MEETING LOG

Meeting Dates: Thursday, February 24

Location: American Chemistry Council Headquarters, Arlington, VA

Subject: Presentation to the Stragteic Science Team (SST) of the Long Range Research Initiative (LRRI)

CPSC Attendees: Treye Thomas, Ph.D.

Dr. Treye Thomas, CPSC Directorate for Health Sciences delivered a presentation entitled "**Human Exposure Assessment Strategies for Consumer Products".** The presentation focused on the approaches to exposure assessment of chemicals in consumer products based on the CPSC Chronic Hazard Guidelines.

Human Exposure Assessment Strategies for Consumer Products

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at
Strategic Science Team (SST) of the American Chemistry Council's (ACC) Long-Range Research Initiative (LRI) Meeting
February 24, 2005

The views expressed in this presentation are those of the staff, have not been reviewed or approved by, and do not necessarily represent the view of the U.S. Consumer Product Safety Commission.

Introduction

- 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 460 total employees and $62 million annual budget
- Technical expertise in the areas of Health Sciences, Engineering, Epidemiology, Human Factors, and Economics
- Jurisdiction over 15,000 types of products used in or around the home
- Exceptions include foods, drugs, cosmetics, medical devices, pesticides, certain radioactive materials, products that emit radiation, and automobiles.[i]
- Regulated products include: toys, electronic equipment, appliances, clothing/textiles, household cleaners/chemicals, and building materials.
- CPSC regulates many chemical hazards under the Federal Hazardous Substances Act (FHSA).

[i] 15 USC §1261 (f)(2).

Definitions of Toxicity

- 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." [i]

[i] 15 USC § 1261 (f)(1)(A).

Chronic and Acute Toxicity

- The FHSA includes both acute and chronic effects. Chronic effects include carcinogenicity, neurotoxicity, and reproductive or developmental toxicity,[i] as well as any other persistent effect[ii] such as organ toxicity.
- Acute toxicity is defined in regulations issued under the FHSA.[iii] For example, a substance is considered "highly" toxic if it has an oral LD50 of 50 mg/kg or less, and "toxic" if it has an oral LD50 between 50 mg/kg and 5 g/kg. Definitions are also provided for inhalation and dermal routes of exposure.

[i] 16 CFR § 1500.3 (c)(2)(ii).
[ii] U.S. Consumer Product Safety Commission (CPSC) (1992) Labeling requirements for art materials presenting chronic hazards; guidelines for determining chronic toxicity of products subject to the FHSA; supplementary definition of "toxic" under the Federal Hazardous Substances Act; final rules. 57 Fed Reg. 46,633 (October 9, 1992).
[iii] 16 CFR § 1500.3 (c)(2)(i).

Exposure and Toxicity

- To be considered a "hazardous substance," a substance or product must satisfy a two-part definition.
- Toxic, or present one of the other hazards enumerated in the statute.
- Potential to cause "substantial" illness or injury during or as a result of "reasonably foreseeable handling or use."
- Potential hazard depends on toxicity, **exposure** and risk.[i]

[i] See also, Babich, M.A. (1998) Risk assessment of low-level chemical exposures from consumer products under the U.S. Consumer Product Safety Commission chronic hazard guidelines. Environmental Health Perspectives, 106: 387-390.

Chronic Hazard Guidelines (CHG)

- In 1992, the Commission issued guidelines for assessing chronic hazards under the FHSA
- **Exposure**, carcinogenicity, neurotoxicity, reproductive/developmental toxicity, bioavailability, risk assessment, and acceptable risk.[i], [ii]
- The chronic hazard guidelines are not mandatory.
- Intended to assist manufacturers in complying with the FHSA.
- CHG are being updated including exposure assessment

[i] U.S. Consumer Product Safety Commission (CPSC) (1992) Labeling requirements for art materials presenting chronic hazards; guidelines for determining chronic toxicity of products subject to the FHSA; supplementary definition of "toxic" under the Federal Hazardous Substances Act; final rules. 57 Fed. Reg. 46,626-46,674 (October 9, 1992).
[ii] The guidelines are summarized at 16 CFR §1500.135.

Assessing Exposure

- Population estimates
  - Diversity of products, variation in use patterns, frequency of use, variation in types of housing.
- Human factors estimates of consumer activity
  - 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 – assume worst-case scenario
- Reasonably foreseeable misuse
  - Mouthing by young children (e.g., mouthing toys)

Estimating Exposure

- Three routes of exposure considered: inhalation, dermal, and ingestion
- 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.

Exposure and Risk

- Hazard Index (HI) calculated for non-cancer risk
- HI = average daily dose (ADD)/ 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 = unit cancer risk (Q) x lifetime average daily dose (LADD)

Examples of Exposure Studies

- CCA in Children's Playsets
  - Hand/surrogate correlation
- Phthalates
  - Chew and spit
  - Head-over-Heels
- Combustion Appliances
  - Extrapolation from chamber to house

How Staff Might Conduct an Exposure Assessment of Nanomaterials

- Comprehensive list of consumer products that contain nanomaterials
- Nanomaterial incorporation into the products
- Characterization of nanomaterials in a consumer product
- Size distribution of particles released from products
  - Is appropriate toxicity data available
- Instrumentation
  - Development of analytical protocols
  - Feasibility

Role of Other Federal Agencies

- Several other federal agencies have regulatory authority over nanomaterials including the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and Occupational Safety and Health Administration (OSHA).
- These agencies regulate many products that are not under CPSC's jurisdiction, such as pesticides (including disinfectant cleaners), cosmetics, food additives, and occupational exposures.

Role of Other Federal Agencies

- The Toxic Substances Control Act (TSCA) gives EPA broad regulatory authority over new and existing chemicals. EPA is the "gatekeeper" for new chemicals and may, if certain statutory requirements are met, require testing of new and existing chemicals.
- Characterization of nanoscale vs. bulk materials
- The CPSC staff works closely with other federal regulatory agencies on issues of common interest.
- NSET, NEHI, ILSI, etc.

Summary

- Exposure assessment is a critical component in assessing potential risks from consumer products
- Nanomaterial regulation may present new exposure assessment challenges