March 15, 2017

Comments from the Natural Resources Defense Council (NRDC) on the TSCA Review and Scoping for Hexabromocyclododecane (HBCD, CASRN: 25637-99-4, 3194-55-6, 3194-57-8)

Submitted to the following docket: EPA-HQ-OPPT-2016-0735

The Natural Resources Defense Council (NRDC) is a national, non-profit environmental organization of lawyers, scientists, and other professionals. NRDC presents these comments on behalf of our 1.4 million members and online activists. NRDC does not have any financial interest in the topic of these comments.

HBCD is a toxic brominated flame retardant found in the environment, wildlife and humans and NRDC is glad that EPA is evaluating this chemical under the new Toxic Substances Control Act (TSCA). HBCD presents human health concerns for developmental and reproductive effects, is highly toxic to aquatic and land-dwelling organisms, bioaccumulates, and is persistent in the environment.[1] HBCD's legacy and continuing uses in building materials and other products has led to ubiquitous contamination of indoor environments[2] and releases throughout the chemical's life cycle,[3] resulting in global environmental pollution and widespread human exposures.

Conditions of use generally under TSCA

EPA interprets the revised TSCA as requiring the Agency to consider all uses encompassed within conditions of use during risk evaluation, and accordingly structures the risk prioritization and scoping processes to obtain and assess information based on this "comprehensive approach" to chemical management.[4] This reading conforms to EPA's proposed risk evaluation rule, where EPA outlines its interpretation that the amended TSCA requires EPA to evaluate all uses of a chemical that constitute the conditions of use, as the best way to meet its statutory obligations and the purpose underlying the revisions of the law.[5] EPA has already formalized this interpretation in denying a citizen petition under TSCA.[6]

[1] 81 FR 85440 EPA Final Rule: Addition of Hexabromocyclododecane (HBCD) Category; Community Right- to-Know Toxic Chemical Release Reporting

[2] Mitro, S.D. et al., 2016. Consumer Product Chemicals in Indoor Dust: A Quantitative Meta-analysis of U.S. Studies. Environmental Science & Technology, p.acs.est.6b02023.

[3] Babrauskas, V. et al., 2012. Flame retardants in building insulation: a case for re-evaluating building codes. Building Research & Information, 40(6), pp.738–755.

[4] *See* Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control, 82 Fed. Reg. 4825, 4829 (January 17, 2017).

[5] *See* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 7562, 7565-6 (January 19, 2017).

[6] Fluoride Chemicals in Drinking Water; TSCA Section 21 Petition; Reasons for Agency Response, 82 Fed. Reg. 11878, 11880 (February 27, 2017).

This interpretation is correct, and we believe compelled by the plain reading of the law.[7] A contrary interpretation providing the Agency discretion to ignore any condition of use would violate the statutory directive concerning the designation of low-priority substances under Section 6(b)(1)(B)(ii) of TSCA. By definition, low-priority substances are chemicals found by EPA as not presenting an unreasonable risk to health and the environment, including to a potentially exposed or susceptible subpopulation, "because of a potential hazard and a potential route of exposure under the conditions of use." (Emphasis added). A single hazard or exposure under the conditions of use, broadly defined in the statute, is sufficient to compel a high-priority designation.[8] Where EPA lacks sufficient information regarding a substance, the default designation is "high priority," under Section 6(b)(1)(C)(iii) of TSCA. This default mechanism demonstrates the statutory obligation to perform a comprehensive chemical evaluation. EPA discretion to ignore some conditions of use would undermine the very purpose of the default mechanism – to confine low priority designations to chemicals which do not present an unreasonable risk under any conditions of use.[9]

A reading of the law requiring consideration of all known, intended, or reasonably foreseeable activities related to a chemical substance is also compelled by further statutory construction and legislative history. Specifically, the statute directs EPA to determine whether a chemical presents an unreasonable risk of injury to health or the environment under "the conditions of use" and to establish a risk evaluation process to conduct this inquiry.[10] In provision after provision, EPA is directed to evaluate the chemical under "the conditions of use."[11]

