UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families on EPA's Draft Risk Evaluation for Cyclic Aliphatic Bromide Cluster (HBCD) under Section 6(b) of TSCA

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Safer Chemicals Healthy Families (SCHF) submits these comments on EPA's draft risk evaluation for the Cyclic Aliphatic Bromide Cluster (HBCD) under section 6(b) of the Toxic Substances Control Act (TSCA).[1] SCHF is a non-profit organization whose mission is to improve public health and well-being through research, analysis, public education, and advocacy. From the start, our work has been focused on issues of chemical safety. We have used a variety of channels to improve public understanding of the health and environmental risks of chemicals of concern, reduce their presence in consumer products and on retail shelves, and strengthen federal laws and regulations that protect the public from unsafe chemicals. In partnership with numerous other organizations, we took a leadership role during the TSCA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today. We strongly support a proactive approach to implementing the new law that uses the improved tools that Congress gave EPA to deliver significant health and environmental benefits to the American public.

In May 2013, HBCD was added to Annex A of the United Nation's Stockholm Convention on Persistent Organic Pollutants (POPs). The Convention is a "global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have harmful impacts on human health or on the environment."[2] Once a chemical is listed in Annex A, parties to the Convention are required to prohibit and/or eliminate the POP's production and use, as well as its import and export, subject to limited exemptions. Following its listing as a POP, 171 of the 188 Parties to the Convention have agreed to ban the production, use, import, and export of HBCD, consistent with their obligations under the Convention.

The US is not a signatory to the Stockholm Convention and thus is not subject to its obligations. At the same time, the global consensus that HBCD should be eliminated from commerce because of its long-term impacts on health and the environment is one that US policymakers should weigh heavily under TSCA. It is therefore surprising and troubling that EPA's draft HBCD evaluation concludes that:

(1) HBCD does not present an unreasonable risk of injury to the environment under all conditions of use within the scope of the risk evaluation; and
(2) HBCD does not present an unreasonable risk of injury to health for workers, occupational non-users, consumers, and the general population by inhalation, oral, or dermal exposure under all conditions of use within the scope of the risk evaluation.

[1] 84 Federal Register 31315 (July 1, 2019).
[2] http://chm.pops.int/TheConvention/Overview/tabid/3351/Default.aspx

This conclusion is at direct odds with HBCD's listing as a POP under the Convention. If it is allowed to stand, unlike the many countries eliminating HBCD in accordance with the Convention, the US will not restrict manufacture, processing, use and disposal of HBCD under TSCA despite its ubiquitous presence in the environment and in human blood and tissue and its known adverse effects on human health.

As we show below, the risk determinations in the draft evaluation are seriously flawed and, if reworked in accordance with the best available science and information, will require a conclusion that HBCD in fact presents unreasonable risks to health and the environment – providing a basis for regulation under TSCA that will bring the US in alignment with the many other industrialized countries that have banned HBCD.

Exclusion of Discontinued Activities from the Risk Evaluation. According to EPA, discontinued HBCD manufacturing, processing and use activities are not TSCA "conditions of use" and are therefore outside the scope of the HBCD risk evaluation. Thus, the evaluation makes no risk determinations for domestic production of HBCD and its use as a chemical intermediate, plastic material and resin manufacturing component, in the manufacture of vehicles and other transportation equipment, and as a flame retardant in high impact polystyrene (HIPS) for electrical and electronic appliances, consumer and commercial textiles, floor coverings, adhesives, coatings, children's products including toys and car seats, and furniture (such as bean bag chairs) (Risk Evaluation at, at 31, 39; HBCD Problem Formulation, at 24-26). Until recently, HBCD was extensively produced and distributed for use in these applications.

EPA bases these risk evaluation exclusions on voluntary and unverified reports from industry and its own research in public databases. It did not survey all HBCD producers and users or use its information collection authorities under TSCA sections 8 and 11 to independently confirm the lack of ongoing HBCD uses. Thus, there is no assurance that the excluded HBCD uses no longer exist. Moreover, industry's promises not to resume these uses are informal and unenforceable and do not provide assurance that they will not be revived in the future. Indeed, the most likely explanation for the recent phase-out of previously well-established HBCD uses is the regulatory and public scrutiny HBCD has received. This consideration could wane in importance in the future, particularly if the final EPA risk evaluation concludes that HBCD does not present an unreasonable risk to health or the environment.

