

Alternatives Assessment 106 Webinar:

The Role of Exposure Information in Alternatives Assessment Processes

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* If you would like to ask a question or comment during this webinar please type your question in the question box located in the control panel.

Goals



Continuing education and dialog

• "To advance the practice of alternatives assessment for informed substitution across federal, state, and local agencies through networking, sharing of experiences, development of common approaches, tools, datasets and frameworks, and creation of a community of practice."

Purpose of this call



To discuss the role of exposure information in chemical prioritization and alternatives assessment and the adoption of safer alternatives. Presenters will give general thoughts and then discuss tools, approaches, and opportunities to apply exposure information in alternatives assessment processes in ways that enhances the transition to safer chemicals and products.





- Elaine Cohen Hubal, Senior Scientist, U.S. EPA's National Center for Computational Toxicology (NCCT)
- Treye Thomas, Toxicologist and Leader of the Chemical Hazards Program, U.S. Consumer Product Safety Commission
- Donna Heidel, Prevention through Design Coordinator, CDC/NIOSH Education and Information Division



Discussion Questions

- Why is important to consider exposure in chemical substitution/ alternatives assessment processes?
- At what point in a chemical substitution decision-process is it appropriate to consider exposure?
- Are there times exposure information is more/less important to consider (for example chemical used for similar functional use)
- Are there generic decision-rules/questions that can/should be asked of any substitution effort that can guide what exposure information is needed?
- What tools exist to rapidly characterize exposure potential or actual exposures to support informed substitution without getting bogged down in quantitative risk estimate debates?
- Are there different tools for considering exposure in manufacturing (workplace/facility emissions) versus during the use and end of life phases?
- How can exposure information effectively be used to prioritize, eliminate, or characterize potential impacts and management/improvement opportunities for specific options.



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Webinar Discussion Instructions

- Due to the number of participants on the Webinar, all lines will be muted.
- If you wish to ask a question, please type your question in the question box located on the right side panel of your webinar control panel.



Disclaimer. Although this work was reviewed by EPA and approved for presentation, it may not necessarily reflect official Agency policy.

The Roles of Exposure Information in Alternatives Assessment

Elaine Cohen Hubal National Center for Computational Toxicology



September 13 2012



Alternatives Assessment: Some Preliminary Thoughts

- Hazard assessments of alternatives involves probing potential for activity and associated endpoints of concern in a variety of biological systems.
- Exposure assessment of alternatives should probe for potential fate in a variety of environmental systems
- Need to consider both if we want to minimize unintended consequences
- Building exposure data landscape for existing chemicals will support efficient evaluation of alternatives



High Throughput Exposure Prioritization

Goal: A high-throughput exposure approach to use with the ToxCast chemical hazard identification.

Proof of Concept: Using off-the-shelf models capable of quantitatively predicting exposure determinants in a high throughput (1000s of chemicals) manner

To date have found only fate and transport models to have sufficient **throughput**

These models predict the contribution from manufacture and industrial use to overall exposure rapidly and efficiently

Applying and developing new high throughput models of consumer use and indoor exposure



Environmental Fate and Transport



Consumer Use and Indoor Exposure

Office of Research and Development Office of Research and Development cology

Wambaugh et al, NCCT, in preparation





Data Availability for Model Predictions and Ground-truthing



Office of Research and Development Office of Research and Development Cology

Wambaugh et al, NCCT, in preparation



Exposure Prioritization from ExpoCast

Uncertainty of prediction indicated by the horizontal confidence interval from the empirical calibration to the NHANES data

Horizontal dotted line indicates the fiftieth percentile rank and ¹⁰⁰ the vertical dotted line indicates the cutoff between overlapping top-half and lower half confidence intervals

Highest Priority 10-100-1e-05 1e-15 1e+00 1e-10 Exposure Prediction (mg/kg BW/day)

Office of Research and Deve Office of Research and Developmenicology

Wambaugh et al, NCCT, in preparation



Rapid Methods to Estimate Potential Exposure to SVOCs in the Indoor Environment (John Little, VT, et al, ES&T, 2012)

Semivolatile organic compounds (SVOCs)

- Vapor pressure 10⁻⁹ to 10 Pa
- Examples: phthalate plasticizers, brominated flame retardants, and OP pesticides
- Sources: polyvinyl chloride (PVC), personal care , food wrap, electronics, etc.

