U.S. Environmental Protection Agency

Cyclic Aliphatic Bromide Cluster (HBCD); Revision to Toxic Substances Control Act (TSCA) Risk Determination;
Response to Public Comments

EPA–HQ–OPPT–2019–0237

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Acronyms and Abbreviations

ACC	American Chemistry Council
COU	Condition of use
EPA	U.S. Environmental Protection Agency
EPS	Expanded polystyrene
HBCD	Cyclic aliphatic bromide cluster
MOU	Memorandum of understanding
NIOSH	National Institute for Occupational Safety and Health
ONU	Occupational non-user
OSHA	Occupational Safety and Health Administration
OSH Act	Occupational Safety and Health Act of 1970
PEL	Permissible exposure limit
PESS	Potentially exposed or susceptible subpopulation
PNOR	Particulates not otherwise regulated
PPE	Personal protective equipment
SACC	Science Advisory Committee on Chemicals
SNUR	Significant New Use Rule
TSCA	Toxic Substances Control Act
U.S.	United States
XPS	Extruded polystyrene

Introduction

On December 29, 2021, the U.S. Environmental Protection Agency (EPA) published a notice of availability and request for comment on a draft revision to the Toxic Substances Control Act (TSCA) Risk Determination for Cyclic Aliphatic Bromide Cluster (HBCD). In the notice, EPA announced that public comments would be accepted until February 14, 2022. On February 17, 2022, EPA reopened the public comment period and announced that public comments would be accepted until March 4, 2022.

EPA received a total of 25 public comment submissions in response to the request for comments. ICF, an EPA contractor, summarized the 25 unique and responsive submissions received. Following this introduction, Table 1, Index of Comment Submissions Sorted by Submission Number, identifies the commenter name and the comment number for the 25 unique submissions included in this summary.

The comment summaries and responses that follow are organized into issue topic areas, as indicated in the table of contents.

Table 1: Index of Comment Submissions Sorted by Submission Number

Submission Number	Organization
EPA-HQ-OPPT-2019-0237-0096	B&C Consortia Management, L.L.C. (BCCM)
EPA-HQ-OPPT-2019-0237-0097	American Chemistry Council (ACC)
EPA-HQ-OPPT-2019-0237-0098	John Vernath
EPA-HQ-OPPT-2019-0237-0099	TSCA Against Whole Chemical Approach Coalition
EPA-HQ-OPPT-2019-0237-0100	Chemical Users Coalition (CUC)
EPA-HQ-OPPT-2019-0237-0101	EPS Industry Alliance
EPA-HQ-OPPT-2019-0237-0102	National Association of Home Builders (NAHB)
EPA-HQ-OPPT-2019-0237-0103	American Federation of Labor and Congress of Industrial Organizations (AFL-CIO)
EPA-HQ-OPPT-2019-0237-0104	National Tribal Toxics Council (NTTC), Dianne Barton
EPA-HQ-OPPT-2019-0237-0106	Plastics Industry Association (PLASTICS), Marie Gargas
EPA-HQ-OPPT-2019-0237-0107	Eastman Chemical Company
EPA-HQ-OPPT-2019-0237-0108	American Chemistry Council, Plastics Division, Building & Construction
EPA-HQ-OPPT-2019-0237-0109	Fragrance Science & Advocacy Council (FSAC)
EPA-HQ-OPPT-2019-0237-0110	Silicones Environmental, Health and Safety Center (SEHSC)
EPA-HQ-OPPT-2019-0237-0111	Fragrance Creators Association and Society of Chemical Manufacturers and Affiliates (SOCMA)
EPA-HQ-OPPT-2019-0237-0112	Alliance for Automotive Innovation (Auto Innovators)
EPA-HQ-OPPT-2019-0237-0113	Ad-Hoc Downstream Users Coalition
EPA-HQ-OPPT-2019-0237-0114	Earthjustice on behalf of Alaska Community Action on Toxics et al.
EPA-HQ-OPPT-2019-0237-0115	Environmental Defense Fund, Samantha Liskow
EPA-HQ-OPPT-2019-0237-0116	Project TENDR (Targeting Environmental Neuro-Development Risks), Jerry Abraham et al.
EPA-HQ-OPPT-2019-0237-0117	International Union, United Automobile, Aerospace & Agricultural Implement Workers of America (UAW)
EPA-HQ-OPPT-2019-0237-0118	Safer Chemicals Healthy Families, Asbestos Disease Awareness Organization, Defend Our Health and NRDC
EPA-HQ-OPPT-2019-0237-0119	American Chemistry Council (ACC), Suzanne Hartigan
EPA-HQ-OPPT-2019-0237-0120	Bergeson & Campbell, P.C. (B&C), Richard E. Engler
EPA-HQ-OPPT-2019-0237-0121	American Chemistry Council Formaldehyde TSCA Risk Evaluation Consortium, Lynn Dekleva

Section 1 – General support for the draft revision to the unreasonable risk determination

Comments that provided general support also provided more substantive arguments that are summarized in other portions of the summary report.

Several commenters provided general support for the HBCD revised unreasonable risk determination including unions (0117, 0103), a tribal organization (0104), and non-governmental environmental and health advocacy organizations (0114, 0115, 0118). The organizations favored the change to a whole chemical approach because, among other things, the whole chemical approach better aligns with the goals of TSCA and the 2016 Lautenberg amendments. The unions and Tribes believe that by removing the assumption that workers wear PPE, EPA can adopt risk management that better protects not only workers but potentially exposed and sensitive subpopulations.

EPA RESPONSE
EPA appreciates the support for the revised unreasonable risk determination.

Section 2 – General opposition to the draft revision to the unreasonable risk determination

An industry trade organization (0100) stated that the draft revisions to the risk determination will change public interpretations of risk and have unwarranted impacts on future risk management decision-making and cause unintended regulatory impacts on articles containing certain substances. Similarly, a chemical manufacturer (0107) stated concern over perceived changes to EPA's overall strategy in determining risk and expressed concern for the potential impacts to future risk determinations and associated supply chains.

EPA RESPONSE
EPA would like to reiterate that this action pertains specifically to the unreasonable risk determination for HBCD. While EPA intends to consider and may take additional similar actions on other of the first ten chemical substances with completed TSCA section 6 risk evaluations, EPA is taking a chemical-specific approach to revising the risk determination of this risk evaluation and is incorporating new policy direction in a surgical manner, while being mindful of Congressional direction on the need to complete risk evaluations and move toward any associated risk management activities.

With respect to impacts from this revised unreasonable risk determination on risk management of HBCD, EPA will propose a regulatory action with requirements under TSCA section 6(a) to the extent necessary so that HBCD no longer presents unreasonable risk. Such proposed regulatory action would be subject to public comments, and EPA would consider such public comments and any additional information before finalizing the rulemaking. As a result, EPA expects that impacts to supply chains and HBCD-containing articles will be considered during rulemaking.

Section 3 – Comments that request an extension to the comment period

A professional association (0096) commented that the complexity and potential impact of the revision to the risk determination is such that additional time is needed to evaluate the proposal. Similarly, an industry trade association (0097) requested that EPA allow for an additional 30 days in the comment period to provide meaningful feedback.

EPA RESPONSE
EPA received and noted both requests and reopened the comment period from February 17 until March 4, 2022.

Section 4 – General legal issues

Comments associated with this issue are summarized below. Legal issues specific to other topics in the issue outline are summarized within the specific section.

Section 4.1 – Strength of the information supporting the risk evaluation

Two commenters provided feedback on EPA's statutory authority under TSCA. One commenter (0117) stated that EPA should use its authority under TSCA to "research and collect" additional occupational exposure data to guide risk management decisions. An individual (0120) commented that EPA has exceeded its statutory authority by issuing a risk determination based on hazard, which is not allowed under TSCA.

