NATURAL RESOURCES DEFENSE COUNCIL

August 31, 2017

Organohalogen Flame Retardants Petition;
Oral Presentation

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Public meeting September 14, 2017
CPSC Docket No. CPSC–2015–0022

Submitted by email to cpsc-os@cpsc.gov

Thank you for the opportunity to present comments to the Consumer Product Safety Commission (CPSC or Commission) to support the Petition HP15-1.

I am a senior scientist at NRDC in the Environmental Health Program, a job I have had for sixteen years, and on faculty at George Washington University, Environmental and Occupational Health Department. NRDC is a non-profit environmental organization of some 500 lawyers, scientists, and policy advocates. NRDC presents these comments on behalf of our over 2 million members and online activists. NRDC does not have any financial interest in the topic of these comments.

The petition is requesting that the Commission initiate rulemaking under the Federal Hazardous Substances Act (FHSA) to protect consumers from the health hazards that result from the use of non-polymeric, additive form, organohalogen flame retardants (OFRs) in children's products, furniture, mattresses and the casings surrounding electronics.

The petition was filed by Earthjustice and the Consumer Federation of America, which are joined by American Academy of Pediatrics, American Medical Women's Association, Consumers Union, Green Science Policy Institute, International Association of Fire Fighters, Kids in Danger, Philip Landrigan, M.D., M.P.H., League of United Latin American Citizens, Learning Disabilities Association of America, and Worksafe.

These comments respond to the CPSC staff briefing package in response to the petition.[1] The CPSC staff recommends that the Commission deny the petition (Staff report, p. 25). Here I provide rebuttal of its reasoning.

CPSC staff reasons that the limited toxicity data on OFRs does not support assessing the OFRs as a single class of hazardous chemicals under the FHSA (Staff report, p. 25).

The CPSC staff are fully aware that the replacement chemicals for the PBDEs have been OFRs in furniture foam and children's products, and that many of these alternative chemicals can be released from the product, "leading to potential human and environmental exposures" (Staff report, p. 100). Moreover, the staff report acknowledges that it lacks toxicity and exposure information for the alternative OFRs, or even the most basic market information regarding what products they are used in (Staff report, p. 100). This is an unforgivable lack of information for chemicals that are used at millions of pounds annually in products found in every home in America.

CPSC staff confess to having "not performed a comprehensive review of the toxicity of TBB or TBPH", the two OFR chemicals that make up FireMaster™ 550 (FM550). Failing to even assess the data that is available is a shocking abdication of CPSC staff responsibility to consumer protection! Nonetheless, after listing a number of study results, but without any systematic review or cogent analysis of any of them, CPSC staff manage to come up with the following rather garbled hazard identification conclusion for FM550:

> "FM550 is considered toxic under the FHSA [See footnote 26 of the report: 16 C.F.R. § 1500.3 (b) (5). LD50 range 50-5000 mg/kg]; however, it is not considered highly toxic. On a preliminary basis, CPSC staff concludes that FM550 may be considered "possibly toxic in humans," based upon limited evidence of developmental toxicity in animal studies for the FM550 mixture. A finding of "possibly toxic" does not meet the definition of "toxic" under the FHSA. This does not mean that this chemical is "safe," only that there are not sufficient data to satisfy the regulatory definition of "toxic." (Staff report, p. 101-102)

Similarly, for TBBPA:

> "CPSC staff has not completed a comprehensive toxicity review of TBBPA. TBBPA is the most widely produced and used brominated FR.... CPSC staff has not performed an in-depth review of TBBPA toxicity... Preliminarily, CPSC staff concludes that TBBPA may be considered "possibly toxic to humans," based on limited evidence of carcinogenicity in animals. A finding of "possibly toxic" does not meet the definition of "toxic" under the FHSA. However, these conclusions are based on limited data. This does not mean that this chemical is "safe," only that there are not sufficient data to satisfy the regulatory definition of "toxic." (Staff report, p. 102-103)

CPSC staff failed to provide a reasoned and defensible systematic review as recommended by the National Academies (2017), the National Toxicology Program (2015), and other government and expert bodies.[2] CPSC staff failed to provide defensible and consistent definitions of key terms like "toxic", "highly toxic", "possibly toxic", or even "safe". Nonetheless, it seems clear that the CPSC staff determined that FM550 and other OFRs are toxic under the FHSA – period. Everything after that reads like a desperate attempt to duck and run from the inevitable political storm that must have followed.

Insufficient data (i.e. data gaps) should not be used to rationalize the failure to protect consumers from OFRs. The petition lays out a strong scientific basis for addressing data gaps and uncertainties using established methods such as QSAR models. In fact, all members of the organohalogen class of chemicals that have been adequately tested have been shown to have adverse effects on systems that are critical to normal human development and function.[3]

As detailed in the petition, Dr. David Eastmond's research concluded that, "*all of the non-polymeric OFRs [organohalogen flame retardants] that we have screened using the QCAT® and related methodologies were found to be either of high concern or toxic* …". His team used standard search strategies to identify any publicly available toxicity date on all the chemicals, including published studies, government

databases, and industry data submissions under the European chemical assessment regulations. US EPA, Health Canada, and European regulatory agencies use these same data based and the information is generally considered reliable.