EPA provides no justification for its assertion that the TSCA definition of "conditions of use" does not apply to recently discontinued uses. As defined in section 3(4), this term includes not simply intended or known uses but the "circumstances under which a chemical substance is . . . reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." It is clearly "reasonably foreseen" that long-standing and significant uses of a chemical that have been phased out may re-enter commerce in the absence of any legal restriction. The goals of TSCA would be defeated if manufacturers of unsafe chemicals could avoid scrutiny simply by ceasing production for specific uses before EPA completes a risk evaluation of those uses and then later re-entering the marketplace free from any restriction or determination of risk. This scenario is particularly troubling where – as here – the product phase-out is likely in response to agency risk concerns and intended to avoid the consequences of an adverse risk finding and subsequent regulatory action.

Because the excluded uses of HBCD could return to the marketplace in the future if not restricted, EPA should account for their potential for exposure and risk in its HBCD evaluation. This should involve not only examining future exposure scenarios that would result from the reintroduction of these uses but characterizing ongoing exposure and related risks from the continued presence of many legacy HBCD-

containing articles and products in thousands of homes, schools and businesses. These articles and products continue to perform ongoing flame retardant, insulating and other functions. Where a chemical is performing an ongoing *in situ* function as a result of previous manufacturing and processing activities, that function comprises a current "use" of the chemical that is "known" to be occurring, thereby meeting the TSCA definition of "condition of use."[3] The HBCD contained in numerous installed products and building materials is and will continue to be a critical source of ongoing exposures and its omission from the EPA evaluation will contribute to a significant understatement of risk.

Assessment of Worker Exposure. As in the case of 1,4-dioxane, EPA concludes that HBCD's risks to workers are significant in the absence of personal protective equipment (PPE) but that workers will be adequately protected if PPE is used. Based on the assumption that PPE will effectively protect workers, the bottom line of EPA's evaluation is that HBCD does not present an unreasonable risk to human health. This determination means that EPA will not take the next step under TSCA and regulate HBCD under section 6(a) to reduce risks to workers or other populations.

It's important to emphasize the magnitude and severity of the workplace risks that HBCD presents in the absence of PPE. In EPA's evaluation, Margins of Exposure (MOEs) are well below benchmark levels for most inhalation workplace scenarios and health effects; for dermal contact, the MOEs often approach or are below 1, meaning that there is little or no difference between anticipated worker exposure levels and concentrations known to cause adverse effects. Thus, in order to conclude that MOEs will be reliably above the risk benchmarks, EPA assumes that "workers and occupational non-users wear respirators for the entire duration of the work activity throughout their career." According to EPA, "similar assumptions apply to the use of gloves and their expected elimination of any dermal exposure." (Draft Evaluation, at 381). These are unrealistic assumptions. Because of its limited effectiveness, PPE use is not a favored worker protection method among regulators and occupational health professionals. As EPA notes in the draft evaluation, under the OSHA "hierarchy of controls," substitution of hazardous chemicals, engineering controls and work practices are the preferred strategies for reducing unsafe worker exposures: "[a]s the last means of control, the use of personal protective equipment (e.g., respirators, gloves) is recommended, when the other control measures cannot reduce workplace exposure to an acceptable level." Id. at 180.

The HBCD risk evaluation provides no evidence that workers are now using adequately protective respirators and gloves during all workplace operations. For example, EPA has not visited user facilities to determine whether and when PPE is in use. The Agency recognized in its TSCA rulemaking to ban methylene chloride in paint removers that respirators are often not feasible and may be used intermittently by workers even where legally required:

> "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the

[3] SCHF and its co-petitioners are challenging EPA's position that ongoing use and disposal of discontinued products are not TSCA "conditions of use" in *Safer Chemicals Healthy Families v. EPA* (No. 17-72260 9th Cir.).

> assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190).'"

82 Federal Register 7464 (January 19, 2017). For similar reasons, glove use cannot be assured. As noted in the draft evaluation, gloves provide effective protection only "if proven impervious to the hazardous chemical, and if worn on clean hands and replaced when contaminated or compromised." (Risk Evaluation at 180).

Effective use of PPE requires clear and understandable hazard warnings and directions for safe use together with adequate employee training and oversight. Yet based on numerous studies, EPA has concluded that "consumers and professionals do not consistently pay attention to labels for hazardous substances; consumers, particularly those with lower literacy levels, often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; [and] even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings." Id. EPA has also noted that label warnings and directives will only be effective if the "employer provides appropriate PPE and an adequate respiratory protection program." 82 Federal Register at 7473---4.