"Conditions of use" is expressly and broadly defined to mean "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[12] Under this statutory definition, and in the various applications of the term in the law, including but not limited to the risk evaluation determination, there are no exceptions embedded in either the definition or in the application of the term when it is used. This absence of discretion to ignore uses for risk evaluation purposes is consistent with the legislative history supporting the comprehensive evaluation of a chemical and with the statutory requirements for priority designation.[13]

Furthermore, as EPA notes at 82 Fed. Reg. 4829, EPA is required to evaluate the "chemical substance"[14] as a whole,[15] not particular uses of the chemical in question. If the statute were interpreted to allow EPA

[7] Therefore, we do not believe different readings of the law are possible, as suggested by the Agency at 82 Fed. Reg. 7565.

[8] *See* 82 Fed. Reg. 4830.

[9] *See* 82 Fed. Reg. 4830.

[10] 15 U.S.C. § 2605(b)(4)(A), (B).

[11] *See, e.g.,* 15 U.S.C. § 2605(b)(1)(B), (b)(4)(F).

[12] 15 U.S.C. § 2602(4).

[13] *See* Senate Floor Debate, 162 Cong. Rec. S.3511-01, S3516 (Jun. 7, 2016) (Analysis and Views of Democratic Members (Boxer, Markey, Udall, Merkley), in regards to the "conditions of use" definition: "In fact, a new definition added to TSCA explicitly provides such authority [to consider reasonably anticipated uses in evaluating risk] and a *mandate* for EPA to consider conditions of use that are not currently known or intended but can be anticipated to occur.") (Emphasis added). If EPA had the discretion to ignore certain uses, there could be no mandate to consider future uses because the discretionary exception would swallow the rule.

[14] NRDC supports EPA's proposal to make clear that any reference to chemical substances in the regulations encompasses categories of chemical substances as defined in the statute, including groups of chemical substances or mixtures which share similar properties. As EPA notes, the statute explicitly states that "[a]ny

to evaluate only a subset of uses of a chemical substance, the chemical substance could be determined to not pose an unreasonable risk based on the consideration of minor uses of the chemical even when other more significant uses were known or foreseen. This would not facilitate a consideration of the chemical substance as a whole, and would thereby undermine the statutory scheme.

This plain language reading is reinforced by the statutory directive to consider aggregate exposures, where relevant, because aggregate exposure assessments cannot be effectively conducted if all uses contributing to aggregate exposures are not considered. Evaluating the total exposure to a chemical is essential for assessing unreasonable risk to potentially exposed or susceptible populations, as directed by the statute.[16] As EPA notes, Section 6(b)(4)(F)(i) of TSCA requires that, in conducting a risk assessment, the Administrator "shall . . . integrate and assess available information on hazards and exposures . . . including information that is relevant to specific risks of injury to health and information on potentially exposed or susceptible subpopulations." (Emphasis added). A "potentially exposed or susceptible subpopulation" is defined as "a group of individuals within the general population . . . who, due to either greater susceptibility or greater exposure, may be at greater risk" of adverse effects.[17] As the definition makes clear, risks to potentially exposed or susceptible subpopulations are premised on greater exposure or susceptibility. For such a subpopulation, a failure to consider the sum of all known or reasonably foreseeable additive exposures would constitute a failure to meet both the Section 6(b)(4)(F)(i) obligation to assess information relevant to susceptible populations, and the fundamental Section 6 obligation to protect potentially exposed or susceptible populations from unreasonable risk. Indeed, in assessing exposures, the statute imposes an explicit "requirement" that EPA "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance,"[18] and repeatedly refers to the EPA's consideration of whether a "combination of activities" involving the chemical presents a risk to health or the environment.[19] To consider the aggregate exposure from the frequency and number of exposures considered or the "combination of activities," EPA must look across the full spectrum of a chemical's use and disposal. [20]

In sum, in light of the plain language of the statute requiring consideration of "the conditions of use," without exception; the requirement to evaluate chemical substances, not particular uses; and the

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action authorized or required to be taken by the Administrator under any provision of this chapter with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures." 15 U.S.C. § 2625(c).