In addition, an industry trade organization (0119) and an individual commenter (0120) added that EPA's proposed approach also does not comply with TSCA's section 26 requirements that risk evaluations be consistent with best available science and based on the weight of the scientific evidence, nor does the legislative record for the TSCA amendments support EPA's new policy direction. The industry trade organization (0119) commented that the EPA 2021 Draft Systematic Review protocol significantly updated the TSCA systematic review process and developed a systematic review protocol to address the National Academies of Science, Engineering, and Medicine (NASEM) recommendations to EPA on its systematic review process for risk evaluations. The industry trade organization (0119) believes the revised unreasonable risk determination should be updated to reflect the EPA 2021 Draft Systematic Review protocol in order to meet the requirements under TSCA section 26.

EPA RESPONSE
EPA acknowledges the comment on the Agency's statutory authority to collect additional data to inform risk management decision-making. EPA identified and reviewed occupational exposure information through the systematic review process and from public commenters to inform the HBCD risk evaluation. EPA considers that information, as reflected in the hazard and exposure assessments and risk characterization in the September 2020 risk evaluation, to be sufficient information on occupational exposure to make the unreasonable risk determination and inform risk management. In particular, "EPA views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i)" (86 FR 74082), and these assessments and risk characterization will inform EPA's risk management decision-making. While EPA welcomes any additional information from stakeholders during the development of the risk management rules, EPA expects to be able to complete proposed and final risk management rules without additional information regarding occupational exposures to HBCD.

EPA also notes that the assertion that the Agency based its determination on hazard alone is not correct; the revised unreasonable risk determination is based on both the hazard of the chemical substance and the exposures or environmental releases, as described in Sections 3 and 2, respectively, of the final HBCD

risk evaluation,[1] and further explained in Sections 5.2 and 5.3 of the revised unreasonable risk determination.

While EPA has undertaken efforts to refine its 2018 approach to systematic review by developing a draft systematic review protocol that has undergone review by NASEM and likely will be revised to reflect the NASEM peer reviewers' feedback, the draft protocol is not yet final. In addition, EPA expects to apply that protocol, when final, prospectively and not retroactively; retroactive application would lead to further delays in completing the risk evaluations for the first ten substances contrary to Congressional intent. Thus, EPA maintains that the 2020 HBCD risk evaluation meets TSCA section 26(h) requirements.

Section 4.2 - Process of revising the risk determination

EPA received comments related to the process of revising the risk determination. Several industry trade organizations and an individual commenter (0120, 0099, 0109, 0119) requested that EPA withdraw the draft revision to the risk determination.

Some commenters (0120, 0099) requested that EPA undertake a notice and comment rulemaking on the risk evaluation rule[2] before revising the risk determination for HBCD or other chemicals. An industry trade organization (0099) stated that EPA's approach to revising the HBCD risk determination is in opposition to its own regulations at 40 CFR 702, subpart B, which allow for risk determinations to be made on individual conditions of use (COUs) or categories of conditions of use. The commenter suggested that the risk evaluation rule (or Final Framework Rule) [3] allows EPA to assess risk and promulgate rules that would apply only to the COUs that present an unreasonable risk, and that those that do not present such risk would not be subject to risk management. The commenter asserted that, by claiming the risk evaluation rule (or Final Framework Rule) is ambiguous, EPA appears to be arguing that its new interpretation – that the rule allows for a -whole chemical approach – is entitled to *Auer* deference[4,5]. The commenter opined that the *Auer* deference should be more exacting according to the Supreme Court in *Kisor v. Wilkie* in saying the existing regulation must be genuinely ambiguous. The commenter further stated that EPA failed to establish that the 40 CFR part 702 regulations are genuinely ambiguous in this revised risk determination for HBCD. EPA's argument that it is justified in moving to a whole chemical approach without engaging in rulemaking thus does not meet the standards of *Auer* deference. The commenter recommended that the EPA instead repropose the risk evaluation rule for notice and comment before proceeding with the Agency's whole chemical approach.

Other commenters (0119, 0109) requested that EPA provide an explanation for the proposed changes and additional public comment opportunity before applying the changes. Specifically, one commenter (0119) stated that by proposing a whole chemical approach EPA contradicts TSCA and its implementing regulations, has failed to use sound reasoning, and lacks science-based justification in compliance with

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[1] https://www.epa.gov/sites/default/files/2020-09/documents/1._risk_evaluation_for_cyclic_aliphatic_bromide_cluster_hbcd_casrn25637-99-4_casrn_3194-5_casrn_3194-57-8.pdf

[2] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726) (July 20, 2017).

[3] *Id*.

[4] A principle of judicial review of agency actions that requires a federal court to yield to an agency's interpretation of an ambiguous regulation issued by such agency.

[5] *Auer v. Robbins* 519 U.S. 452, 117 S. Ct. 905, 137 L. Ed. 2d 79 (1997).

TSCA section 26. Furthermore, the commenters believe the whole chemical approach lacks clarity and will have substantial impacts on future chemical analysis.

Another industry trade association (0108) recommended that EPA reconsider and withdraw the draft revision to the risk determination for HBCD and continue to use known data to make science-driven decisions. Another industry trade organization (0106) stressed that EPA should initiate a public consultation process, engage in discussions about how newly proposed policies are justified and how the risk evaluation and management processes will be impacted, and inform the public on the additional information EPA intends to collect and its intended approach to addressing potential exposure.

A commenter (0120) argued that EPA's proposal to withdraw the orders determining certain conditions of use present no unreasonable risk in the 2020 HBCD final risk evaluation was not supported by TSCA.

Another commenter (0120) believed EPA was selective in the regulatory text used to justify the whole chemical approach. Some industry trade organizations (0099, 0100, 0110) commented that there is no ambiguity to the approach in the Risk Evaluation Rule as EPA explicitly determined and described its intent to employ an individual COU-based risk determination approach. An organization and individual commenter (0110, 0120) also said that the preamble of the Risk Evaluation Rule explicitly states in detail the application of the use-by-use approach and that the whole chemical approach violates the final Risk Evaluation rule.

A few industry trade organizations (0099, 0121) discussed how *Kisor v. Wilkie* does not support a whole chemical approach. The organizations state that when the "*Kisor* factors" are correctly applied, 40 CFR 702.47 is not genuinely ambiguous, nor could any interpretation allow a whole chemical approach to be deemed reasonable. The organizations also reasoned that under the *Kisor* test, EPA must repropose the 40 CFR Part 702, subpart B regulations for notice and comment before proceeding with the whole chemical approach (*refer to Section 4.2 for further discussion on the process of revising the risk determination*). The commenters argued that the plain language of 40 CFR 702.47 clearly requires a use-by-use determination.

In contrast, an advocacy group (0115) argued at length that *Kisor* reaffirmed the long-standing principle that courts must generally defer to agencies' reasonable interpretations of their own ambiguous regulations, and that the list of considerations provided by the Court in *Kisor* favors a reviewing court granting deference to EPA on its whole chemical approach.

Other comments discussing legal issues with the whole chemical approach, including its consistency with TSCA, are discussed below in Section 5.1.

EPA RESPONSE

The draft revised unreasonable risk determination for HBCD was published in December 2021 along with the Federal Register Notice explaining the whole chemical approach to the HBCD risk determination, and why EPA believes that a whole chemical approach to HBCD better aligns with TSCA's objective of protecting health and the environment. EPA provided notice and an extended opportunity for public comment on the draft revised risk determination for HBCD and the approach described in the Federal Register Notice.

