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Organohalogen Flame Retardants Petition; Oral Presentation
By Phone

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The Program on Reproductive Health and the Environment's (PRHE) mission is to create a healthier environment for human reproduction and development through advancing scientific inquiry, clinical care, and health policies that prevent exposures to harmful chemicals in our environment. We have no financial interest in the products or chemicals that are the topic of these comments.

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, adjunct faculty at the University of San Francisco, and staff scientist at the Natural Resources Defense Council (NRDC). My research focuses on chemicals in the indoor environment and I have published on human exposure pathways related to flame retardant chemicals, consumer products, and building materials.[1–3] I am currently Director of Research Translation at PRHE.

A number of the statements and conclusions in the staff briefing do not fully consider scientific studies that are in the record and/ or that are available in the open literature. In this testimony, I am highlighting some of those key areas related to the exposure pathways for these chemicals and considering organohalogen flame retardant chemicals as a class, topics covered in my previous testimony and in NRDC's responses to the Commissioner's Questions for the Record.

What is the evidence linking organohalogen flame retardants in the product categories that are the subject of the petition to human exposure?

Responsive to: The presence of OFR chemicals in household dust does not establish a link to the four product categories that the petitioners identify. Petitioners have not submitted data establishing this connection, and staff is not aware of such information.[a]

There is ample evidence connecting furniture, children's products, mattresses, and electronics to organohalogen flame retardant levels in dust, some of which was referenced in the original petition and answers to questions for the record. Though the staff briefing package cites a few of these studies, it does not review the evidence on this question in a

[a] United States Consumer Product Safety Commission. Staff Briefing Package: In Response to Petition HP15-1, Requesting Rulemaking on Certain Products Containing Organohalogen Flame Retardants. May 24, 2017. Pg. 6

comprehensive manner, nor does it consider the factors which indicate this is a strong body of evidence. The Federal Hazardous Substances Act (FHSA) requires a finding that substances *may cause* harm based on exposures from customary use—it does not require a quantitation of those exposures or a calculation of risk.

I have referenced more of the studies linking the products in question to exposures, and described the factors to consider in evaluating this evidence below, but caution that I have not performed a systematic literature search. I am confident a comprehensive literature search would reveal further data on these products' contribution to flame retardant contamination in air and dust.

In relation to furniture, children's products, mattresses, and/ or electronics, studies find:

- Concentrations of organohalogen flame retardants in dust change with distance to products (highest concentrations observed near products); [4–6]
- Statistically significant relationships between the presence and/ or number of products and contamination levels of organohalogen flame retardants in air or dust; [7–13]
- Product removal from a room is associated with significant decreases in the levels of organohalogen flame retardants in air or dust;[6,14] similarly, product introduction into a room is associated with significant increases in the levels of organohalogen flame retardant contamination in air or dust; [6,15] and
- Organohalogen flame retardants are directly emitted from products when products are placed in an experimental chamber and the emissions measured.[16,17] In an actual indoor environment, such emissions would result in flame retardant chemical contamination of the room's air and dust.

To evaluate the relationship between a presumed cause and effect (in this case, organohalogen flame retardants in furniture, children's products, mattresses, and electronics and flame retardant levels in dust/ subsequent human exposure), scientists often consider the following factors: evidence of a gradient, strength of the effect, consistency, specificity, temporality, experimental evidence and coherence (known as the Bradford-Hill factors, which have been integrated into decision-making for evidence-based medicine).[18,19] Each of the factors is described below with brief summaries of the supporting studies.

Factor	Supporting Studies and Products Investigated
Evidence of gradient (there is a clear relationship between the factor in question and the level of the chemical)	Takigami, 2008 (Ref 4): **Electronics**: This study found the highest levels of brominated flame retardants in the dust inside televisions, strongly suggesting the brominated compounds are transferred from TV components into dust. Harrad, 2009 (Ref 5): **Electronics**: This study found that concentrations of the organohalogen flame retardant HBCD were 4-5 times higher in dust sampled closest to a computer and related electronic equipment compared to samples taken from other areas in the same room. They also found that a television was the epicenter of levels of HBCD – HBCD levels were extremely high on and near the television, and dropped dramatically with increasing distance from the TV. This strongly suggests that electronics are sources of HBCD emissions to dust, which is a subsequent source of human exposure. Muenhor, 2012 (Ref 6): **Furniture, electronics, mattresses**: This study found higher levels of PBDEs in areas close to electronics and furniture compared

