The Role of Exposure Modeling in Assessing the Safety of Consumer Products: Focus on North America

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Objective

Describe the North American experience and activities in assessing exposure to chemicals in consumer products

Consumer products: Household cleaning, Laundry, Beauty, Personal Care

Outline

- Overview of exposure assessment
- US government
- Canadian government
- Industry
- Key Learnings and Challenges

Acknowledge information sources
Exposure Assessment Overview

- What is objective of the Exposure Assessment for an ingredient in a consumer product (Tier)
  - Prioritization – Is the exposure likely to be high enough to require risk assessment? Or what product type has the highest exposure for that ingredient?
  - Screening (risk assessment) – What is the likely magnitude of the exposure?
  - Definitive (risk assessment) – Evaluate quantitatively the exposure from all possible use scenarios.

- Differences may include
  - Conservatism exposure
  - High-end versus realistic versus average H&P data or exposure estimate
  - Consumer versus population
United States
Consumer Product Assessment

- US EPA
  - Assessment of New and Existing Chemicals
    - Household cleaners, paints, detergents, auto care, adhesives, do-it-yourself products, hobbyists products, and furniture polishes.
  - Consumer Exposure Module within E-FAST ([http://www.epa.gov/opptintr/exposure/pubs/efastdl.htm](http://www.epa.gov/opptintr/exposure/pubs/efastdl.htm))
  - Limited default products via dermal and inhalation pathways – flexible enough to use for other products.

- Mature Program
  - Operating platform, databases that are disappearing, etc.
  - Connected with international activities

- EPA SAB (Sept 7th) Guidelines for Exposure Assessment Review
  - Recognizes advances in probabilistic analyses, human activity factors, and consideration of susceptible populations and life stages
  - So should EPA revise these guidelines
FDA – Cosmetic Products

- Cosmetic products are the safest products regulated by the Food and Drug Administration
- CTFA is working with FDA to provide consumers with accurate information on safety of products and that proper steps are being taken by government and industry to assure continued safety of cosmetic products

CTFA Product Safety Code of Practice

- Every ingredient and finished product substantiated for safety (Cosmetic Ingredient Review (CIR), internal assessments)
- Companies must document safety in Dossier and make data available for inspection by FDA
- Dossier will include exposure estimates

CTFA on-going effort to gather H&P data for products

- Shampoo, conditioner, lipstick, eye shadow, body lotion, face cream, foundation, hair spray, perfume, body wash, facial cleanser, deodorant.
“protect the Canadian public by researching, assessing and collaborating in the management of the health risks and safety hazards associated with the many consumer products, including pest management products, that Canadians use everyday.”

- All age groups, aggregate exposure including from environmental media

- Priority setting: Volume in commerce, types and number of product categories

- Screening Assessments: Use Sentinel Products based on Use Profiles
  - Sentinel Product - specific type of consumer product that yields highest exposure to an individual compared to other similar products that contain that ingredient.
  - Use Profile – all possible uses of ingredient that would result in exposure. Specific concentration not necessarily known.

- Consumer Product Exposure: For specific Product types.
Current Projects
Evaluating all available models to develop iterative approach.
Chose based on transparency, validation, acceptance documentation of default parameters.
Starting with most common use/product categories with most conservative default values.
Sources include ConsExpo, ECETOC, E-FAST, SDA etc.
See presentation in TS1-13 on Sept 5th by Meek, Sutcliffe, Doyle
With the advent of HPV programs, industry increased efforts to place these hazard data into perspective via exposure estimates.

- Alliance for Chemical Awareness
- American Chemistry Council
- Soap and Detergent Association
- Paint Manufacturers
- Fragrance Manufacturers (RIFM)
- Etc.
Developing and communicating use and exposure information to ensure risk-based decision-making.

Contents

- About exposure assessments
- Initial Steps
  - Critical information collection and qualitative assessment
- Assessing the magnitude of exposure
  - Assessment approaches and tools for screening assessment
  - Choosing product exposure models (type of product, route of exposure)
  - Workplace, community, consumer/product exposure, ecological exposure
  - Overall exposure guidance documents
  - Publications, Case studies, etc.
- Comparing exposure to relevant hazards
- Is the chemical sufficiently studied?
Exposure Characterization Program (Alliance for Chemical Awareness)
- Web based series of questions on
  - Form, how used, function, industrial applications, etc
  - Report indicates what potential exposures can occur and how physical and chemical properties affect exposure potential

Promise (Probabilistic Methodology for Improving Scenario-Driven Exposure Assessment)
- Estimating single exposure (occupational and certain consumer-type applications) for chemicals with some volatility
- Input variable ranges and distributions rather than single point estimates

Main purpose is to present methodologies and specific consumer exposure information ... used for screening-level risk assessments .. HPV chemical ... consumer products, mainly laundry, cleaning and personal care products.

- Exposure scenarios, equations
- Tables of Habits and Practices data
- Sources of equations and data
- Case studies
Others

- RIFM http://www.rifm.org/
- Dermal Sensitization Quantitative Risk Assessment (QRA) for Fragrance Ingredients (2006)
  - Summary of available habits and practices and calculation scenarios for wide range of beauty (cosmetics) and personal care (dentifrice, mouthwash)
Planned Project

Approach to refine exposure to consumer products after screening level assessment have been completed.

Four product categories

- Personal Care products
- Household cleaning products
- Fabric
- Leather products

Still in data gathering and scoping phase
Key Learnings and Challenges

- Numerous efforts to characterize and estimate exposure in North America
  - Lead by Health Canada
  - Industry is making more information available
  - US is more mature program but EPA SAB Input on revision to Exposure Assessment Guidelines
- Building on knowledge and experience across government and industry
Key Learnings and Challenges

- What products are priority?
- What data and algorithms to use?
- What exposure estimates can these be used for?
  - Prioritization, screening, detailed
- Sentinel Products approach?
- Probabilistic Exposure Assessments
- Focus has been on consumer but what about aggregation and need to understand co-use and non-use to estimate population exposure?
Conclusion

- Much progress has been made in communicating and predicting exposure to consumer products.
- More information available publicly.
- Still many questions remaining and challenges.