The revised unreasonable risk determination for HBCD is based on the peer reviewed risk characterization of the September 2020 risk evaluation, which was developed according to TSCA section 26(h) requirements to make science-driven decisions, consistent with best available science. Changing the risk determination to a whole chemical approach does not impact the underlying data and analysis

presented in the risk characterization of the risk evaluation. While EPA has undertaken efforts to refine its 2018 approach to systematic review by developing a draft systematic review protocol that has undergone review by NASEM and likely will be revised to reflect the NASEM peer reviewers' feedback, the draft protocol is not yet final. In addition, EPA expects to apply that protocol, when final, prospectively and not retroactively; retroactive application would lead to further delays in completing the risk evaluations for the first ten substances contrary to Congressional intent. Thus, EPA maintains that the 2020 HBCD risk evaluation meets TSCA section 26(h) requirements.

With respect to EPA's approach to changing the HBCD risk determination, or the comment on EPA's proposal to withdraw the TSCA section 6(i) order containing no unreasonable risk determinations stating that EPA did not follow 40 CFR 702, Subpart B requirements (please note that 40 CFR part 702, subpart B does not address the revocation of TSCA section 6(i) orders), EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the to the extent permitted by law and supported by reasoned explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Further, on August 10, 2021, the Ninth Circuit granted EPA's motion for voluntary remand without vacatur, so that EPA may conduct reconsideration proceedings on the HBCD Risk Evaluation, particularly to reconsider the no unreasonable risk determinations made within.[6]

As to the final Risk Evaluation Rule or framework rule,[7] EPA acknowledges a lack of specificity in the statute and inconsistency in the regulations with respect to the presentation of risk determinations in TSCA section 6 risk evaluations. In the September 2020 HBCD risk evaluation, EPA applied 40 CFR 702.47 based on one particular passage in the preamble to the final Risk Evaluation Rule, which stated: "The final step of a risk evaluation is for EPA to determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment. EPA will make individual risk determinations for all uses identified in the scope. This part of the regulation is slightly amended from the proposed rule, to clarify that the risk determination is part of the risk evaluation, as well as to account for the revised approach to [sic] that ensures each condition of use covered by the risk evaluation receives a risk determination." 82 FR 33726, 33744. However, in contrast to this portion of the preamble of the final Risk Evaluation Rule, the regulatory text itself and other statements in the preamble reference a risk determination for *the chemical substance* under its conditions of use, rather than separate risk determinations for each of the conditions of use of a chemical substance. In the key regulatory provision excerpted previously from 40 CFR 702.47, the text explains that "[a]s part of the risk evaluation, EPA will determine whether *the chemical substance* presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents" (emphasis added). Other language reiterates this perspective. For example, 40 CFR 702.31(a) states that the purpose of the rule is to establish the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B). Likewise, there are recurring references to whether the chemical substance presents an unreasonable risk in 40 CFR 702.41(a). Notwithstanding the one preambular statement about condition-of-use-specific risk determinations, the preamble to the final rule also contains support for a risk

[6] *Alaska Community Action on Toxics, et al.* v. *U.S. Environmental Protection Agency* (Ninth Cir. No. 20-73099).
[7] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726) (July 20, 2017).

determination on the chemical substance as a whole. In discussing the identification of the conditions of use of a chemical substance, the preamble notes that this task inevitably involves the exercise of discretion on EPA's part, and, "[a]s EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk." (82 FR 33729).

Therefore, notwithstanding EPA's choice to issue condition-of-use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole-chemical risk determinations. Either approach is permissible under the regulation, and the Agency's interpretation is entitled to *Auer* deference when using the multifactor test set forth in *Kisor*. As such, notice and comment rulemaking is not necessary before revising the HBCD risk determination.

With respect to risk management for HBCD, EPA has been engaging with stakeholders while determining a proposed regulatory path under TSCA section 6(a) to address unreasonable risks from HBCD. During such engagement, EPA has encouraged stakeholders to provide any additional information EPA should consider during rulemaking. EPA has not initiated any formal data collection actions to obtain additional information during rulemaking, and stakeholders and the public in general will have an opportunity to provide comments and any additional information during the comment period of the proposed risk management rule.

Finally, as a general matter, EPA must apply one or more requirements in TSCA section 6(a) to the extent necessary to address the unreasonable risk determined to be presented through a TSCA section 6(b) risk evaluation. Under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, commercial use, and disposal in order to address the unreasonable risk. For instance, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities driving unreasonable risk (e.g., consumer use) even if the upstream activities do not drive the unreasonable risk.

EPA appreciates comments concerning the application of *Kisor* to EPA's draft revised unreasonable risk determination for HBCD. Contrary to the view taken by the industry trade organizations (0099, 0121), EPA's interpretation of 40 CFR 702.47 as permitting the issuance of either condition-of-use or whole-chemical risk determinations is a reasonable interpretation of that regulation, and would be entitled to *Auer* deference when using the multifactor test set forth in *Kisor*.

The text of 40 CFR 702.47 can reasonably be interpreted as permitting a whole-chemical risk determination, because EPA is directed to determine whether the "chemical substance" presents an unreasonable risk of injury to health or the environment. 40 CFR 702.47. However, the regulation also states that EPA's determination is to be made "under each condition of use[]" of the chemical substance, without clarifying whether EPA's determination(s) are to inform a single whole-chemical determination or stand apart as COU-specific determinations. *Id*. EPA's interpretation that either the whole-chemical or condition-of-use risk determination is permitted by the regulation is reinforced by the structure and history of the regulatory text. On the one hand, the preamble to the 2017 final rule adding 40 CFR part 702 subpart B – Procedures for Chemical Substance Risk Evaluations (the Risk Evaluation Rule) states that "[t]he final step of a risk evaluation is for EPA to determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment[,] and *EPA will make individual risk determinations for all uses identified in the scope*." 82 Fed. Reg. 33,726, 33,744 (Jul. 20, 2017) (emphasis added). On the other hand, 40 CFR 702.31(a) states that the purpose of 40 CFR Part

702 Subpart B is to establish "the EPA process for conducting a risk evaluation to determine whether *a chemical substance* presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B)." Likewise, there are recurring references in 40 CFR 702.41(a) to whether the chemical substance presents an unreasonable risk (see, e.g., 40 CFR 702.41(a)(6)). And in addition to the above-described preambular statement about condition of use-specific risk determinations, the preamble to the final Risk Evaluation Rule also contains support for a risk determination on the chemical substance as a whole. In discussing the identification of the conditions of use of a chemical substance, the preamble notes that this task "will inevitably involve the exercise of some discretion" on EPA's part, and, "[a]s EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk." 82 Fed. Reg. 33,726, 33,729 (Jul. 20, 2017).

Furthermore, EPA's interpretation of 40 CFR 702.47 implicates its policy expertise with respect to its administration of TSCA. Congress was clear that TSCA provides EPA broad authority to regulate existing chemicals, and delegated to EPA responsibility for implementing and overseeing a process to conduct risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment…under the conditions of use." *See, e.g.,* S. REP. 114-67 (2015); 15 U.S.C. 2605(b)(4)(A). Fully consistent with that delegation, EPA expects that its interpretation of 40 CFR 702.47 will provide greater flexibility in the Agency's ability to evaluate and manage unreasonable risk from individual chemical substances. For instance, circumstances in which an unreasonable risk determination is potentially driven by a single condition of use that does not impact or intersect with other evaluated uses (such as a single consumer use of a substance out of a wide range of other manufacturing, processing and consumer uses evaluated, for example) may warrant different treatment than circumstances in which the majority of the chemical substance's conditions of use contribute to unreasonable risk, and the Agency might adopt different approaches to the risk determinations in those particular instances. As discussed in the Federal Register Notice announcing the availability of the draft revised risk determination for HBCD, issuing COU-specific or whole-chemical risk determinations on a case-by-case basis "will provide greater flexibility in the Agency's ability to evaluate and manage unreasonable risk from individual chemical substances" and "will better serve TSCA's objectives by helping ensure that EPA is best positioned to present, and initiate risk management to address, chemical-specific unreasonable risk determinations." 86 FR 74,085.