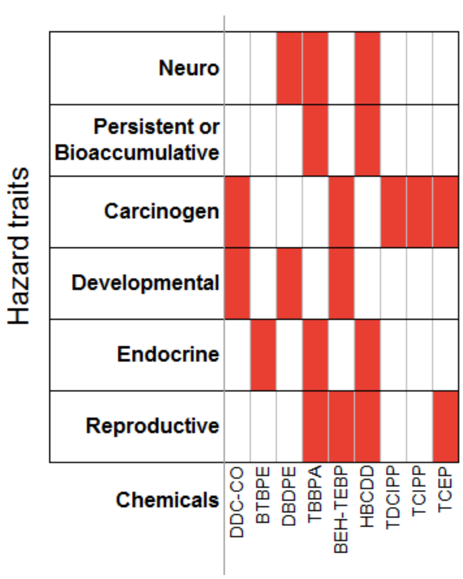
Factor	Supporting Studies and Products Investigated
	to areas further away from these products.
Strength of effect (the size or magnitude of the effect)	Harrad, 2004 (Ref 13): **Furniture, electronics**: This study found a significant positive correlation between PBDE concentrations in indoor air and the number of electrical appliances and/ or polyurethane foam-containing chairs. D'Hollander, 2010 (Ref 8): **Electronics**: This study observed a statistically significant contribution of electronic devices to the concentration of PBDEs in dust collected from randomly selected homes and offices. de Wit, 2012 (Ref 9): **Electronics, furniture, mattresses**: Significant correlations were found between concentrations of some PBDEs and HBCD in air and/ or dust and the presence of electronic/electrical devices, foam furniture, and polyurethane foam mattresses. Ali, 2012 (Ref 10): **Mattresses:** This study found a significant positive correlation between concentrations of the organohalogen flame retardant chemicals BTBPE, DBDPE, and TBPH in dust collected from mattresses and the levels of these chemicals in floor dust. This strongly suggests that mattresses contribute significantly to the loading of flame retardants in dust, which is a subsequent source of human exposure. Bradman, 2014 (Ref 11): **Children's products**: This study found that levels of the organohalogen flame retardant chemicals TCEP and TDCIPP in dust were significantly higher in children's facilities with napping equipment made out of foam. Since foam nap mats are known to contain these chemicals, this strongly suggests that these items contribute significantly to the loading of flame retardants in dust, which is a subsequent source of human exposure. Hoffman, 2015 (Ref 12): **Children's products**: This study found that the number of baby products in the home was strongly associated with an infant's exposure level to the organohalogen flame retardant chemical TDCIPP. Infants with the largest number of baby products in the home had exposure levels ~7 times higher than other infants. Because baby products are known to contain TDCIPP, this clearly suggests that the products are an important source of the infant's flame retardant exposure.
Consistency (different studies show the same results)	These studies were conducted in geographical locations around the world, with products from different countries, with similar outcomes.
Specificity (the effect is modified by variations in the putative cause)	Allen, 2008 (Ref 7): **Furniture and electronics**: Using a handheld device that can measure bromine in products, this study linked residential dust concentrations of PBDEs to household furniture and televisions. The results indicate that the bromine content of foam furniture is strongly associated with the concentration of pentaBDE in house dust. Bromine levels in televisions predict decaBDE in household dust, an association that was affected by the number of residents in a home, a potential surrogate for TV usage.
Temporality (the effect occurs after the cause)	Hazrati, 2006 (Ref 14): **Electronics**: This study finds that a computer contributed significantly to PBDE levels in an office because when the computer was removed, PBDE levels fell dramatically.

Factor	Supporting Studies and Products Investigated
	Stuart, 2008 (Ref 15): **Mattresses**: This study found a significant increase in dust concentrations of PBDEs after the introduction of a new mattress into a bedroom. Muenhor, 2012 (Ref 6): **Electronics, mattresses**: This study found levels of PBDEs increased significantly during time periods when electronics (a TV, laptops) were present in a room compared to when the products were not present. Also, levels of PBDEs decreased significantly when an old bed was replaced with a new one.
Experimental evidence	Kemmlein, 2003 (Ref 16): **Furniture, mattresses, and electronics**: In this study, products were placed in an experimental chamber and the emission of organohalogen flame retardant chemicals was directly measured. Furniture, mattresses, and electronics emitted halogenated flame retardants including TCPP, HBCD, PBDEs and TBBPA. Destaillats, 2008 (Ref 17): **Electronics**: This review summarized the measurements of the organohalogen flame retardant chemicals TCPP, TBBPA and PBDEs direct emissions from computers in experimental chambers.
Coherence (laboratory and observational studies "in the real world" have consistent findings)	Experimental chamber studies finding emissions of organohalogen flame retardants from products are consistent with the observational studies relating these products to flame retardant levels in indoor air and dust.

Overall, considering each of the factors related to causality and the evidence provided by these studies, this strongly supports that these products contribute to flame retardant levels in air and dust and subsequent human exposures.