[15] 15 U.S.C. § 2605(b)(4)(A).

[16] 15 U.S.C. § 2605(b)(4)(A).

[17] 15 U.S.C. § 2602(12) (emphasis added).

[18] 15 U.S.C. § 2605(b)(4)(F)(iv) (emphasis added).

[19] *See, e.g.,* 15 U.S.C. § 2605(a) (stating that "If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that *any combination of such activities*, presents an unreasonable risk of injury to health or the environment . . .") (emphasis added); § 2605(d)(3)(A) (referring to the Administrator's consideration of the effects of "the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or *any combination of such activities*") (emphasis added); § 2604(b)(2)(B) (requiring manufacturers or processors of new chemicals or of significant new uses of a chemical to submit information showing that "the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or *any combination of such activities* will not present an unreasonable risk of injury to health or the environment") (emphasis added).

[20] Accordingly, we fully expect the Analysis Plan in the scoping documents, as proposed in 40 CFR 702.39(c)(5), to expressly identify the aggregate exposure scenarios EPA intends to include in a chemical's risk evaluation.

requirement to consider aggregate exposures, where relevant, TSCA as revised compels EPA to evaluate all known, intended, and reasonably foreseeable activities associated with a chemical, as embodied in "the conditions of use."

Intended, known, or reasonably foreseeable circumstances

We now turn to what are considered "intended, known, or reasonably foreseeable" circumstances under the law. These are three separate and independent descriptors of the circumstances constituting conditions of use, therefore EPA must give meaning to each of the descriptors when identifying conditions of use for a particular chemical.

Some have suggested these descriptors preclude EPA's consideration of conditions of use which violate federal environmental or workplace regulations, exposures inconsistent with labels, and/or uses inconsistent with the manufacturer's intended use of a chemical or product.[21] However, as explained below, such limitations would violate the statute since they fail to give independent meaning to each of the descriptors. Moreover, EPA's mandate to protect "potentially exposed or susceptible populations," as the term is defined in the law, precludes EPA from summarily dismissing such conditions of use without considering whether existing regulations adequately protect such populations.

For example, the manufacturer's intended use of a chemical or product is only one descriptor applying to the conditions of use. Where the manufacturer knows the chemical or product is actually used in other ways, the public knows of other uses, and/or the Administrator can reasonably foresee other uses (based upon the chemical or product's properties and functionality), the statute compels EPA to identify such conditions of use. The reality is chemicals and products are often used in multiple ways, particularly if there are no legal constraints against such uses, and these conditions of use cannot be rejected simply because the manufacturer alleges it never intended those uses (while profiting from the sales).[22]

The same legal analysis holds true for chemical or product labels, which may largely reflect manufacturer intent. Moreover, in the case of labels for consumer products particularly, adherence to label use instructions cannot be assumed as a factual matter, particularly where the public and EPA "knows," or EPA can reasonable foresee, exposure scenarios inconsistent with labels. Indeed, EPA recently identified 48 relevant studies or meta-analyses concluding consumers and professionals do not follow the advice on the label for a variety of reasons.[23]

Even in the case where federal environmental or workplace standards apply, the relevant considerations are what is known to the Agency or the public, or what EPA can reasonably foresee, regarding uses and exposures related to the chemical. This will be a fact-based, chemical-specific inquiry, which may lead EPA to conclude exposures can exceed the relevant standards, or that the regulations themselves were not set (or adequately complied with) to protect the susceptible populations EPA is charged to protect under Section 6 of TSCA. The reality is some standards are either outdated or intended to protect the

[21] *See*, *e.g.*, Comments of the American Chemistry Council to Inform EPA's Rulemaking on the Conduct of Risk Evaluations Under the Lautenberg Chemical Safety Act, August 24, 2016, p. 10.

[22] Indeed, one potential outcome of the Section 6 regulatory process is a risk management rule prohibiting the very uses the manufacturer claims it does not intend.

[23] Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a), 81 Fed. Reg. 91592, 91601 (December 16, 2016).

general population, not the vulnerable populations specially targeted for protection under the revised TSCA.