For HBCD, the whole chemical approach better aligns with TSCA's objective of protecting health and the environment, based in part on benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle) for both health and the environment and considering the physical and chemical properties of HBCD, as a persistent, bioaccumulative, and toxic substance, as well as the irreversible health effects associated with exposure to HBCD. *Id*. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, the Agency's risk findings and conclusions encompass a majority of those conditions of use, and the Agency is better positioned to achieve its TSCA objectives when issuing a whole chemical determination for HBCD, the Agency has concluded that the risk determination for HBCD is better characterized as a whole chemical determination than on a condition-of-use by condition-of-use basis.

Section 4.3 - Other legal issues

An advocacy organization (0114) asserted that the revised risk determination did not fix existing legal flaws in the final risk evaluation. The commenter stated that EPA did not adequately include exposures to the general public near landfills or incinerators, residential HBCD sources, or consumer exposure to

HBCD-treated electronics, furniture, and other products. The commenter also stated that EPA did not evaluate the risk to all relevant subpopulations, including Alaska Indigenous Peoples, firefighters, and infants. The commenter recommended that EPA reassess the risk posed by HBCD, adhere to the standards of assessment under TSCA, and reissue a Final Risk Evaluation.

EPA RESPONSE

The revised unreasonable risk determination for HBCD is based on the peer reviewed risk characterization in the September 2020 risk evaluation, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science. Changing the risk determination to a whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation.

As explained in the *Summary of External Peer Review and Public Comments and Disposition for Cyclic Aliphatic Bromide Cluster (HBCD)*,[8] EPA incorporated aggregate exposures covering all potential exposure routes for the general population and consumers in the final risk evaluation and the revised unreasonable risk determination. As explained in the HBCD final risk evaluation, estimates of general population exposures were based on environmental monitoring and biomonitoring data representing the conditions present at the time the data was collected. It is unknown which combination of potential sources associated with conditions of use as described in the risk evaluation contribute to the monitoring data. However, given the wide range of exposures shown within and across the monitoring data, there is a plausible contribution from some of the conditions of use evaluated. The totality of background exposure includes steady-state environmental exposures from ongoing releases not associated with a particular COU, background/indirect exposures from minor use products (e.g., textiles, electrical and electronic products, adhesives, and coatings) (Section 1.2.8), and releases stemming from historical activities (Section 1.2.9) due to HBCD's persistence in the environment. To be health protective, general population risks for background exposure were estimated based on the total aggregate exposure. In addition, Sections 2.4.2 to 2.4.8 of the final risk evaluation detail the exposures to the general population and consumers from 12 conditions of use.

As explained in the *Summary of External Peer Review and Public Comments and Disposition for Cyclic Aliphatic Bromide Cluster (HBCD)*, infants and subsistence fishers are identified as potentially exposed or susceptible subpopulations (PESS) and risks are reflected in the final risk evaluation. EPA acknowledges that breast milk concentrations may be higher in women who consume more fish. EPA did an infant exposure sensitivity analysis to capture high-end exposure up to and exceeding the 99th percentile, which would account for very high-end breast milk exposure. EPA excluded the direct consumption of fish for infants, with the assumption that breast milk is the main dietary source of HBCD for infants. Sections 2.4.2.5 and 4.2.3.2 of the final risk evaluation include EPA risk estimates for subsistence fishers based on monitored fish concentrations and estimated increased fish ingestion rates.

In addition, in the *Summary of External Peer Review and Public Comments and Disposition for Cyclic Aliphatic Bromide Cluster (HBCD)* EPA explains that the potential exposures for firefighters are discussed in Section 2.4.1.15 Assumptions and Key Sources of Uncertainty for Occupational Exposures.

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[8] Summary of External Peer Review and Public Comments and Disposition for Cyclic Aliphatic Bromide Cluster (HBCD) Response to Support Risk Evaluation of Cyclic Aliphatic Bromide Cluster (HBCD) https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0237-0069

EPA did not identify data specific to firefighters' potential exposure to HBCD through the initial systematic review. EPA performed a limited supplemental data search to find information on firefighter exposure to HBCD. EPA found only one source that sampled for settled dust on PPE, but the study did not detect HBCD. EPA provides a discussion of other identified literature in Section 2.4.1.15.5, titled Firefighter Potential Occupational Exposure, finding that firefighters may be exposed to flame retardants and combustion by-products. EPA acknowledges that firefighter exposure to HBCD is an uncertainty in the risk evaluation.

Section 5 – Revisions to the risk determination

Comments associated with this issue are summarized below.

Section 5.1 - Whole chemical approach vs individual condition of use

Section 5.1.1 - Support for the whole chemical approach

Several commenters, including unions (0103, 0117), a tribal organization (0104), and non-governmental environmental and health advocacy organizations (0114, 0115, 0118), supported the whole chemical approach to the risk determination, noting that the approach is consistent with the language and purpose of TSCA. An organization (0118) commented that TSCA requires whole chemical determinations of unreasonable risk to satisfy the mandate to integrate and assess available information on hazards and exposures from the condition of use, especially in cases of potentially exposed or susceptible subpopulations, multiple routes of exposure, and combined risk to exposed populations across the chemical's COUs and life-cycle stages. A few advocacy organizations (0114, 0115, 0118) commented that TSCA unambiguously mandates EPA to conduct a whole chemical risk determination since the language of the statute referencing decision-making for a chemical substance dictates that EPA cannot segment its determination into separate findings of unreasonable risk for some COUs and no unreasonable risk for others. An advocacy group (0115) urged EPA to take a whole chemical approach for all future risk determinations to fulfill TSCA's mandate that EPA identify the full risk posed by each chemical.

A few unions (0103, 0117) asserted that data EPA relied on for its risk assessment was too sparse and uncertain to justify excluding some COUs for risk management while including others. The commenters stated that a whole chemical approach would allow EPA to consider risk management rules for all workers exposed to unsafe levels of HBCD.

EPA RESPONSE

EPA thanks the commenter for the comments in support of the whole chemical approach. As EPA explained in the Federal Register Notice announcing the availability of the draft revised risk determination for HBCD, EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency's obligations under TSCA. For HBCD, the whole chemical approach is appropriate because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (import), processing, commercial use, and disposal) for both health and the environment, and HBCD is a persistent, bioaccumulative and toxic substance, and the health effects associated with HBCD exposures are irreversible. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, a substantial amount of conditions of use drive the unreasonable risk, therefore, it is

appropriate for the Agency to make a determination that the whole chemical presents an unreasonable risk.

Section 5.1.2 - Opposition to the whole chemical approach

Several commenters, including industry trade associations (0100, 0101, 0106, 0108, 0110, 0112, 0113, 0119, 0121) and an individual commenter (0120), opposed the whole chemical approach. Some arguments against the approach included:

- The transition to the whole chemical approach ignores the fact that the scope of EPA's risk determination has proceeded on COUs (0101).
- EPA provides no reason or evidence to support its whole chemical determination especially given the Agency's previous determinations that certain COUs pose no unreasonable risk (0108, 0121, 0120).
- EPA has not supported its claim that its whole chemical approach to risk determinations is science-based and has provided no science-based support for why a majority of COUs should trigger a whole chemical unreasonable risk determination (0108, 0109, 0119, 0120).
- EPA has provided no principles or criteria by which it will determine when to take a whole chemical approach in risk determinations (0119).
- Some individual uses do not present an unreasonable risk, but EPA could still use the whole chemical approach to issue a determination that would lump together uses that do not present unreasonable risk with those that do (0106, 0121).
- EPA's approach blurs any distinction between negligible concerns and unreasonable risk within the context of risk evaluation and risk management (0121).
- Manufacturers will no longer have an incentive to request risk evaluations only to have EPA determine the risk posted by the whole chemical unreasonable (0121).

