Dr. White (ACC) gave a brief presentation (slides are attached) on the CPSC staff’s risk assessment of subclasses of OFRs and the recommendations of the National Academies of Science, Engineering, and Medicine’s (NASEM) report on *A Class Approach to Hazard Assessment of Organohalogen Flame Retardants*. Dr. White’s presentation included two possible approaches, based on either product class or chemical class. The presentation was followed by questions from the staff and a general discussion. Questions from the staff included whether ACC could provide assistance in obtaining information on uses of different types of OFRs.
CONSIDERATIONS FOR CPSC FLAME RETARDANT REVIEW

February 12, 2020
NAFRA: Resource for Flame Retardant Information

Ongoing Federal Agency Risk Evaluations of Flame Retardants

Notable Take-aways from NASEM Flame Retardant Report

Potential Considerations for CPSC Evaluation of Flame Retardants
NAFRA: Resource for Flame Retardant Information
NAFRA Overview

Leading producers of flame retardants used in wide variety of industrial & consumer applications

- Represents cutting edge fire-safety chemistry & technology
- Dedicated to improving fire safety performance in product applications
- Sponsors scientific research and evaluations to improve understanding of flame retardants


Ongoing Federal Agency Risk Evaluations of Flame Retardants
Ongoing and Recently Initiated EPA Risk Evaluations

- Cyclic Aliphatic Bromide Cluster (HBCD)
- Tris(2-chloroethyl) phosphate (TCEP)
- Phosphoric acid, triphenyl ester (TPP)
- 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)
Components of EPA TSCA Risk Evaluations

Safety Determination
EPA will determine if a chemical meets LCSA’s safety standard, meaning it does not pose an unreasonable risk.

Chemicals that meet the safety standard are cleared for use.
Chemicals that do not meet safety standard require risk management.

Risk Management
Chemical uses that do not meet the LCSA’s safety standard are subject to risk management.

Agency options include:
- Labeling requirements
- Handling instructions
- Use restrictions
- Phase Outs
- Bans

Risk management requirements must consider costs & benefits.
Notable Take-aways from NASEM Flame Retardant Report
Can OrganoHalogen Flame Retardants (OFRs) Be Evaluated as a Single Class?

- The NASEM committee determined that they cannot.

- Determination was made by creating an inventory of 161 OFRs and then identifying analogues on the basis of chemical structure, physical and chemical properties, toxicology data and predicted bioactivity information to facilitated hazard characterization.
Notable Take-Aways from NASEM Report

Proposed Subclass Approach

- Identified commonly occurring core features of OFRS
- Grouped the OFR inventory into eight structural classes on the basis of predicted biologic activity; then used additional information to identify 14 OFR categories
- Focused on conducting a hazard assessment for OFRs
Potential Limitations of the NASEM Approach

- Criteria and selection of “anchor” chemical in relation to other chemicals grouped in a particular subclass
- Differences in toxicity and environmental impacts of chemicals grouped into a particular subclass
- Understanding of In Vitro Data (i.e. ToxCast) demonstrating activation but not necessarily indicative of adverse effects
Potential Limitations of the NASEM Approach

- Incorporation/Consideration of exposure Information
- Understanding and differentiation between OFR uses and applications (i.e. non-polymeric vs. additive vs. reactive)
  - Different level of exposure patterns
  - Different compounding and component specifications
Key Considerations in CPSC Evaluation of Flame Retardants
## FHSA Designation of A Hazardous Substance

### Identifying a Substance as Hazardous Under the FHSA:

- Product must have potential to cause substantial personal injury or substantial illness during or as a result of any customary or reasonable foreseeable handling or use, including reasonably foreseeable ingestion by children.

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Low Toxicity</th>
<th>Mild Toxicity</th>
<th>High Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Exposure</td>
<td>MINIMAL RISK</td>
<td>MILD RISK</td>
<td>MODERATE RISK</td>
</tr>
<tr>
<td>Medium Exposure</td>
<td>MILD RISK</td>
<td>MODERATE RISK</td>
<td>SUBSTANTIAL RISK</td>
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<tr>
<td>High Exposure</td>
<td>MODERATE RISK</td>
<td>SUBSTANTIAL RISK</td>
<td>HIGH RISK</td>
</tr>
</tbody>
</table>
APPLICATION BASED APPROACH

- Focus on a specific product application based on:
  - Fire safety risk
  - Highest potential for human health exposure
  - Available and relevant toxicology data
- Identify relevant subclasses of substances applicable to the product category
  - Exclude polymeric substances
  - Exclude reacted substances
  - Closely consider/evaluate the relevance of “anchor” chemical to other chemicals in subclass and anticipated risk
APPLICATION BASED APPROACH

- Calculate a Safe Reference Dose based on available data
- Determine confidence in reference dose and applicability to other chemicals in subclass
- Generate a Margin of Exposure/Margin of Safety Estimate to determine if increased risk exist
- Identify risk management recommendations if warranted by available data
TOXICOLOGY BASED APPROACH

- Focus on specific NASEM Subclasses based on:
  - Increased fire safety risk
  - Most data rich
  - Highest potential for human health risk
  - Exclude polymeric substances or reacted substances that are in the subclasses
  - Closely consider/evaluate the relevance of “anchor” chemical to other chemicals in subclass and anticipated risk
Potential Approaches/Considerations

TOXICOLOGY BASED APPROACH

- Calculate a Safe Reference Dose Based on Available Data
- Determine confidence in reference dose and applicability to other chemicals in subclass
- Generate a Margin of Exposure/Margin of Safety Estimate to determine if increased risk exist
- Identify risk management recommendations if warranted by available data