Dr Eastmond conducted a literature search for data on approximately 90 organohalogen flame retardants, about 85 of which were non-polymeric, and then used modeling to fill data gaps. The work of Dr. Eastmond and colleagues demonstrates that there are sufficient data – either by individual chemical testing, or by applying standard read-across techniques – to show that the whole class is hazardous and may cause substantial personal injury or illness. Dr. Eastmond's team applied a standard screening tool developed by the Washington State Department of Ecology called Quick Chemical Assessment Tool (QCAT).

Dr. Eastmond's declaration in the petition concluded that, "*The results of our screening show that critical toxicological data are lacking for many OFRs, and that those for which data are available have the potential to pose significant hazards for human or environmental health*." (see Eastmond declaration in petition). This work is the most thorough hazard screen of organohalogen flame retardants of which we are aware, and should have been considered by CPSC as either affirmative evidence of toxicity or plausible evidence of toxicity.

CPSC staff reasons that the limited exposure data on OFRs does not support assessing the OFRs as a single class of hazardous chemicals under the FHSA (Staff report, p. 25).
All available exposure data demonstrates that population exposure to OFRs is widespread across the American population. These hazardous chemicals are measured in the blood of all US residents (Human exposure is discussed in the Petition at pages 36-41). Young children have even higher levels than adults; a study of 2-18 month old infants in North Carolina reported that they had the flame retardant TDCPP at levels that were on average 3 times greater than adults.[4] In the study, some infants had levels 50-100 times higher than adults, and very high levels were correlated with a higher number of baby products in the home.

Widespread population exposure is expected because OFR compounds are not covalently bound to the matrix of the construction material, so they migrate out of consumer products and into the home environment, house dust, foods, indoor air, and the surfaces of products where people are exposed.[5]

Exposure is also consistent with the chemical characteristics of OFRs. Many are lipophilic and persistent in adult human adipose tissue for years. [6] These characteristics make this class of chemicals especially prone to contaminating our body tissues including critical organs such as the brain, fetal cord blood, and breast milk.[7] [8] This also means that labeling is inadequate and the chemicals are unavoidable.

Only by taking meaningful actions can CPSC prevent harmful exposures and avoid health harms.

CPSC staff reasons that variability across data sets does not support assessing the OFRs as a single class of hazardous chemicals under the FHSA (Staff report, p. 25).
Variability across data sets will always occur to some degree and should not be used to dismiss evidence of harm without a properly reasoned scientific basis. The CPSC staff should have conducted a robust systematic review of the data to assess the quality and reliability of each study, as recommended by the National Academies (2017), the National Toxicology Program (2015), and other government and expert bodies.[9] This should have included a consideration of risk of bias, unexplained inconsistency, indirectness in the relationship between a measured outcome and a health effect, imprecision, and

publication bias serious enough to significantly decrease confidence in the body of evidence. Ultimately, the CPSC conclusions should have been based on the whole body of literature, excluding very low-confidence studies.

Unfortunately, the CPSC staff failed to use a coherent and consistent systematic review process to select which studies to base the assessment on, or provide scientifically-vetted definitions of the level of evidence for health effects, or how different types of evidence (animal studies, mechanistic studies, epidemiologic studies, pharmacokinetic models, etc) contributed to the overall determination. The CPSC include over nine pages of study references that it claims to have relied upon, but fails to provide a reasoned explanation for how it chose to list some and not others, or what contribution each study made to the final recommendations, and why (Staff report, p. 120-129). In short, CPSC staff has no credible or defensible hazard identification system.

Based on the scientific evidence Dr. Linda Birnbaum – the Nation's preeminent toxicologist and author of over 700 peer reviewed scientific papers, book chapters, and reports[10] - emphasized in her 2015 testimony to this Commission that it is appropriate to consider all additive OFRs as a class as the petition proposes because all of them have the potential to cause adverse effects.[11] The CPSC staff should make their recommendations consistent with Dr. Birnbaum and her staff of respected toxicologists and hazard assessment experts.

The CPSC staff report notes that there are insufficient data in CPSC's databases to evaluate consumer incidents associated with OFR use in these categories (Staff report, p. 6, 16).
Endocrine disrupting chemicals like the OFRs wreak havoc on complicated biological systems, sending them into directions they were never meant to go, and ultimately creating chaos where precise coordinated order was meant to occur. The harmful outcomes often aren't as instantaneous and acute as a blinded eye or third-degree facial burns, such as may occur from the lawn darts and firecrackers that are more typical of CPSC's product recalls.[12] But, ask yourself if you'd rather suffer a burn or your ability to become a parent. While chronic and systemic effects such as growth and metabolic abnormalities or reproductive fitness are more difficult to attribute to a specific cause, particularly when the exposure and outcome may be separated by years, they nonetheless should be considered a "substantial personal injury or substantial illness" as defined by the FHSA.