A few industry trade organizations (0112, 0113, 0119) and an individual commenter (0120) discussed substantial unintended consequences of this new approach, including prolonged uncertainty for the regulated community, non-science-based market impacts, continued use of resources to research uses which pose no risk, a negative finding on uses that may not have an unreasonable risk, regrettable substitutions as manufacturers seek to quickly implement functional alternatives, and confusing the public as the public will not know which uses are safe and which pose risk.

Another industry trade organization (0100) urged EPA to continue to make COU-specific risk determinations for HBCD and other chemical substances because such an approach is grounded in the statute and regulations and supported by sound science; this commenter said that using the whole chemical approach would result in skewed understandings of the risk of chemical substances.

EPA RESPONSE

EPA has articulated the basis for a whole chemical approach to HBCD in detail in the Federal Register Notice announcing the availability of the draft revised risk determination for HBCD, and the Agency has inherent authority to replace, revise, reconsider, or repeal previously made decisions to the extent permitted by law, with a reasoned explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983).

The revised unreasonable risk determination for HBCD reflects EPA's objective of conducting a technically sound, manageable evaluation to determine whether the chemical substance—not just individual uses or activities—presents an unreasonable risk. EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance. In the case of HBCD, six of the twelve conditions of use drive the unreasonable risk and the chemical-specific properties cut across the conditions of use within the scope of the risk evaluation; therefore, the risk determination for HBCD is better characterized by the whole chemical approach. Based on the statutory text and the Risk Evaluation Rule, EPA may take different approaches to different chemical substances. EPA believes this is a reasonable approach under TSCA and the Agency's implementing regulations.

Responding to commenter's ideas concerning conditions of use which do not present unreasonable risk for HBCD, in the final revised risk determination, EPA identifies which conditions of use drive the unreasonable risk of HBCD. Consistent with the statutory requirements of TSCA section 6(a), EPA would propose risk management actions to the extent necessary so that HBCD no longer presents an unreasonable risk. Therefore, it is expected that EPA's risk management actions will focus on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. For example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities driving unreasonable risk (e.g., consumer use) even if the upstream activities are do not drive the unreasonable risk. The public will have an opportunity to provide comments and any additional information during the comment period of the proposed risk management rule. The proposed rule would also include consideration of technically and economically feasible alternatives to HBCD, when deciding whether to prohibit or substantially restrict the use of HBCD.

Section 5.1.3 - Inconsistency with TSCA and Risk Evaluation Rule

Several industry trade organizations (0100, 0101, 0106, 0108, 0110, 0112, 0119, 0121) noted that the whole chemical approach is not consistent with TSCA and its implementing regulations. In support of this, a few industry trade organizations (0106, 0110, 0119) cited TSCA section 6(b)(4)(F)(i) and (iv) that EPA must integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance and consider the likely duration, intensity, frequency and number of exposures under the conditions of use. Relatedly, another industry trade organization (0106) stated that EPA must consider actual exposure in addition to hazard.

A few industry trade organizations (0100, 0106) reasoned that the whole chemical approach is inconsistent with the structure created by Congress in the Lautenberg Amendments to TSCA in 2016. The commenters (0100, 0106) stated that the practical effect of the whole chemical approach is that there are unlikely to be any determinations of no unreasonable risk. One of the industry trade organizations (0100) said that future risk evaluations will be conducted for chemical substances that EPA has already determined "may present" an unreasonable risk through the prioritization process. The commenter stated that if the whole chemical approach is used, the distinction between the "may present" an unreasonable risk standard for prioritization and the "presents" standard for triggering risk management regulations would be lost. Some commenters (0106, 0110, 0112, 0113, 0119) also reasoned that if the individual COU approach is no longer employed, then any opportunity for obtaining the federal preemption of state

or local requirements provided for under 15 U.S.C. 2617(a) for COUs that pose no unreasonable risk would either be delayed by years until EPA promulgated a final risk management rule or potentially eliminated depending on the scope of the risk management rule. A few organizations (0106, 0113) said that the whole chemical approach, by covering all circumstances of use as presenting unreasonable risk, would seem to preclude the case-specific risk determination for replacement parts and other articles and instead defer the assessment of risk to the risk management stage. One commenter (0113) requested that EPA clarify that the whole chemical approach would not impact the treatment of replacement parts in the HBCD draft revision as the use of replacement parts is critical to maintaining, servicing, and ensuring a high level of quality to meet customers' needs.

As to inconsistency with the Risk Evaluation Rule, a commenter (0107) noted that the determination of unreasonable risk based on the evaluation of a chemical substance as a whole was only mentioned and not highlighted as the actual approach to be taken, because by assigning risk on the chemical level, a hazard-based evaluation has been conducted rather than a risk-based evaluation.

EPA RESPONSE

EPA followed the requirements under TSCA section 6(b)(4) in issuing this revised unreasonable risk determination for HBCD, including all requirements for a risk evaluation under TSCA section 6(b)(4)(F). Specifically, Section 4 of the final risk evaluation describes how EPA integrated and assessed available information on hazards and exposures for the conditions of use for HBCD considering factors such as environmental releases, environmental monitoring and biomonitoring, potential trophic transfer, as well as frequency, duration, intensity and number of exposures. As EPA explained in the Federal Register Notice announcing the availability of the draft revised risk determination for HBCD, EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency's obligations under TSCA. For HBCD, the whole chemical approach is appropriate because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (import), processing, commercial use, and disposal) for both health and the environment, HBCD is a persistent, bioaccumulative and toxic substance, and the health effects associated with HBCD exposures are irreversible. Therefore, it is appropriate for the Agency to make a determination that the whole chemical presents an unreasonable risk.

As explained in the Federal Register Notice to the draft revised unreasonable risk determination for HBCD, EPA has the inherent authority to reconsider previous decisions when permitted by law and supported by reasoned explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Further, on August 10, 2021, the Ninth Circuit granted EPA's motion for voluntary remand without vacatur, so that EPA may conduct reconsideration proceedings on the HBCD Risk Evaluation, particularly to reconsider the no unreasonable risk determinations made within.[9] EPA acknowledges a lack of specificity in the statute and inconsistency in the regulations with respect to the presentation of risk determinations in TSCA section 6 risk evaluations. In the September 2020 HBCD risk evaluation, EPA applied 40 CFR 702.47 based on one particular passage in the preamble to the final Risk Evaluation Rule, which stated: "The final step of a risk evaluation is for EPA to determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment. EPA will make individual risk determinations for all uses identified in the scope. This part of the regulation is slightly

[9] *Alaska Community Action on Toxics at al.,* v. *U.S. Environmental Protection Agency* (9th Cir. No. 20-73099).

amended from the proposed rule, to clarify that the risk determination is part of the risk evaluation, as well as to account for the revised approach to [sic] that ensures each condition of use covered by the risk evaluation receives a risk determination." 82 FR 33726, 33744. However, in contrast to this portion of the preamble of the final Risk Evaluation Rule, the regulatory text itself and other statements in the preamble reference a risk determination for *the chemical substance* under its conditions of use, rather than separate risk determinations for each of the conditions of use of a chemical substance. In the key regulatory provision excerpted previously from 40 CFR 702.47, the text explains that "[a]s part of the risk evaluation, EPA will determine whether *the chemical substance* presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents" (emphasis added). Other language reiterates this perspective. For example, 40 CFR 702.31(a) states that the purpose of the rule is to establish the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B). Likewise, there are recurring references to whether the chemical substance presents an unreasonable risk in 40 CFR 702.41(a). Notwithstanding the one preambular statement about condition-of-use-specific risk determinations, the preamble to the final rule also contains support for a risk determination on the chemical substance as a whole. In discussing the identification of the conditions of use of a chemical substance, the preamble notes that this task inevitably involves the exercise of discretion on EPA's part, and, "[a]s EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk." (82 FR at 33729).