The presence of a chemical in a product or waste stream as an impurity or byproduct does not affect the conditions of use definition or scope. Its existence will generally be "known" or "reasonably foreseen" by the manufacturer or EPA. The uses and exposures associated with impurities or byproducts can be significant and their contribution to overall exposure and risk must be accounted for in EPA's risk evaluations.

EPA must also consider uses and potential routes of exposure that are not under EPA's regulatory jurisdiction under TSCA, including in food processing and packaging, and via use in such items as personal care products and cosmetics. The risk evaluations conducted by EPA cannot accurately assess whether a chemical poses an unreasonable risk if all such uses and potential sources of exposure are not accounted for. Whether and how to address uses and potential sources of exposure that are found to contribute to an unreasonable risk is a matter for the risk management stage of the process, including potential exercise of the Agency's authority under Section 9 of TSCA.

Conditions of use and exposure scenarios as applied to HBCD

Uses and indoor exposures

EPA identifies building insulation materials (polystyrene foams) as the major commercial use of HBCD.[24] HBCD is a semi-volatile organic chemical which is used additively (not bound to) these foam plastics; HBCD can migrate out of products and partition into air and dust in the occupied spaces of buildings.[25] EPA's previous TSCA Work Plan Chemical assessment noted that "HBCD has been detected in the dust of residences, commercial buildings, automobiles, and airplanes both in the US and other countries."[26]

A recent quantitative meta-analysis[27] of chemicals in U.S. indoor dust compiled and analyzed data on HBCD from the following studies:

1. Abdallah Mohamed, A.-E. et al., 2008. Hexabromocyclododecanes in indoor dust from Canada, the United Kingdom, and the United States. Environmental Science & Technology, 42(2), pp.459–64.
2. Dodson, R.E. et al., 2012. After the PBDE Phase-Out: A Broad Suite of Flame Retardants in Repeat House Dust Samples from California. Environmental Science & Technology, 46(24), pp.13056–13066.
3. Johnson, P.I. et al., 2013. Associations between brominated flame retardants in house dust and hormone levels in men. Science of The Total Environment, 445–446, pp.177–184.

[24] US EPA, 2017. Preliminary information on manufacturing, processing, distribution, use and disposal: Cyclic aliphatic bromide cluster (HBCD). Office of Chemical Safety and Pollution Prevention, Support document for docket EPA-HQ-OPPT-2016-0735

[25] Weschler, C.J. & Nazaroff, W.W., 2008. Semivolatile organic compounds in indoor environments. Atmospheric Environment, 42(40), pp.9018–9040.

[26] US EPA, 2015. TSCA Work Plan Chemical Problem Formulation and Initial Assessment: Cyclic Aliphatic Bromides Cluster Flame Retardants. Office of Chemical Safety and Pollution Prevention, EPA Document# 743-D1-5001, pg. 26

[27] Mitro, S.D. et al., 2016. Consumer Product Chemicals in Indoor Dust: A Quantitative Meta-analysis of U.S. Studies. Environmental Science & Technology, p.acs.est.6b02023.

4. Schreder, E.D. & La Guardia, M.J., 2014. Flame Retardant Transfers from U.S. Households (Dust and Laundry Wastewater) to the Aquatic Environment. Environmental Science & Technology, 48(19), pp.11575–11583.
5. Stapleton, H.M. et al., 2014. Flame retardant associations between children's handwipes and house dust. Chemosphere, 116, pp.54–60.

Across the studies, HBCD was detected in 92-100% of the samples, indicating that the chemical is ubiquitous in indoor dust. Though these studies sampled residential (home) environments, other studies also find HBCD in school, daycare, and vehicle dust.[28,29]

In developed countries, people spend more than 90% of their time indoors,[30] and the above data indicate that the U.S. population has nearly continuous exposure to HBCD from the dust of indoor environments. Young children are of particular concern- they have greater exposure to contaminated dust because they crawl, play on the floor, and put their hands in their mouths;[31] children would experience HBCD exposure throughout the day as they move between home, cars and school or daycare.

