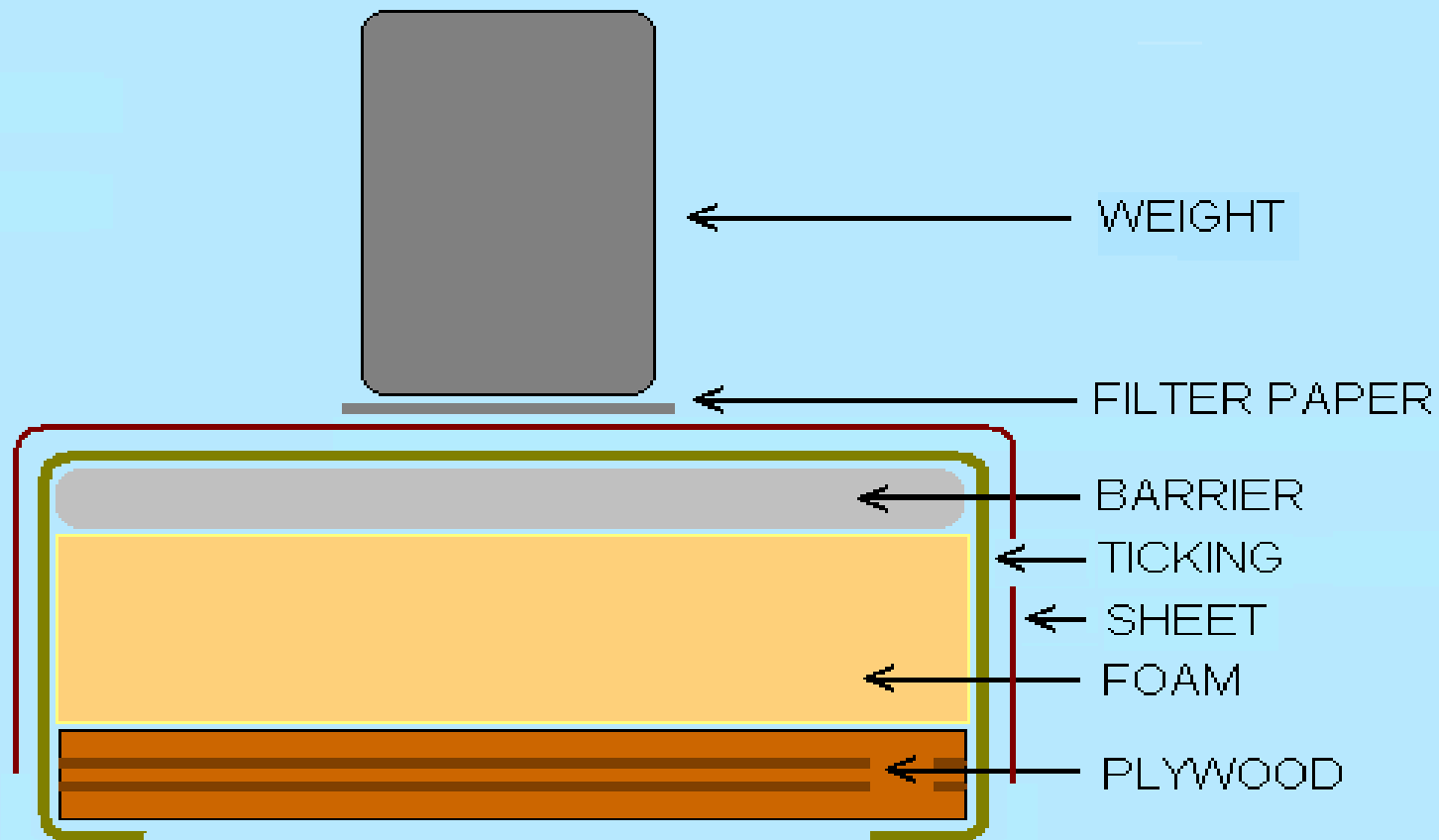
Head-over-Heels Apparatus



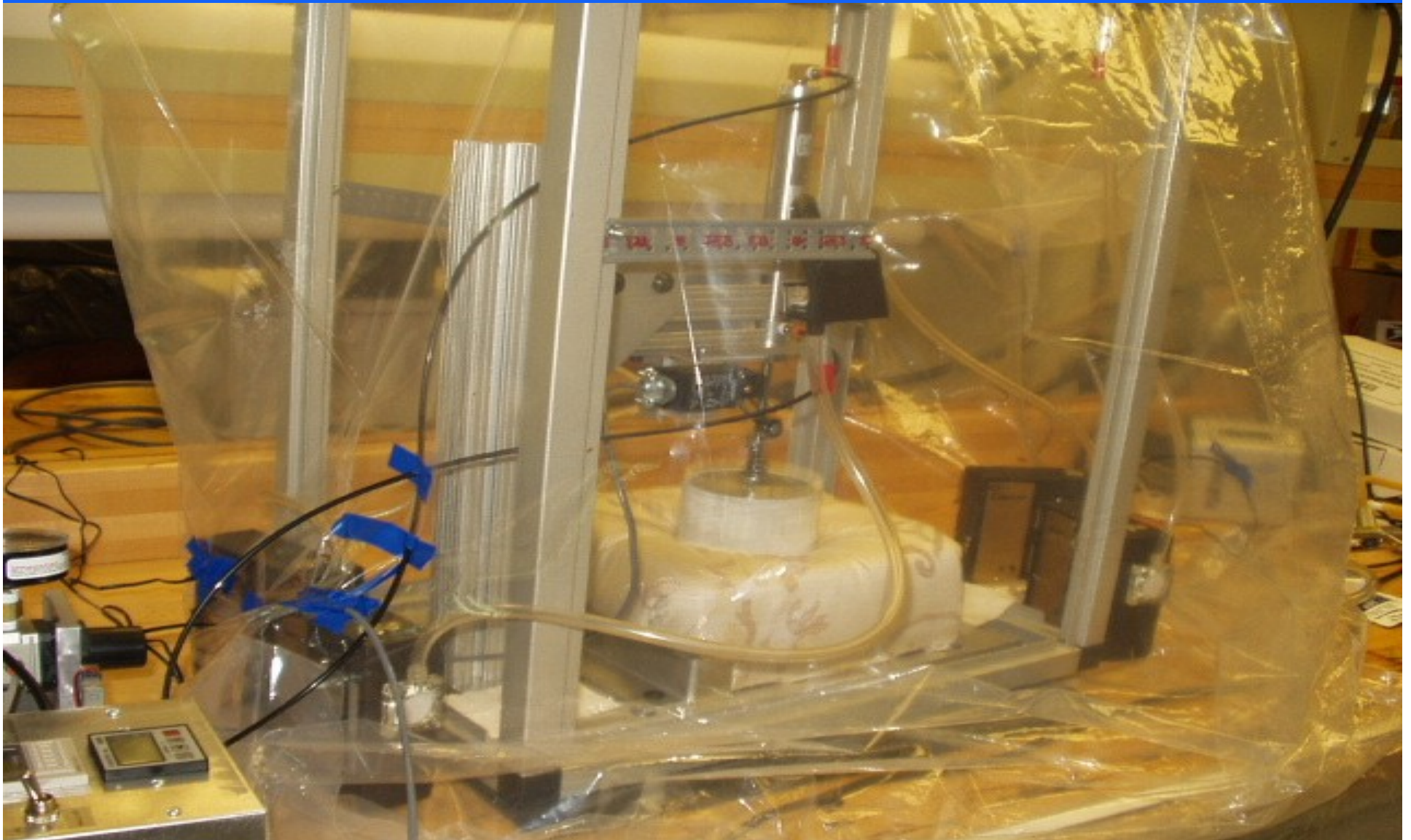
Dermal Exposure



Dermal Exposure Mini Mattress



Inhalation Exposure Study



Possible Exposure and Risk Assessment Approaches

- Toxicity data for nanomaterials in product
 - Calculation of ADI
- Determination and characterization of nanomaterial presence
 - Size distribution, agglomeration
- Is toxicity data relevant for actual nanomaterial exposures?

Data Needs for Exposure and Risk Assessment of Nanomaterials

- Identify consumer products that contain nanomaterials
- Characterize nanomaterials in a consumer product
- Determine size distribution of particles released from products
 - Toxicity data for those sizes - does toxicity change ?
 - Coatings – does toxicity change?
- Instrumentation
 - Development of analytical protocols
 - Feasibility

Summary

- Toxicity and exposure assessment are critical components in assessing potential risks from consumer products
- Approach to regulating products with nanomaterials will likely be similar to approach used to regulate products containing other chemicals
- Need for new toxicity data and exposure assessment (analytical) techniques appropriate for nanomaterials
- Exposure assessment studies needed to determine potential risks from nanomaterials
 - Critical for public acceptance of nanomaterials in products