Therefore, notwithstanding EPA's choice to issue condition-of-use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole-chemical risk determinations. Either approach is permissible under the regulation.

While some commenters believe that this whole chemical approach will set a precedent for all future existing chemical risk evaluations, this action, a revised risk determination for HBCD, pertains only to the risk determination for HBCD. While EPA intends to consider and may take similar actions on other of the first ten chemicals, EPA is taking a chemical-specific approach to reviewing the unreasonable risk determinations and is incorporating new policy direction in a surgical manner, while being mindful of the need to complete risk evaluations and move toward any associated risk management activities. To the extent the Agency deems appropriate, additional actions may follow that are specific to each of the other chemical substances for which EPA has issued completed risk evaluations under TSCA section 6.

EPA also notes that there are separate statutory standards and processes for designating chemical substances as high-priority for risk evaluation and conducting TSCA risk evaluations. Under TSCA section 6(b), EPA must designate as a high-priority substance "a chemical substance that the Administrator concludes, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator."(TSCA section 6(b)(1)(B)(i)). EPA is required to consider statutorily-prescribed factors when conducting prioritization and to provide several opportunities for public comment, and the prioritization process must last between 9-12 months (TSCA section 6(b)(1)(A), (C)). Once EPA designates a chemical substance as a high-priority substance for risk evaluation, EPA must then initiate a longer 3- to 3.5-year risk evaluation process. Through that risk evaluation process, EPA must "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an

unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." (TSCA section 6(b)(4)(A)). That process is subject to separate statutory requirements and considerations applicable to risk evaluations (e.g., TSCA section 6(b)(4)(D), (F)). If EPA finds unreasonable risk through a risk evaluation, EPA must proceed to address that unreasonable risk through TSCA section 6(a) risk management action. Although EPA must conduct a risk evaluation after designating a chemical substance as a high-priority substance, and the reasonably available information and findings informing prioritization will also inform EPA's risk evaluation on a high-priority substance, the standards and processes for TSCA prioritization and risk evaluation are separate and distinct.

TSCA section 18(c)(3) defines the scope of federal preemption with respect to any final rule EPA issues under TSCA section 6(a). That provision provides that federal preemption of "statutes, criminal penalties, and administrative actions" applies to "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to [TSCA section 6(a)]." EPA reads this to mean that states are preempted from imposing requirements through statutes, criminal penalties, and administrative actions relating to any "hazards, exposures, risks, and uses or conditions of use" evaluated in the final risk evaluation and informing the risk determination that EPA addresses in the TSCA section 6(a) rulemaking. For example, federal preemption applies even if EPA does not regulate in that final rule a particular COU, but that COU was evaluated in the final risk evaluation.

Furthermore, there is no change in the underlying HBCD risk evaluation nor in the proposed revised risk determination for HBCD with regard to conditions of use that may relate to replacement parts or articles. The revised risk determination identifies conditions of use that drive unreasonable risk from HBCD, which include conditions of use that relate to replacement parts or articles (e.g., processing: incorporation into article). Under TSCA section 6(c)(2) (D) and (E), the consideration of replacement parts and articles will take place during the risk management rulemaking stage, based on the risk evaluation findings.

The unreasonable risk determination does not consider costs or other nonrisk factors. In making the unreasonable risk determination, EPA considers relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any PESS); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties. EPA takes into consideration the Agency's confidence in the data used in the risk estimate. This includes an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization. Therefore, HBCD chemical risk determination is not based only on the hazard of HBCD.

Notwithstanding EPA's choice to issue condition-of-use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole-chemical risk determinations. Either approach is permissible under the regulation. A panel of the Ninth Circuit Court of Appeals also recognized the ambiguity of the regulation on this point. *Safer Chemicals* v. *EPA*[10] (holding a challenge about "use-by-use risk evaluations [was] not justiciable because it is not clear, due to the ambiguous text of the Risk Evaluation Rule, whether the Agency will actually conduct risk evaluations in the manner Petitioners fear"). EPA plans to consider the appropriate approach for each chemical

[10] *Safer Chemicals v. EPA.* 943 F.3d 397, 413 (9th Cir. 2019)

substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency's obligations under TSCA. EPA expects that this case-by-case approach will provide greater flexibility to evaluate and manage unreasonable risk from individual chemical substances. EPA anticipates that this flexibility will better serve TSCA's objectives by helping ensure that EPA is best positioned to present, and initiate risk management to address, chemical-specific unreasonable risk determinations. EPA believes this is a reasonable approach under TSCA and the Agency's implementing regulations.

Section 5.1.4 - Other comments on the whole chemical approach

Some commenters, including industry trade organizations and an individual commenter, requested that EPA:

- Review the whole chemical approach in the context of TSCA's risk-based decision-making framework and requirements for risk management rules (0109, 0119);
- Explain how the change to a whole chemical approach may affect risk management (0100, 0119) and what new risk management rulemaking options are open to the Agency (0106);
- Clarify what the intended practical and legal implications are or are likely to be from adopting this new approach (0106);
- Develop principles and criteria that would dictate when and how the whole chemical approach would be applied and when it would not (e.g., will it be applied if 50% of the COUs show unreasonable risk? 10%? at least one?) (0100, 0109, 0110, 0119, 0120). How will EPA treat the COUs that it determines do not present an unreasonable risk in its risk management plan when a whole chemical approach has been taken? (0108, 0119); and
- Explain how the whole chemical approach is employed in a manner consistent with the best available science or a weight of scientific evidence approach or compelled by the factors and standards dictated by Congress in the amendments to TSCA section 26 (0100).

EPA RESPONSE

EPA appreciates other comments received in connection with the draft revised unreasonable HBCD risk determination. As stated previously, this action pertains only to the risk determination for HBCD. While EPA may consider similar actions on other first ten chemicals, EPA is taking a chemical-specific approach to reviewing these risk evaluations and is incorporating new policy direction in a surgical manner, while being mindful of Congressional direction on the need to complete risk evaluations and move toward any associated risk management activities.

In general, EPA expects that this case-by-case approach will likely provide greater flexibility in the Agency's ability to evaluate and manage unreasonable risk from individual chemical substances. As previously stated, for HBCD, the whole chemical approach is appropriate because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (import), processing, commercial use, and disposal) for both health and the environment, HBCD is a persistent, bioaccumulative and toxic substance, and the health effects associated with HBCD exposures are irreversible. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, a substantial amount of the conditions of use drive the unreasonable risk, therefore it is appropriate for the Agency to make a determination that the whole chemical presents an unreasonable risk.

The revised unreasonable risk determination for HBCD is based on the peer reviewed risk characterization of the September 2020 risk evaluation, which is based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science. Changing the risk determination to a whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation.

With respect to the risk management, consistent with the statutory requirements of TSCA section 6(a), EPA would propose risk management actions to the extent necessary so that HBCD does not present unreasonable risk. In the revised risk determination for HBCD, EPA has identified the conditions of use that drive the unreasonable risk from HBCD and will focus its risk management efforts on addressing that unreasonable risk, as required by TSCA. The public will have another opportunity to provide comments during the comment period of the proposed risk management rule.

Section 5.2 - Determination of unreasonable risk from baseline scenario

Comments associated with this issue are summarized below.

Section 5.2.1 - Support for EPA's intention not to assume mitigation measures are in place

Some commenters, including trade unions (0103, 0117), non-governmental environmental and health advocacy organizations (0114, 0115, 0118, 120), and a tribal organization (0104), supported EPA's decision to no longer rely on the assumption that workers always and properly use PPE when evaluating exposures in a risk evaluation, agreeing that EPA's baseline for estimating risk to workers should not assume the use of PPE. The tribal organization (0104) noted that assuming the use of proper PPE at all times would result in an underestimation of risk for many workers. Several advocacy organizations (0114, 0118, 120) stated that EPA's previous assumption that workers who encounter HBCD on the job are protected by PPE was unlawful and arbitrary. One advocacy organization (0118) added that the assumption lacked legal basis, departed from established federal workplace protection policy and practice, and is contrary to the realities of worker exposure to chemicals. The advocacy organization stated that EPA's revised policy approach follows the recommendation of its Science Advisory Committee on Chemicals (SACC) to base unreasonable risk determinations for workers on measured or estimated exposure levels in the absence of PPE.

