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On the Petition Requesting Rulemaking on
Products Containing Non-polymeric Additive Organohalogen Flame Retardants,
Docket No. CPSC-2015-0022

The Natural Resources Defense Council is a non-profit organization with over 2.4 million members and activists and has no financial interest in the products or chemicals that are the topic of these comments. We strongly support the petition to ban the sale of four categories of consumer products containing additive, non-polymeric organohalogen flame retardant chemicals.

I received my PhD in Cell Biology from University of California, San Francisco and my B.S. in Chemistry with High Honors from University of California, Berkeley. I was a postdoctoral teaching fellow at Stanford University and adjunct faculty at the University of San Francisco.

Why is it appropriate to consider additive, non-polymeric, organohalogen flame retardant chemicals together as a class?

The approach of considering related chemicals as a group, rather than as individual chemicals, is well-established in regulatory science. Guidance on chemical categories was first developed by the US Environmental Protection Agency (EPA) for the High Production Volume Challenge almost 15 years ago:

> A chemical category is a group of related chemicals that lend themselves to evaluation and testing as a group. The chemicals can be grouped based on similarities in chemical structure or functionality.[1]

Since then, the science has continued to develop and EPA's New Chemicals Program now describes 55 chemical categories used for assessing chemicals[2].

According to the *Guidance on Grouping of Chemicals*[3] from the Organization for Economic Cooperation and Development (attached to these comments), there are four key factors to consider when evaluating a potential chemical grouping:

1. **Structural similarity**
   A common functional group is often the foundation for creating a class of chemicals based on structural similarity. A "functional group" in chemistry means a part of a larger molecule that has consistent properties. For example, alcohol is the functional group that is part of the chemical that we drink (ethanol), also part of the chemical that we use for sterilization as rubbing alcohol (isopropanol), and is also part of the chemical in some paint strippers (benzyl alcohol). Though they are otherwise structurally different, these chemicals are grouped together as alcohols because they all contain that functional group.

For the organohalogen flame retardants, the carbon-halogen linkage (carbon-chlorine or carbon-bromine) is the key functional group common to the class. The other properties of interest described below all stem from the foundation of the carbon-halogen linkage. The non-polymeric structure is another important shared structural feature that defines the class under discussion.

2. **Physical and chemical properties**
Physical and chemical properties such as boiling point and solubility determine how a chemical interacts with any other substance, including air, water and living tissues.

Organohalogen flame retardants have key physical-chemical properties in common:

a. Boiling point. As described in Dr. Diamond's statement, organohalogen flame retardants are semi-volatile organic compounds (SVOCs), defined as having a boiling point from 200-400°C. Many people are familiar with volatile organic compounds, like paint thinner, which can exist as a liquid and a gas at room temperature— the strong smell when you open up this type of product is the gaseous chemical. SVOC organohalogen flame retardants, on the other hand, exist as a solid and a gas at room temperature. They do not off-gas as quickly or strongly as volatile organic compounds, but still continuously transition from the solid to the gaseous phase.
b. Hydrophobicity. This means how much a chemical repels water. For example, table sugar can dissolve in water and is not very hydrophobic, while olive oil does not dissolve in water and is hydrophobic. Chemicals that are hydrophobic also tend to be 'fat-loving' (lipophilic) and collect with other fatty, hydrophobic substances. As described in Dr. Halden's statement, the presence of a halogen (bromine or chlorine) in an organic molecule correlates with increased hydrophobicity.

These two characteristics, being SVOCs and hydrophobic, are important because they are key drivers of how organohalogen flame retardant chemicals interact with the world and get into people.

Organohalogen flame retardants used additively in any type of plastic material (such as polyurethane foam or a plastic electronics case) are not bonded to the material and will not stay in the plastic because they are SVOCs. They will continuously migrate out of the plastic (transition from the solid to the gaseous phase), and because they are hydrophobic and fat-loving, tend to move from the air to particles like dust that are also hydrophobic. As described in Dr. Rudel's statement, a wide variety of organohalogen flame retardants are found repeatedly in house dust.

Once organohalogen flame retardants leave the plastic materials of products, they can get into people's bodies in three main ways:

- *Inhalation*: people breathe in the gaseous chemical
- *Through their skin*: people touch a product containing flame retardants, touch dust contaminated with flame retardants, and/ or flame retardants go from the air directly onto a person's skin
- *Ingestion*: People touch dust and then accidentally get the dust in their mouths

3. **Environmental fate characteristics**
   "Environmental fate" is what happens to a chemical once it leaves a product and enters the indoor or outdoor environment. If a chemical does not break down quickly into more benign substances, that means there is an extended period of time for the chemical to enter plants, animals and people and cause harm.