Exposure to SVOCs in Consumer Products

- Propose suite of mechanistic models
- Key determinants based on product use category
- Rapid exposure assessment and alternative evaluation



Rapid modeling of indirect exposure from consumer use Reprivation Agency

- Accounting for product use, emission characteristics, and physico-chemical properties, can estimate exposure
 - -via inhalation of SVOCs in the gas-phase,
 - inhalation of SVOCs sorbed to airborne particles,
 - ingestion of SVOCs sorbed to dust





Rapid modeling of indirect near-field exposure

- To make rapid exposure estimates for SVOCs:
 - -Need critical parameter y_0 (equilibrium gas-phase concentration of SVOC in the air in contact with the source/product), known in some cases (for example, DEHP), can be estimated/measured for others
 - Approach can be applied to SVOCs present as "Additives or Solvents" in indoor materials: flame retardants, plasticizers, antioxidants, preservatives and coalescing agents
 - Similar approach can also be applied to SVOCs that are "Sprayed as a Liquid or Applied as a Powder": pesticides, termiticides, herbicides, sealants, stain repellants and water repellants
- Need to evaluate materials and products to make sure that emissions of SVOCs are consistent with assumed mechanisms



Estimating exposure to SVOCs proposed as substitutes in specific products

- Using this model, we can gain insight into how exposure to the general public might change if chemical substitutions are made.
- Exposure of high-risk compound A is known or can be estimated (i.e., modeled)
- If y0 of replacement compound B is unknown, can reasonably assume related to y0 of compound A through Vp.
- Can then evaluate the ratio of known to unknown exposure for three indoor exposure pathways
 - inhalation of gaseous plus particle phase
 - Ingestion of dustborne compound
 - Dermal absorption from gas phase



Exposure information required for alternatives assessment

- Comprehensive set of models including additional product types and additional exposure pathways
- Methods (and supporting data) for estimating or measuring key parameters
- When combined with rapid hazard estimates, screening-level exposure estimates can contribute to alternatives assessment for a wide range of chemicals of concern



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Evaluation of Chemical Substitutes in Consumer Products

Treye A. Thomas, Ph.D.



This report was prepared by the CPSC staff; it has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

Federal Hazardous Substances Act (FHSA)

- Risk-based
 - Considers toxicity, exposure, and bioavailability
 - Includes acute and chronic effects
- Does <u>not</u> require specific testing for chronic hazards
- <u>No</u> pre-market approval
 - Consumer Product Safety Improvement Act (CPSIA) requires 3rd party certification for children's products
- Requires manufacturers to ensure that their products either are not hazardous or are properly labeled
 - Children's products that are hazardous are banned

Evaluation of Chemical Substitutes

- Avoid "Merry-Go-Round" Substitutions
 - E.g., one phthalate for another; one flame retardant for another
- Federal Hazardous Substances Act (FHSA)
 - Quantitative risk assessment
- Consider Alternatives and Substitutes
 - Substitute—replace a chemical with another having a similar function
 - E.g., replace one plasticizer with another
 - Alternative—different technology
 - E.g., replace PVC with another plastic that does not require a plasticizer



Evaluation of Chemical Substitutes

- Identify Potential Substitutes
 - Difficult to do prospectively
 - Potentially many substitutes (e.g., >50 FR chemicals)
 - Prioritize to develop a manageable number
- Quantitative Risk Assessment
 - Resource intensive
 - May be limited toxicity data
 - Need to develop exposure data
 - Helpful if there is a risk assessment for the chemical being replaced

Data Gaps for Exposures from Consumer Products

- Product formulations
 - Matrices (*e.g.*, plastic, textile, household chemicals)
 - Coatings and paints
- Product release and residue data
 - Variation by chemical and product
 - Frequency and duration of use of product
- The proportion of the population using product
- Scope of uses associated with products
- Secondary chemical by-products of health concern

Exposure Assessment

- Field data preferred
 - E.g., pollutant levels in indoor air
- Laboratory data
 - Emission or migration data
 - Combined with a mathematical model
- No exposure data
 - Surrogate chemical
 - Theoretical model

NIOSH Prevention through Design (PtD)

Mission: Design out hazards and minimize risks associated with:



Facilities

Work methods

Processes

Equipment

Products & new technologies





The challenge of "designing-out" chemical hazards

- Elimination/substitution of chemical hazards begins with the ability to identify the agents that are hazardous and assess the severity of risk from occupational exposures
- But there are relatively few authoritative occupational exposure limits
- Mechanism to quickly and accurately assign chemicals into "categories" or "bands" based on their health outcomes and potency considerations, is needed



OSHA GHS* Link

- Occupational Exposure Banding (OEB) concept
- OEB toxicological endpoints and potency aligned with GHS classification and labeling system*
- Data quality

*Globally Harmonized System for Hazard Communication: CLP 2008 1272



Criteria

- Criteria include qualitative, semi-quantitative, and quantitative data for each toxicological endpoint
 - Acute toxicity
 - Skin corrosion/irritation
 - Serious eye damage/eye irritation
 - Respiratory and skin sensitization
 - Germ cell mutagenicity
 - Carcinogenicity
 - Specific target organ toxicity, both single and repeated exposure
 - Reproductive toxicity



DRAFT Examples of Qualitative Criteria and GHS Phrases

Band	А	В	C (default)	D	E
Signal Word	Warning	Warning	Danger	Danger	Danger
OEL Ranges	> 1,000 µg/m³	> 100 and < 1,000 μ g/m ³	> 10 and < 100 μ g/m ³	> 1 and < 10 µg/m ³	< 1 µg/m³
	> 1000 ppm	> 100 - < 1000 ppm	> 10 - < 100 ppm	> 1 - < 10 ppm	< 1 ppm
<u>Examples</u> of Health Outcomes and Potency Considerations	Minor, reversible health effects occurring at high doses. Skin and eye irritation.	Reversible organ toxicity, skin and eye corrosion (reversible), possible dermal sensitizer at high doses.	Irreversible organ toxicity at high doses, irreversible skin and eye corrosion, dermal sensitizer at moderate doses.	Irreversible organ toxicity at low doses, <i>in</i> <i>vivo</i> genotoxicity, dermal sensitizer at low doses, evidence of mutagenicity, potential developmental and reproductive toxicants.	Human carcinogens at low doses, respiratory sensitization
<u>Examples</u> of GHS Hazard Statements and Hazard Categories	May cause drowsiness or dizziness	Harmful if inhaled (4). Harmful in contact with skin (4).	Toxic if inhaled (3). Toxic in contact with skin (3). Suspected of causing cancer (2). May cause damage to organs (2)	Fatal if inhaled (2). Fatal in contact with skin (1). Causes damage to organs (1). May cause cancer (by route of exposure)— 1A or B. Presumed or known human reproductive toxicant (1A or 1B). Causes damage to organs through prolonged or repeated exposure (1)	Fatal if inhaled (1). Fatal in contact with skin (1). May cause cancer (by route of exposure)—1A. May cause allergy or asthma symptoms or breathing difficulties if inhaled (1A resp.). Known human repro toxicant (1A). Causes damage to organs through prolonged or repeated exposure (1)

Alignment with Alternatives Assessment

- Design Assessment for new chemicals, materials, or products
 - Define desired attributes
 - Identify alternatives
- **Comparative Assessment** of existing chemicals materials, or products
 - Identify target(s) for action
 - Characterize end uses and functions (and occ. hazards and risks)
 - Evaluate and compare alternatives considering human health (occupational) and the environment, social justice, economic feasibility, and technical performance



Project plan

- 1. Establish minimum viable dataset, including data quality requirements
- 2. Establish process and decision logic
- 3. Validate data endpoints and band cut points, process, and decision logic
- 4. Identify data sources
- 5. Develop NIOSH guidance
- 6. Educate stakeholders



Expected project outputs

- NIOSH guidance
- Overall process, including the decision logic
- Tools to facilitate finding and evaluating hazard data and assign chemicals to hazard bands
- Education materials for H&S professionals, managers, and workers



The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy





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Next Webinars

- Alternatives Assessment 107: Criteria for Defining Safer Alternatives
 - October 23, 2012 at 12pm Eastern/ 9am Pacific.
- Alternatives Assessment 108:Lifecycle Consideration in the Context of Alternatives Assessment
 Fall 2012- Date and Time TBA
- Alternatives Assessment 109:Alternatives Assessment in Procurement
 - Fall 2012- Date and Time TBA



Webinar Audio & Slides

The audio recording and slides shown during this presentation will be available at:

http://www.chemicalspolicy.org/alternativesassessme nt.webinarseries.php