COMPARATIVE EXPOSURE CHARACTERIZATION

The State of the Science of Alternatives Assessment Methods

2nd International Symposium on Alternatives Assessment

November 1, 2018

Margaret H. Whittaker
ToxServices LLC
21 Century Exposure Agenda

- Exposure, exposure everywhere...What is exposure....?!
- How does comparative exposure assessment fit into Alternatives Assessment (AA)?
- Why incorporate comparative exposure assessment into AA?
- What changes are needed to foster use of comparative exposure assessment?
- How can you propel yourself into the exposure assessment realm?
  - Steps to get yourself into orbit here at the AA Symposium!
  - Steps to remain in orbit after the AA Symposium!
Introduction

• I am a toxicologist with 25 years of experience at work at ToxServices.
• ToxServices is a 15-year old, U.S.-based consulting firm comprising expert toxicologists, chemists, engineers, and environmental scientists.
• Relevant areas of expertise:
  – Third Party Reviews Under Numerous Ecolabels
  – Hazard, Exposure, Alternatives, and Risk Assessments
    • California Proposition 65 Safe Harbor Evaluations
    • Cosmetics/Personal Care Product Assessments
    • Medical Device Biocompatibility Assessment
    • Assessment of Products, Components, Materials, Biologics, and Discrete Chemicals
Alternatives Assessments and Exposure Assessment: Where on Earth are We Now?

- Most completed AAs are hazard-based rankings
- Most AAs don’t address differences in human and/or ecosystem exposure
- Four AA frameworks (BizNGO, CA SCP, IC2, REACH) include exposure assessment as a part of their methodology
- Lift off has not yet begun!!
Definitions: Exposure-Related Jargon

**Exposure** is defined by the IPCS as a concentration or amount of a particular agent that reaches a target organism, system, or (sub)population in a specific frequency for a defined duration.

**Exposure assessment** is the process of considering and estimating the extent of exposure among human and ecological receptors.

**Comparative exposure assessment** estimates relative exposure differences between potential alternatives and the original chemical of concern.

An AA exposure assessment is NOT the same thing as an exposure assessment conducted in a risk assessment!
Exposure: Coming Late to the AA Party

Why such limited exposure in AAs performed to date?

• Many AA frameworks have a *stated principle* to prevent harm by focusing first on inherent toxicity rather than controlling exposure

• Example: Of the 32 AA case studies available in the OECD AA Toolbox, only 22 AAs incorporate exposure rigorously.
What is Comparative Exposure Assessment?

- **Comparative exposure assessment** estimates relative exposure differences between potential alternatives and the original chemical of concern.


- Exposure in the NAS framework is not to demonstrate “safe” levels of exposure (so, different than a risk assessment).

- Instead, exposure is *comparative* and is focused on intrinsic potential for exposure without physical or administrative controls.
What is Comparative Exposure Assessment?

The NAS (2014) report outlines 2 approaches for comparative exposure assessment:

**Path A** is a quantitative approach, employing models and applying them to foreseeable use and disposal for a product containing an ingredient and its potential alternatives.

**Path B** is a property-based approach, comparing physical/chemical properties to predict human exposure and environmental fate while considering foreseeable use and disposal.
Challenges with Hazard-Based Tools

A comparison of two solvents reflects some of the challenges:

- Methylcyclohexane is a GreenScreen Benchmark™ 2 chemical (“Use but Search for Safer Substitutes”), while 3-Ethoxyperfluoro(2-methylhexane) is a GreenScreen Benchmark™ 1 chemical (“Avoid – Chemical of High Concern”)
- Methylcyclohexane is more toxic than 3-Ethoxyperfluoro(2-methylhexane) in terms of human health hazards—particularly to workers, so just selecting based on hazard only may not be the best choice

Additional information such as conditions of use, exposure, and life cycle considerations should be considered to support informed substitution.
The goal of a comparative exposure assessment is to identify potential exposure for each alternative to assess whether each is:

a) substantially equivalent
b) inherently preferable, or
c) potentially worse than a chemical of concern

If exposure is substantially equivalent between an alternative and the chemical of concern, then determination of “safer” can be limited to the relative hazard of the chemicals.

Comparative Exposure Assessment is best suited for products with discrete end uses.

Challenging to assess exposure to chemicals that don’t have clearly defined end uses.
Today’s afternoon session: Comparative Exposure Evaluation and Consideration of Life Cycle Impacts

We have seven exposure-focused presentations this afternoon!

- Qualitative Approach to Comparative Exposure in Alternatives Assessment
- Addressing Exposure to 8000+ Chemicals in Consumer Products with Quantitative High Throughput Methods for Alternatives Assessment
- The Supply Chain Dimensions of Alternatives Assessment
- Bridging Life Cycle and Exposure Ontologies to Enable Integration of Data Streams for Rapid Exposure Estimation and Comparative Exposure Assessment
The focus of AAs over the next five years should be the incorporation of comparative exposure assessments.

Small steps, such as incorporating qualitative exposure assessments into AAs will strengthen our ability to move away from hazardous substances and avoid regrettable substitution.
Dr. Marie Fortin (a big advocate of AA) is holding a two day boot camp on January 10 and 11, 2019 at Rutgers University.

- The course is free, although they would appreciate donations to their grad student travel fund.
- The focus is on risk assessment methods, but many of the concepts and tools are relevant for Comparative Exposure Assessments.
- Our goal as an AA community should be to hold an AA Boot Camp course annually!

Sign up for a 2-day Boot Camp on Risk Assessment in the Environmental and Occupational Health Sciences Institute at Rutgers University. Topics will include risk analysis, systematic review, data quality, weight of evidence, hazard identification, susceptible populations, exposure pathways, point-of-departure, reference values, and more. Case studies and hands-on exercises will provide real world scenarios for application of content. Lunch will be provided both days. There are no costs to participants.

Register at https://goo.gl/wcWP7E

Donate tab
Thank You and Enjoy the Symposium!

mwhittaker@toxservices.com
202-429-8787