Awaiting consumer incidents is a failure of our federal agencies to protect consumers from such incidents. It is collecting data in the form of human pain and suffering, and then presenting the cold numbers with the tears wiped away. In the words of DC Circuit Court of Appeals, "There is no indication in the language of the [FHSA] or its legislative history that the Commission was bound to develop a precise 'body count' of actual injuries that will be reduced by each regulatory provision".[13]

It is a strength of the FHSA that it is a hazard based standard, rather than a much less protective risk based standard.[14] That is, the FHSA intends to prevent harm, rather than calculate some acceptable level of harm across a statistical population. Risk calculations are inherently unjust in that real harm, unlike statistical harm, is never distributed equally across a population – after all, each person doesn't have 1/millionth or even 1/10th of a cancer. In reality some people have cancer, and someone don't. Taking protective action based on evidence of hazard is using the available evidence to predict a problem and prevent harm – we wear seatbelts and bike helmets using the same logic. In other contexts, CPSC understands this. CPSC staff do not accept that it is ok that a certain number of kids will drown in badly designed baby tubs or that it is ok for some % of kids to get their heads stuck between crib bars. However, in the case of OFRs the CPSC staff have veered off the path of consumer protection.

The staff report cites as other reasons for its recommendation the lack of use of these chemicals in the product categories, current regulatory measures for OFRs, economic burden, and staff resources. We address these speculative and unsupported claims here:

- **The lack of use** is not a mandatory legal restriction, so it will not prevent OFRs including PBDE's from being imported into the US. Only regulatory measures can provide the backstop to prevent the stealth re-introduction of these toxic chemicals onto the market.
- **Current regulatory measures** do not address the OFRs that have replaced the discontinued use of PBDEs. This is a problem because many of the same properties as PBDEs: they are semi-volatile and migrate out of products into the environment, causing human exposures during normal use, and they have been shown to be toxic, such as chlorinated Tris (TDCPP), Firemaster 500™, and decabromodiphenyl ethane (DBDPE) which replaced decabromodiphenyl ether (decaBDE) (Petition p. 12-14). Only regulatory action to restrict the whole class of OFR's can prevent the regrettable substation of one toxic OFR for another.
- **Economic burdens** are routinely over-estimated by industry. For example, the vinyl chloride industry issued dire predictions of job losses and plant closures if OSHA finalized regulations to reduce workplace exposure limits from 500 ppm to 1 ppm within the year, 1975.[15] Industry cried economic hardship even though internal corporate documents showed that industry leaders well knew at the time that the 500 ppm limit was excessive and unsafe.[16] When the regulations came into force, not only did the industry meet the new standards by the end of the year, but it saved money by making the polymerization process more efficient. There is no evidence that moving markets away from OFRs will add significantly to anyone's production costs. In contrast, moving away from toxic chemicals can save money by reducing the need for worker protections, workplace monitoring, handling of hazardous waste, insurance claims and potential liabilities.

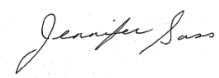
In contrast to the large body of data demonstrating exposure and hazard from OFRs, we are not aware of data showing consumer benefits from the use of non-polymeric additive organohalogen flame retardants in the four product categories covered by the Petition for Rulemaking.

Dr. Ronald Melnick, a government toxicologist retired from the National Institutes of Environmental Health Sciences (NIEHS), warned of serious public health consequences if chemicals are misclassified as less hazardous or non-hazardous based on untested hypotheses, poorly validated tests, or incomplete data sets "Declaring a chemical as not hazardous, or reducing a level of health protection, should require validation, not speculation" (Melnick et al 2003). Instead, the CPSC staff report treats data gaps and uncertainties as if they were affirmative evidence of safety, leaving the public unprotected from anything that doesn't explode or ignite.

We respectfully request that CPSC grant the petition, and protect consumers from continuing exposure to these toxic chemicals.

Thank you for the opportunity to provide comments.

Respectfully,



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[1] The CPSC briefing package is here: https://www.cpsc.gov/s3fs-public/PetitionHP15-1RequestingRulemakingonCertainProductsContainingOrganohalogenFlameRetardants.pdf?aTsa_sSaCiSMf1Z_2CfvISjMHFEdWKZ7

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[12] http://fox8.com/2017/06/27/cpsc-recalls-fireworks-sold-at-ohio-walmart-target-stores/

[13] *Forester v. CPSC*, 559 F.2d 774, 788 (D.C. Cir. 1977) as referenced in testimony to the CPSC from Rachel Weintraub, Consumer Federation of America, December 9, 2015. Available online http://consumerfed.org/wp-content/uploads/2015/12/12-9-15-Flame-Retardants-Hearing_Testimony.pdf

[14] In the FHSA, 15 U.S. Code § 1261 - Definitions, a 'hazardous substance" is described as follows: (f) The term "hazardous substance" means: (1) (A) Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

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