Additional information documenting organohalogen flame retardant chemicals' presence in U.S. homes and health hazards

This information is from data in: Mitro, S. D., Dodson, R. E., Singla, V., Adamkiewicz, G., Elmi, A. F., Tilly, M. K., & Zota, A. R. (2016). Consumer Product Chemicals in Indoor Dust: A Quantitative Meta-analysis of U.S. Studies. *Environmental Science & Technology*, acs.est.6b02023. https://doi.org/10.1021/acs.est.6b02023



The above study published in 2016 documented 47 flame retardant chemicals found in U.S. indoor dust, with 14 organohalogen flame retardants measured in 3 or more datasets. Two organohalogen flame retardants (TDCIPP and HBCD) were found in 90% or more of samples tested, indicating that these flame retardants are ubiquitous and widespread in U.S. indoor environments.

The study also examined health hazards as designated by authoritative lists. As shown at left, organohalogen flame retardants present multiple health hazards. This analysis, though smaller than the Eastmond study presented in the original petition, is independent verification of the Eastmond findings because it used different methods but came to similar conclusions about the hazards of organohalogen flame retardant chemicals.

These hazard findings also raise concern for consumers' co-exposure to multiple flame retardant chemicals present in dust, and the potential cumulative impacts. The National Academies of Sciences concluded that for chemicals that can contribute to the same adverse health outcome, co-exposures can add up to a bigger risk than any individual exposure.[20,21]

It is important to note that the varying hazards presented by the organohalogen flame retardants here do not preclude their consideration together as a class. The staff briefing states:

> "However, even the limited data on OFRs show varying toxicity and exposure potential among individual OFR compounds. These varying properties of individual OFR compounds indicate that OFRs, in fact, represent several subclasses of chemicals that should be examined separately. However, even then, individual compounds within the same subclass may differ in the effects that they cause, their potency, mechanism of action, and bioaccumulation potential."[b]

But, to the contrary, the standard in the Federal Hazardous Substances Act (FHSA) only requires a finding that substances have the capacity to cause illness (are toxic) and may cause harm—it does not require that chemicals be toxic or cause harm in exactly the same way. The National Academies of Sciences recommends focusing on adverse health outcomes, not the pathways that lead to them.[21] The fact that each of these chemicals presents some kind of human health hazard is the relevant evidence under the FHSA, not that they have the same hazard.

My testimony from December 2015 and NRDC's responses to the Commissioner's Questions for the Record cover in great detail why the approach of considering related chemicals as a group, rather than as individual chemicals, is well-established in regulatory science. Since that time, additional studies supporting this approach have been published.[22,23] I would urge the CPSC to consider these submissions, as well as evidence in the open literature germane to this issue.

When there are data gaps on a chemical's toxicity, how can these be filled?

Responsive to: CPSC does not have guidelines that address the use of surrogate data for determining toxicity of a chemical where no toxicity data are available.[c]

As provided in my previous testimony and NRDC's answers to Commissioner's Questions for the Record, there are existing, well-established guidelines used in a regulatory context by other agencies on how to use Structure Activity Relationships (SAR), Quantitative Structure Activity Relationships (QSAR), read-across, chemical groupings, models, and other tools to fill data gaps. These references are listed again below.

> ECHA. Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.6: QSARs and Grouping of Chemicals (2008). Available: http://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf

> OECD Toolbox for carcinogenicity and mutagenicity: ISS Quantitative Structure

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[b] United States Consumer Product Safety Commission. Staff Briefing Package: In Response to Petition HP15-1, Requesting Rulemaking on Certain Products Containing Organohalogen Flame Retardants. May 24, 2017. Pg. 6
[c] Id., Pg. 10

Activity Relationship (QSAR) model and Oncologic; Guidance documents available: http://www.oecd.org/chemicalsafety/risk-assessment/theoecdqsartoolbox.htm#Guidance_Documents_and_Training_Materials_for_Using_the_Toolbox.

OECD, 2014. Guidance on grouping of chemicals, Second Edition. Series on Testing and Assessment, (No. 194). Pg. 9 Available at: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)4&doclanguage=en

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

Conclusion

As described in detail in my previous testimony, the group of additive, non-polymeric organohalogen flame retardants should be considered together as a class under the FHSA. Because these types of flame retardants migrate out of products into indoor air and dust, 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 flame retardants used in furniture, children's products, mattresses and electronics contribute significantly to the levels of indoor air and dust contamination, and subsequent human exposures. 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 have the capacity to produce illness and may cause harm to human health.

Thank you for the opportunity to testify on this important issue. Please do not hesitate to contact me if I can provide further information or answer additional questions.

Sincerely,

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