Comments on "Draft Regulatory Determinations Report to the Legislature Draft Regulatory Determinations Report to the Legislature"

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By way of background, I have a doctorate degree in toxicology and am certified in toxicology by the American Board of Toxicology. I have spent over 35 years as a toxicologist examining the safety of a wide range of chemicals primarily used in products that consumers, including children, encounter. An important component of my work, in addition to understanding the hazard, or inherent toxicity of chemical and its potency, is the scientific estimation of exposure and, most important, risk. I have experience with various ways to accomplish this and with the approaches that different regulatory agencies and governments have taken in this regard.

I appreciate that you are dealing with an important, yet very complex topic. We have a mutual desire to protect human health and the environment. Given limited resources, both time and financial, how can your efforts best be focused for maximum public good?

My comment concern the following topics:

- Complexity of evaluation process
- Hazard versus risk
- Distinction between additive, reactive, and polymeric flame retardants
- Grouping of chemicals

Complexity of Evaluation Process

The process by which you made your determinations with respect to the OFRs was not clear. I tried my best to follow it but ended up confused. What data sources and what data were used?

I am also concerned about the use of Green Screen. The tool is useful for to screen various formulas one may be considering, but I don't think it's appropriate for regulatory purposes nor have I seen applied in such venues. My issues relate to transparency of the data used and the general anti-halogen bias built into the system.

Hazard versus risk

Risk to humans and/or the environment is a function of both toxicity, a property inherent to the chemical, and the extent of exposure that a human or environmental species receives. We are exposed to many chemicals, both natural and synthetic, every day that have inherent toxicity, but because of the level of exposure and our body's ability to detoxify many of these chemicals, risk

is low or nonexistent. Regulation purely on the basis of hazard, or inherent toxicity will result in the elimination or de-selection in the market of chemicals for which the actual risk to human based on exposure, is very low. Some of the product uses contained in your report likely pose minimal exposure potential.

Distinction between additive, reactive, and polymeric flame retardants

I am concerned that you are not making a distinction between additive flame retardants and those which are either polymeric or reactive. The polymeric flame retardants have large molecular weights and are certainly not bioavailable and therefore should not pose a hazard. Likewise, reactive flame retardants are ones which have been reacted with other chemicals in the matrix they are treating and similarly should not be bioavailable and not pose a hazard. Failure to make this distinction means that many effective flame retardants will be eliminated needlessly: no net public health benefit is likely. The focus should be on additive flame retardants.

Grouping of chemicals

The concept makes sense and I respect the idea of being precautionary with respect to data poor chemicals. But I do not think that is appropriate to group all halogenated flame retardants together in a single group as you propose. Your report states:

> "This conclusion is consistent with opinions expressed by the scientific community in the San Antonio Statement on Brominated and Chlorinated Flame Retardants, which was signed by over 200 scientists from 30 countries with expertise on human health, the environment, and fire safety (Birnbaum & Bergman, 2010). The statement summarizes concerns from scientific experts on the persistent, bioaccumulative, and toxic properties of chlorinated and brominated flame retardants, their use, and resulting exposure in humans and wildlife."

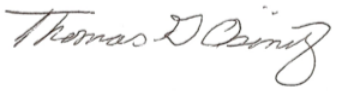
This statement is largely based on knowledge of an older class of flame retardants, the PBDEs, which have been replaced in many cases by better alternatives that do not share these properties.

Most significant is the findings of the 2019 National Academies of Sciences (NAS) consensus report on grouping of flame retardants. Below is a summary of their effort their recommendations:

> "The committee used cheminformatic approaches to create OFR subclasses. A public set of chemotypes and methods that have been developed by Yang et al. (2015) and Richard et al.(2016) were used to identify the chemotypes present in the seed chemicals, which are listed in Figure 3-1. Using the chemotypes, the committee was able to identify several generic classes that represented the entirety of the OFR seed set (Table 3-1). Merging the biology-informed groups with the chemotypes listed in Figure 3-1 led to the formulation of 14 OFR categories for the inventory of 161 OFR chemicals (Table 3-2). Appendix B provides additional details on how the subclasses were formed and evaluated. The committee recommends that CPSC use the subclasses in Table 3-2 at least as a starting point for the class-based hazard assessment of OFRs."

I support their conclusions and urge you to carefully reconsider your decision to assess essentially all OFRs are being unacceptable.

Thank you for the opportunity to comment.



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These comments are submitted in my individual capacity. I serve as a consultant to the North American Flame Retardant Alliance (NAFRA) on its Science Advisory Council, but I have not been compensated for these comments by NAFRA or its Council, nor do I submit these comments on their behalf.