   Organohalogen FRs have key similarities in environmental fate characteristics:
   a. Persistence. As described in Dr. Halden's and Dr. Diamond's statements, organohalogen flame retardants do not break down quickly either indoors or outdoors. Generally, there are few natural processes that break the carbon-halogen linkage. Indoor persistence means that once flame retardants migrate out of a product, they stick around and people are continuously exposed to contaminated air, dust and surfaces.
   b. Bioaccumulation. As described in Dr. Halden's and Dr. Collins' statements, bioaccumulation stems from the physical-chemical property of hydrophobicity. Because they are hydrophobic and fat-loving, organohalogen flame retardants partition from the environment into living tissues that contain fats. As described in Dr. Epel's statement, this fat-loving nature means that organohalogen flame retardants can easily cross into living cells, because the protective outer layer of a cell (the membrane) is made of fats (lipids).

4. **Toxicity**
   Organohalogen flame retardants share key characteristics that cause toxicity:
   a. As described in Dr. Epel's statement, once organohalogen flame retardants are inside cells, they resist breakdown, are not transformed into less toxic substances and are not removed from cells.
   b. The carbon-halogen bond is a key feature that causes these molecules to evade the mechanism (ABC transporters) that normally removes foreign chemicals from cells.
   c. As described in Dr. Eastmond's statement, assessment of 85 organohalogen flame retardants found that all present human health hazards.

Based on the structural similarity of a common functional group, and shared physical-chemical, environmental fate and toxicity properties it is appropriate to group additive, non-polymeric organohalogen flame retardants together as a class.

Why is it appropriate to use data from some organohalogen flame retardants to predict the properties of other organohalogen flame retardants?

Using data from more well-studied, data-rich "index" or "source" chemicals to fill data gaps on other chemicals within a group is also well established in regulatory science. The Read Across Assessment Framework from the European Chemicals Agency (attached to these comments) describes the methodology and process for doing so[4].

As described in Dr. Harley's and Dr. Herbstman's statements, the risks to human health from polybrominated diphenyl ethers (PBDE) flame retardants are extensively studied. Other chlorinated and brominated flame retardants, such as hexabromocyclododecane (HBCD) also have a wealth of data available. Conclusions can be drawn about other, less well-studied organohalogen flame retardants based on the existing data.

Conclusions drawn from read across are scientifically robust and support regulation. The European Union relied on qualitative read across to support the June 2014 directive limiting the organohalogen flame retardants TCEP, TDCPP, and TCPP in toys to the lowest detectable levels:

> In its opinion SCHER agrees with the conclusion of the alternatives' risk assessments that there is sufficient information from the structures, physical-chemical properties, toxicokinetics and mutagenic profiles of TCEP, TDCP and TCPP to support a qualitative read across, indicating a potential concern for carcinogenicity for TCPP by a non-genotoxic mechanism. The read-across implies, according to SCHER, that considerations given for TCEP could be applied to its halogenated alternatives as well, if used in toy manufacturing. [5]

Read across was also used in the European Union to classify certain nickel compounds as dangerous substances.[6]

Conclusion

The group of additive, non-polymeric organohalogen flame retardants meets the criteria for being considered together as a class. Consumers cannot protect themselves from the exposures that result when this class of flame retardants is used in the products specified in the petition. There is strong evidence that the molecular characteristics of this class of flame retardants result in toxicity to humans, with pregnant women and children being especially vulnerable. These flame retardants used in the specified products present risks to human health and CPSC rulemaking is needed to protect consumers.

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[1] US EPA. High Production Volume Chemicals Frequently Asked Questions. (March 1999) at http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=7000052X.TXT

[2] US EPA. TSCA New Chemicals Program (NCP) Chemical Categories. (August 2010) at http://www2.epa.gov/sites/production/files/2014-10/documents/ncp_chemical_categories_august_2010_version_0.pdf

[3] OECD. Guidance on grouping of chemicals, Second Edition. *Series on Testing and Assessment* (2014). at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono%282014%294&doclanguage=en

[4] ECHA. Read-Across Assessment Framework (RAAF). (2015). doi:10.2823/546436

[5] European Commission, *Commission Directive 2014/79/EU of 20 June 2014 amending Appendix C of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards TCEP, TCPP and TDCP* (2014), *at* http://eurlex.europa.eu/legalcontent/EN/TXT/PDF/?uri=CELEX:32014L0079&from=EN

[6] Judgment of the Court (Fourth Chamber) of 21 July 2011.Nickel Institute v Secretary of State for Work and Pensions. *European Court Reports 2011 I-06609* at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:62010CJ0014