Another advocacy organization (0115) commended EPA for recognizing that just because one or some facilities have mitigation measures in place intended to protect workers, it is not reasonable to assume that all facilities have adopted such practices. The commenter urged EPA to independently evaluate industry practices and not rely on them in developing risk management rules if they do not represent the most protective approaches to dealing with the unreasonable risk. Further, the advocacy organization discussed how the OSHA safety standard is more lenient than the TSCA standard in terms of deciding whether a hazard necessitating protections exists; in addition, the commenter noted that workers may face unreasonable risk even considering OSHA requirements. The commenter concluded that, given this legal reality, EPA cannot accurately assume that OSHA regulations will effectively require that workers always and appropriately use PPE.

A couple of advocacy organizations (0118, 0115) and trade unions (0117, 0103) discussed the many limitations of PPE, including EPA's own statements that respirators are often not feasible and may be used only intermittently by workers even where legally required. The commenters urged that OSHA and NIOSH, too, have acknowledged the limitations of PPE, having prioritized hazard elimination,

substitution, engineering and administrative controls over the use of PPE in the hierarchy of controls. The trade unions (0103, 0117) and one of the advocacy organizations (0118) also noted the SACC's assessment that EPA's characterization of unreasonable risk relying on use of PPE is not sufficiently supported by the practical realities of many workplaces.

Two trade unions (0117, 0103) expressed concern that EPA continues to falsely believe that some OSHA regulations may require the use of PPE to protect against exposure to HBCD. The trade unions noted that current industry practices are voluntary, not binding, and should not be credited in EPA's baseline assumptions about worker exposures. The trade unions discussed how OSHA's respiratory protection standard relies on employer professional judgment and not a standard which is triggered based on available scientific information. The trade unions stated that even if OSHA's respirator standard did apply when EPA finds an unreasonable risk, that standard does not permit employers to place primary reliance on respirators to protect workers from toxic exposures. The commenters emphasized that voluntary practices do not negate the need for mandatory, enforceable worker protections and suggested that OSHA PPE regulations could be used to obtain data to confirm whether PPE is, in fact, used. The commenters recommended that EPA use its statutory authority to obtain better exposure data, including evaluations of HBCD conducted under the OSHA's respiratory protection standard, which imposes a threshold duty on employers to evaluate potential exposures to respiratory hazards, and related information regarding relevant control measures to verify its assumptions about respirator use; if employers do not have such data, that is evidence they are not requiring respirators.

EPA RESPONSE

EPA appreciates the feedback concerning assumptions on the use of PPE, the interaction of EPA and OSHA regulation, and worker protection.

As stated in the revised unreasonable risk determination for HBCD, EPA believes it is appropriate to evaluate the levels of risk present in scenarios considering applicable OSHA requirements as well as scenarios considering industry or sector best practices for industrial hygiene because such evaluation can help inform potential risk management actions (i.e., by informing EPA's assessment of the feasibility and efficacy of different risk management options). However, as commenters note, EPA cannot reasonably assume that all facilities will have adopted these practices. Therefore, EPA is making its determination of unreasonable risk from a baseline scenario that does not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. This reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

In accordance with TSCA section 26(k), EPA considers reasonably available information, including information on occupational controls and PPE usage, when conducting TSCA section 6 risk evaluations and risk management rules. Under TSCA section 6(a), EPA must apply one or more risk management requirements to the extent necessary so that a chemical substance no longer presents unreasonable risk. Those requirements may include restrictions on the manufacture, processing, distribution in commerce, commercial use, or disposal of a chemical substance.

Consistent with TSCA section 9(d), EPA will consult and coordinate TSCA activities with OSHA and other relevant federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose

rules that require risk management practices that may already be common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk.

Section 5.2.2 - Opposition to EPA's intention not to assume mitigation measures are in place

Many commenters, including industry trade organizations (0099, 0100, 0106, 0108, 0109, 0110, 0111, 0113, 0121, 0119, 0112), a chemical manufacturer (0107), and an individual commenter (0120), expressed opposition to EPA's intention not to assume personal protective equipment is always and properly used when conducting risk evaluations. For example, several industry trade organizations (0099, 0100, 0115, 0111, 0121, 0119) and an individual commenter (0120) commented that EPA's decision not to assume the use of personal protection equipment (PPE) is inconsistent with the definition of conditions of use under the TSCA and contravenes the TSCA's explicit requirement under TSCA section 26(k) to take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator. A couple of industry trade organizations (0099, 0100) argued that when EPA rendered unreasonable risk determinations for workers in the HBCD risk evaluation and the other nine initial risk evaluations, EPA's assumption that workplaces comply with the OSHA regulations was reasonable, appropriate, and driven by data. One of the industry trade organizations (0100) added that such an approach is grounded in the statute and regulations and is supported by sound science.

Several commenters, including industry trade organizations (0106, 0109, 0110, 0119) and an individual commenter (0120), urged that EPA's proposal to determine risk without considering the effects of current occupational safety standards and PPE practices is not supported by the record nor reasonably justified by any of the reasons offered by the Agency. Specifically, one industry trade organization (0119) commented that EPA cited no data or records to support its belief concerning the insufficiency of PPE at OSHA regulated facilities. Similarly, another industry trade organization (0111) requested that EPA carefully consider and describe what it means when it says that it will assume nonuse of any particular workplace controls, commenting that it is difficult to imagine how EPA would assume nonuse of engineering or administrative controls in the absence of exposure data collected when they were not being used.

Likewise, a couple of industry trade organizations (0108, 0119) stated that EPA has not presented any evidence of widespread refusal to comply with OSHA requirements and urged that OSHA does require the use of appropriate PPE where needed to protect workers from chemical exposures at jobsites. The commenters added that EPA's assumption of no PPE only serves to create negative and unhelpful messaging for manufacturers that are heavily invested in the safety of their employees and customers. One commenter (0108) stated that it also may falsely give the perception that compliance with OSHA requirements is optional and/or unenforceable. A couple of other industry trade organizations (0112, 0113) similarly stated that EPA's proposed approach would likely leave the public with the perception that facilities are out of compliance with federal and state safety standards. An industry trade organization (0119) stated that EPA's proposal is not transparent about its plans for implementation of the proposed change in the risk management rule itself and would request the Agency to develop clear, accurate communication materials to explain EPA's new approach to PPE to the already OSHA-regulated community. A couple of industry trade organizations (0112, 0113) stated that if EPA believes that certain workplace risks are not being adequately controlled, then EPA has an obligation under TSCA section 9(a) to consult with OSHA before superseding OSHA's authority. Any such result from coordination and

consultation with OSHA should also be made publicly available to further transparency, process, and due diligence.

A couple of industry trade organizations (0106, 0119) stated that EPA's proposal could inadvertently create regulatory confusion and potentially subject companies to overlapping workplace protection requirements for workplaces that are already subject to OSHA. One of the industry trade organizations (0119) added that such requirements would be costly and either duplicative of or inconsistent with those that OSHA has already imposed on employers and employees in OSHA-regulated businesses. The commenter argued that EPA's rationale for no assumption of PPE in risk evaluations is inconsistent with the statutory and regulatory requirements in the Occupational Safety and Health Act of 1970 (OSH Act) and that EPA must consult with OSHA and the National Institute for Occupational Safety and Health (NIOSH) to understand whether current worker protection from exposure to chemicals is consistent with best available science before making any determinations about the adequacy of OSHA controls.