Further, recent testing of car seats also indicated the presence of HBCD,[32] therefore close contact with such products should also be considered as a source of exposure for infants and young children.

Occupational

EPA's Initial Assessment highlighted potential risks to manufacturing and processing workers,[33] but worker exposures can occur throughout the lifecycle of HBCD: manufacturing, processing, product installation, recycling and/ or disposal. Construction workers may be exposed when they handle, cut and install HBCD-containing insulation boards.[34]

Routes of Exposure

Dust ingestion

The HBCD chemical assessment under TSCA must include dust ingestion as part of the aggregate exposure assessment. A recent study predicted that dust ingestion was the major contributor to a young

[28] Harrad, S. et al., 2010. Dust from U.K. primary school classrooms and daycare centers: The significance of dust as a pathway of exposure of young U.K. children to brominated flame retardants and polychlorinated biphenyls. Environmental Science and Technology, 44(11), pp.4198–4202.

[29] Harrad, S. & Abdallah, M.A.-E., 2011. Brominated flame retardants in dust from UK cars – Within-vehicle spatial variability, evidence for degradation and exposure implications. Chemosphere, 82(9), pp.1240–1245.

[30] Klepeis, N. E.; Nelson, W. C.; Ott, W. R.; Robinson, J. P.; Tsang, A.M.; Switzer, P.; Behar, J. V.; Hern, S. C.; Engelmann, W. H. The National Human Activity Pattern Survey (NHAPS): a resource for assessing exposure to environmental pollutants. J. Exposure Anal. Environ. Epidemiol. 2001, 11 (3), 231−252.

[31] United States Environmental Protection Agency. Child-Specific Exposure Factors Handbook; National Center for Environmental Assessment: Washington, DC, 2002.

[32] Ecology Center 2016. Children's Car Seat Study 2016- Report. Available: http://www.ecocenter.org/healthy-stuff/pages/childrens-car-seat-study-2016-report

[33] US EPA, 2015. Initial Assessment: Cyclic Aliphatic Bromides Cluster Flame Retardants. pg. 24-25

[34] Zhang, H. et al., 2012. Co-release of hexabromocyclododecane (HBCD) and Nano- and microparticles from thermal cutting of polystyrene foams. Environmental Science & Technology, 46(20), pp.10990–6.

child's total residential exposures to HBCD.[35] Further, EPA's Initial Assessment notes that available assessments likely underestimate HBCD dust exposures for U.S. consumers, and that exposure to HBCD-contaminated dust from schools/ daycare and vehicles should be considered for children.[36]

Dermal absorption

The HBCD chemical assessment under TSCA must include dermal exposures as part of the aggregate exposure assessment. Studies find that HBCD can be absorbed through the skin,[37] including potentially through dermal contact with contaminated dust[38] or products containing HBCD. EPA's Initial Assessment found that dermal exposure was an important pathway for workers.[39]

Additionally, HBCD exposure can also occur from the air-to-dermal pathway in indoor environments.[40] A recent study predicted that the air-to-dermal pathway would contribute to a young child's total residential exposures to HBCD.[41]

Breathing contaminated air

The HBCD chemical assessment under TSCA must include inhalation exposures as part of the aggregate exposure assessment. EPA's Initial Assessment found that inhalation exposures were important for workers, and that HBCD is widely measured in the air of indoor environments.[42] A recent study predicted that inhalation would contribute to a young child's total residential exposures to HBCD.[43]

Incineration of HBCD-containing materials can generate toxic combustion by-products such as brominated dioxins and furans.[44] Inhalation exposure assessment must also consider combustion by-products and include communities near incineration facilities.

Drinking contaminated water

The HBCD chemical assessment under TSCA must include drinking water exposures as part of the aggregate exposure assessment. HBCD has been measured in surface water and sediments in the U.S., and drinking water in other countries. [45] Absent USA testing data, EPA should use conservative default values based upon the drinking water measurements in other countries.

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[35] Mitro, S.D. et al., 2016. Consumer Product Chemicals in Indoor Dust: A Quantitative Meta-analysis of U.S. Studies. Environmental Science & Technology, p.acs.est.6b02023. See Figure 3.

