

Sam Kacew

I am in Ontario, Canada and not in a state.

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 pharmacology at the University of Ottawa and a post-doctoral fellowship in toxicology at the University of Montreal. I was certified as a toxicologist by the Academy of Toxicological Sciences (ATS). I have spent over 40 years as a toxicologist examining the safety of a wide range of chemicals primarily used in products that consumers, including children, encounter. I have authored and edited over 5 text books on effects of chemicals on fetuses and newborns. I am currently the Editor-in-Chief of the Journal of Toxicology and Environmental Health. In my capacity one of my duties is to review paper submissions with understanding the hazard, or inherent toxicity of chemical and its potency for scientific estimation of exposure. In order to accomplish this task my approach needs to consider regulatory agencies and governmental policies.

I appreciate that you are dealing with an important, yet very complex topic. Clearly there is 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 three topics:

- (1) Risk versus hazard
- (2) Distinction between additive, reactive, and polymeric flame retardants
- (3) Grouping of chemicals

Hazard versus risk

Risk to humans and/or the environment is a function of toxic consequence attributed to a property inherent to the chemical. In addition, the extent of exposure that a human or environmental species receives also affects risk. Individuals are exposed daily to many chemicals, both natural and synthetic that possess inherent toxicity, but because of the amount of exposure and the body’s ability to detoxify many of these chemicals, risk is considered low or non-existent. If regulation is undertaken purely on the basis of hazard, or inherent toxicity this will result unnecessarily in the elimination or de-selection in the market of chemicals for which the actual risk to human based on exposure, is very low. It should be noted that some of the

product which are beneficial for humans that are contained in your report likely pose minimal exposure potential.

Distinction between additive, reactive, and polymeric flame retardants

It is important to note that a distinction needs to be made between additive flame retardants and those which are either polymeric or reactive. The polymeric flame retardants possess large molecular weights, are certainly not bioavailable and hence should not pose a hazard. Similarly, reactive flame retardants are ones which have been reacted with other chemicals in the matrix they are treating would thus not be bioavailable and not pose a hazard. Failure to make this distinction indicates that many effective flame retardants will be eliminated needlessly with no net public health benefit such as failure to delay a fire. The focus should be on additive flame retardants.

Grouping of chemicals

This concept makes sense and the idea of being precautionary with respect to data poor chemicals is important. However, it is not 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 upon knowledge of an older class of flame retardants, the PBDEs, which have been banned and replaced in many cases by safer 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 the conclusions of the National Academies of Sciences (NAS) and urge you to carefully reconsider your decision to assess essentially all OFRs as being unacceptable.

Thank you for the opportunity to comment.

Sam Kacew, PhD.

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.

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