These conditions are unlikely to be present for HBCD. There are no OSHA or NIOSH exposure limits for the HBCD cluster and thus users of HBCD are under no obligation to control exposure to any particular level, conduct workplace monitoring or use PPE (let alone on a continuous basis). Not surprisingly, the industry Safety Data Sheets (SDSs) referenced in the draft evaluation generally fail to describe the HBCD health hazards identified in the EPA risk evaluation, do not call for any limit on exposure and provide weak recommendations for PPE. A typical statement is that "Respiratory protection may not be required under normal operating conditions if adequate ventilation is provided." Moreover, as EPA notes, almost none of the SDSs specify the type of gloves to be used. (Risk Evaluation at 181).

In sum, EPA has no basis to conclude that PPE is effectively protecting workers exposed to HBCD from unreasonable risks. Without that evidence, EPA must base its risk determinations for workers on the assumption that PPE is not protective and examine the magnitude of exposure and risk in the absence of PPE. Based on the MOE analysis in the draft evaluation, this would require a finding of unreasonable risk of injury to workers and require regulation to eliminate this risk under TSCA section 6(a).

Accounting for HBCD PBT Properties and Long-term Buildup in People and Wildlife. HBCD is highly bioaccumulative and is classified as a Persistent Bioaccumulative Toxicant (PBT) by EPA, the EU, Canada and other authorities. (Risk evaluation at 65-66). Thus, past exposure to the wide range of ubiquitous products containing HBCD has resulted in a continuing body burden in the human population that will increase as exposure continues. Reflecting this body burden, HBCD has been measured in human adipose tissue, blood, breast milk, feces, fetal tissue, hair, and placental tissue. (Risk Evaluation at 226-227). HBCD has also been

detected in a wide range of animal organisms and is believed to bioconcentrate up the food chain. (Risk Evaluation at 66). It is this evidence of HBCD's long-term buildup in people and biota, coupled with its demonstrated adverse health effects, that motivated its listing as a POP under the Stockholm Convention.

We are concerned that the draft evaluation has not adequately captured the cumulative risks to people and the environment from long-term buildup of HBCD.

First, EPA has not taken into account the contribution to aggregate human exposure of the ongoing use and presence in the built environment of discontinued products containing HBCD that are excluded from the scope of the risk evaluation. Instead, the consumer exposure pathways that EPA has evaluated all involve the smaller number of active HBCD-containing products that EPA treats as TSCA conditions of use.

Second, EPA does not combine general population exposure resulting from HBCD's releases into the environment with consumer exposure from HBCD-containing products even though these two pathways of exposure affect the same people and thus should be aggregated to assess overall risk.

Third, the Uncertainty Factors (UFs) EPA uses to calculate benchmark MOEs do not reflect EPA's recognition it lacks sufficient data to reach a determination concerning HBCD's immunotoxicity,[4] male reproductive effects,[5] and carcinogenicity[6] and that it cannot address developmental neurotoxicity risks because of "inconsistencies and/or limitations with the database."[7] These are serious database deficiencies that, under EPA guidance, should result in an additional UF of 10X.[8]

Finally, EPA acknowledges that it is "unable to model the potential effects of bioaccumulation in human tissues over time" and elsewhere recognizes that levels of accumulation are highly variable within the human population. (Risk Evaluation at 379). To compensate for these uncertainties, EPA relies on the standard 10X Uncertainty Factor (UF) for extrapolating from subchronic studies to chronic exposure. However, EPA is applying this standard UF already because it is using a non-lifetime study to predict adverse effects of a chemical over a lifetime. (Risk Evaluation at 319). Compared to a typical chemical, internal doses of a bioaccumulative substance for a given administered dose will be higher over a lifetime and should further increase in later generations assuming continuing exposure. The normal and otherwise required UF of 10X to extrapolate from non-chronic studies to lifetime exposure does not account for these considerations. EPA should thus apply an additional UF (perhaps 100X) to reflect the lifetime and multi-generational buildup of HBCD in the general population/consumers and highly exposed subpopulations due to its highly accumulative properties.

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[4] Risk Evaluation at 308 ("While there is some evidence to support immune system effects following HBCD exposure, that data are inconclusive.")

[5] *Id.* at 305 ("[H]uman and animal evidence for male reproductive effects were insufficient for drawing conclusions regarding the relationship between HBCD exposure and male reproductive toxicity.")

[6] *Id.* at 298 ("There is not adequate available information to assess the carcinogenic potential of HBCD.")

[7] *Id. at 300.*

[8] A Review of the Reference Dose and Reference Concentration Processes," December 2002, Prepared for the Risk Assessment Forum U.S. Environmental Protection Agency, available at https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf

These and other flaws in the draft evaluation explain EPA's surprising conclusion that the buildup in body burden from long-term general population and consumer exposure scenarios will not present an unreasonable risk. EPA should carefully reexamine and rework this portion of its risk evaluation.

We appreciate this opportunity to submit comments.

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Respectfully submitted,

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