[36] US EPA, 2015. Initial Assessment: Cyclic Aliphatic Bromides Cluster Flame Retardants. pg. 31

[37] Abdallah, M.A.-E., Pawar, G. & Harrad, S., 2015. Evaluation of 3D-human skin equivalents for assessment of human dermal absorption of some brominated flame retardants. Environment International, 84, pp.64–70.

[38] Pawar, G. et al., 2017. Dermal bioaccessibility of flame retardants from indoor dust and the influence of topically applied cosmetics. Journal of Exposure Science and Environmental Epidemiology, 27(1), pp.100–105.

[39] US EPA, 2015. Initial Assessment: Cyclic Aliphatic Bromides Cluster Flame Retardants. pg. 24

[40] Weschler, C.J. & Nazaroff, W.W., 2012. SVOC exposure indoors: fresh look at dermal pathways. Indoor air, 22(5), pp.356–77.

[41] Mitro, S.D. et al., 2016. Consumer Product Chemicals in Indoor Dust: A Quantitative Meta-analysis of U.S. Studies. Environmental Science & Technology, p.acs.est.6b02023. See Figure 3.

[42] US EPA, 2015. Initial Assessment: Cyclic Aliphatic Bromides Cluster Flame Retardants.pg. 24 and 26

[43] Mitro, S.D. et al., 2016. Consumer Product Chemicals in Indoor Dust: A Quantitative Meta-analysis of U.S. Studies. Environmental Science & Technology, p.acs.est.6b02023. See Figure 3.

[44] Desmet, K., Schelfaut, M. & Sandra, P., 2005. Determination of bromophenols as dioxin precursors in combustion gases of fire retarded extruded polystyrene by sorptive sampling-capillary gas chromatography–mass spectrometry. Journal of Chromatography A, 1071(1–2), pp.125–129.

[45] US EPA, 2015. Initial Assessment: Cyclic Aliphatic Bromides Cluster Flame Retardants. pg. 23-25

Food contamination/ breast milk

The HBCD chemical assessment under TSCA must include food (or breast milk for infants) exposures as part of the aggregate exposure assessment. HBCD has been measured in a variety of supermarket foods, including fish, peanut butter, beef and poultry. [46,47] EPA's Initial Assessment cites nine biomonitoring studies of HBCD in breast milk[48] and additional studies have since been published.

Because HBCD bioaccumulates and has been widely measured in fish and marine mammals,[49] the exposure assessment must also account for high-end fish consumption by subsistence communities, as well as communities in the Arctic that rely on fish and marine mammals.

Potential susceptible populations of concern, based on conditions of use and exposures

Virtually the entire population is at risk of exposures because of widespread contamination of air and dust in homes, offices, schools and cars. Reproductive aged men and women, pregnant women, infants and children, elders, and people with health conditions, are likely exposed daily to HBCD. EPA must consider all populations, including the following vulnerable populations:

Children: Early life exposures

The chemical assessments for HBCD under TSCA must include risk estimates for pregnant women and children due to early life exposures (prenatal through childhood). Children are more susceptible to potential reproductive toxicity of HBCD during critical windows of development; further they also have greater exposure to contaminated dust.

Arctic indigenous communities

The HBCD chemical assessment under TSCA must include risk estimates for Arctic indigenous communities that rely on traditional foods. Such communities, including the American Indian and Alaska Native peoples and communities, are vulnerable by almost any definition, including those in the EPA's EJSCREEN.[50] These people face a legacy of myriad disadvantages that includes environmental pollution, but more broadly involves economic adversity and poor social conditions, including limited healthcare, with the population facing disproportionate health conditions and an overall lower life expectancy and decreased quality of life as compared to other ethnic populations.[51,52]

People with impaired liver function

The HBCD chemical assessment under TSCA must include risk estimates for people with impaired liver function, who may be more susceptible to HBCD liver toxicity. According to data from the Centers for

[46] Schecter, A. et al., 2010. Polybrominated diphenyl ethers (PBDEs) and hexabromocyclodecane (HBCD) in composite U.S. food samples. Environmental Health Perspectives, 118(3), pp.357–62.

[47] Schecter, A. et al., 2012. Hexabromocyclododecane (HBCD) Stereoisomers in U.S. Food from Dallas, Texas. Environmental Health Perspectives, 120(9), pp.1260–1264.

[48] US EPA, 2015. Initial Assessment: Cyclic Aliphatic Bromides Cluster Flame Retardants. pg. 25

[49] Id. pg. 24

[50] US EPA, June 2016. EJSCREEN Environmental Justice Mapping and Screening Tool: Technical Documentation. Available: https://www.epa.gov/sites/production/files/2016-07/documents/ejscreen_technical_document_20160704_draft.pdf

[51] Indian Health Service (HIS). Disparities. Available online from: https://www.ihs.gov/newsroom/factsheets/disparities/

[52] Jones, D.S. The persistence of American Indian health disparities. *Amer. J. Public Health* **2006**, *96*, 2122–2134.

Disease Control and Prevention, liver disease is the eighth leading cause of death in the U.S., with billions of dollars a year in direct costs.[53]

Aggregate and cumulative exposure

To guarantee that ample information is collected and data gaps appropriately identified, EPA must identify all potential sources of information related to, but not limited to, chemical properties (e.g., physical and chemical characteristics, related chemistries, metabolic potential, etc.), sources of hazard and dose response information (e.g., animal, non-animal, epidemiologic, mechanistic studies, etc.), sources of aggregate and cumulative exposure information (e.g., sources of near- and far-field exposure including environmental release information, production volume, presence in consumer and household products, dietary intake, occupational exposure, modeling tools with mechanisms for quantifying uncertainty and variability, etc.), and sensitive and/or vulnerable subpopulations for each condition of use.

Using this information, EPA is required to evaluate at least the following realistic aggregate exposures:

1. The general population is exposed to HBCD by the aggregation of inhalation, dermal and dust ingestion exposures in indoor environments (home, school, offices, cars); consumption of contaminated foods (or breast milk for infants), drinking water, and contact with consumer products containing the compound. The target subpopulations identified above warrant particular emphasis as part of the aggregate exposure evaluation.

2. Communities near manufacturing, processing, recycling, incineration or disposal facilities would have the exposures experienced by the general population, as well as additional exposures due to air and water releases from facilities.

3. Adults of reproductive age, including and in many cases especially men, can be exposed to the aggregate of both the general population exposures (described in #1 above) and occupational exposures. For example, a construction worker is exposed to HBCD through routine daily tasks in the workplace, and then again at home, and through food. The aggregate of occupational and other exposures must be included in EPA's analysis.

<u>Cumulative exposures should consider exposure to other similar chemicals</u>

Indoor environment: Of the 45 chemicals commonly found in indoor dust, 25 including HBCD share the human health hazard of reproductive toxicity.[54] Ten other flame retardants commonly are found in indoor dust. Studies indicate that exposure to mixtures of brominated flame retardant chemicals increases the likelihood for developmental effects.[55]

[53] Kim, W., 2002. Burden of liver disease in the United States: Summary of a workshop. Hepatology, 36(1), pp.227–242. Available at: http://www.ncbi.nlm.nih.gov/pubmed/12085369.

[54] Mitro, S.D. et al., 2016. Consumer Product Chemicals in Indoor Dust: A Quantitative Meta-analysis of U.S. Studies. Environmental Science & Technology, p.acs.est.6b02023. See Figure 4.

[55] Berger, R.G. et al., 2014. Exposure to an environmentally relevant mixture of brominated flame retardants affects fetal development in Sprague-Dawley rats. Toxicology, 320(1), pp.56–66.

Communities: Arctic communities and communities near facilities that release HBCD likely suffer from legacy contamination and/ or other sources of pollution.

HBCD exposures should be considered in the context of these other ongoing chemical exposures.

Thank you for your consideration of these comments. We look forward to working with EPA to ensure that unreasonable risks of this persistent, bioaccumulative and toxic flame retardant chemical are properly identified and fully mitigated to protect environmental and human health.

Sincerely,

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