A few industry trade organizations (0106, 0112, 0113) warned that EPA's proposed approach would artificially increase the calculated human health risk for particular uses of a chemical and create a false and misleading perception of worker risk. One of the industry trade organizations (0106) added that it is inconsistent with the requirements that risk determinations must be made considering the known COUs and improperly defers risk determination decisions to the risk management stage.

An industry trade organization (0106) commented that presumed non-compliance with an applicable legal standard can never be used as the basis for ignoring that standard to find an unreasonable risk, absent some rational basis to conclude that the EPA standard will be followed when the OSHA standard will not. The commenter suggested that, rather than the Baseline Scenario Approach, if during risk evaluation EPA determined that applicable OSHA standards were insufficient in and of themselves to prevent an unreasonable occupational exposure risk, then EPA should, during the subsequent risk management phase, build on the existing standards using TSCA authorities (or a TSCA section 9 referral to OSHA) to supplement and strengthen the existing standards enough to mitigate the unreasonable risk where it exists.

A chemical manufacturer (0107) commented that, in the limited cases where there are OSHA violations in relation to the misuse or absence of PPE each year, the issue is addressed under OSHA's purview and with corrective actions. Further, the commenter purported that for those who do not receive inspection from OSHA, it can be theorized that not utilizing PPE is the exception to the rule and not normal behavior, since the average consumer has their best interest at heart and will take measures to prevent bodily or environmental harm. On the contrary, an individual commenter (0120) professed that it may be reasonably foreseen that consumers and employees not covered by the OSH Act may not use PPE. The commenter urged, however, that such persons are also unlikely to be exposed to the neat substances or to the substance at elevated concentrations.

A couple of industry trade organizations (0112, 0113) suggested that EPA continue the approach of presenting both scenarios – HBCD use with and without PPE – in its risk determinations, claiming that doing so would provide the appropriate bounding scenarios for HBCD risk exposures in the workplace. One of the industry trade organizations (0113) added that it would also be appropriate for EPA to review and revise its modeling assumptions for various manufacturing industries to ensure they reflect the state-of-the-art facilities and current industry practices. An individual commenter (0120) also commented on EPA's previous evaluations of HBCD use with and without PPE, stating that EPA did not include in the draft revision a reasoned explanation as to why these evaluations should be repealed.

A couple of industry trade organizations (0112, 0113) commented that waiting until EPA proceeds to the risk management phase to include the use of OSHA-required PPE and related workplace standards creates a false impression of risk that lacks transparency, will be misleading to the public, and overestimates the risk of exposure in workplaces that require workers to follow PPE practices. In addition, it would create an extra layer of work for EPA and industries to work through the risk management phase, when adequate protections may already be in place.

A chemical manufacturer (0107) suggested that if EPA would like to highlight the COUs that introduce unreasonable risk when no PPE is utilized, an appendix could be included that demonstrates this concept instead of making inaccurate assumptions to conduct the entire risk evaluations.

An individual commenter (0120) remarked that EPA did not identify employees not covered by OSHA requirements as a potentially exposed or susceptible subpopulation in the HBCD risk evaluation, as required by TSCA section 6, and therefore did not properly review the risks to this subpopulation.

EPA RESPONSE

In the final risk evaluations for the first ten chemical substances, the previous administration generally assumed that for certain conditions of use workers were always provided, and used, PPE in a manner that achieved the stated assigned protection factor (APF) for respiratory protection, or protection factor (PF) for dermal protection. EPA, however, has revisited the assumption that PPE is always used, and always used properly and effectively, in occupational settings when making risk determinations for a chemical substance and this revised approach is reflected in the revised unreasonable risk determination for HBCD. EPA made this change in approach due to data on violations of PPE use that indicated assumptions that PPE is always provided to workers, and worn properly, are not justified.[11] Further, some occupational exposures are not covered by OSHA standards, such as those of self-employed individuals and public sector workers who are not covered by a State Plan. Continued use of this assumption could result in a risk evaluation that underestimates the risk, and in turn, a risk management rule that may not provide the needed protections. EPA plans to consider reasonably available information on use of PPE, or other ways industry protects its workers, as a potential way to address unreasonable risk during the risk management process. In EPA's view, the risk determination should not rely on assumptions regarding the use of PPE in making the unreasonable risk determination under TSCA section 6; rather, the use of PPE should be considered during risk management.

When conducting the HBCD risk evaluation, EPA considered reasonably available information on HBCD hazards and exposures under the conditions of use, including information on state-of-the-art facilities and current industry practices, occupational controls and PPE use at commercial and industrial facilities handling HBCD as explained in Section 2.4 in the final risk evaluation. EPA used this information when developing exposure assessments for HBCD.

The revised unreasonable risk determination for HBCD is based on the peer reviewed risk characterization of the September 2020 risk evaluation, which is based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science.

[11] OSHA Standards and Violation Data https://www.osha.gov/top10citedstandards

The final risk evaluation already includes exposure analysis with and without PPE. Table 4-27 in the final risk evaluation presents risk estimates for each condition of use with and without PPE. EPA has made no changes to this analysis. Therefore, removing the assumption that all workers always and appropriately wear PPE when making the unreasonable risk determination does not create a need for new analysis. In the revised unreasonable risk determination for HBCD, this shift did change the conclusions about risk on some conditions of use. Specifically, this shift caused four of the six conditions of use that drive the unreasonable risk determination based only on risk of injury to the environment to also drive the unreasonable risk determination based on risk of injury to health (workers). The four conditions of use affected by removing the assumption that all workers always and appropriately wear PPE were: Import; Processing: Incorporation into formulation, mixture, or reaction products; Processing: Incorporation into articles; and Processing: Recycling (of XPS and EPS foam, resin, panels containing HBCD). Overall, six conditions of use would drive the HBCD whole chemical unreasonable risk determination due to risks identified for both human health and the environment.

EPA disagrees with those commenters who thought that eliminating the assumed use of PPE for risk determination purposes would be misleading to the public. EPA explicitly stated in the draft revised HBCD risk determination and accompanying Federal Register Notice that basing the unreasonable risk determination on the baseline scenario without PPE should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location or that there is widespread non-compliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for workers (which are included in the risk evaluation as a potentially exposed or susceptible subpopulation) that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. In some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place.

Because the requirements and application of TSCA and OSHA regulatory analyses differ, it is appropriate that EPA conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates, and it is expected that EPA's findings and requirements may sometimes diverge from OSHA's. However, it is also appropriate that EPA consider the standards that OSHA has already developed, so as to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers.

As a general matter, when undertaking risk management actions, EPA will consider occupational risk mitigation measures that could address unreasonable risk identified by EPA, and for any such measures included in a proposed or final TSCA risk management rule, EPA intends to seek consistency with applicable OSHA requirements that address the unreasonable risk and industry best practices, including appropriate application of the hierarchy of controls. When undertaking risk management actions, EPA intends to develop occupational risk mitigation measures to address any unreasonable risks identified by EPA, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk.

EPA identified the conditions of use that drive the unreasonable risk in the risk determination, and options are developed during the process of the Agency working on the risk management rulemaking to address the unreasonable risk presented by the chemical substance. The risk management rulemaking stage is not when EPA determines which conditions of use present or drive unreasonable risk.

Under TSCA section 9(a), if EPA determines, in the Administrator's discretion, that an unreasonable risk may be prevented or reduced to a sufficient extent by action taken under a federal law that is not administered by EPA, EPA must submit a report to the agency administering that other authority and undertake a statutorily-prescribed referral process. EPA retains the discretion to make this finding in the first instance.

Consistent with TSCA section 9(d), EPA is regularly consulting and coordinating TSCA activities with OSHA and other relevant federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk.

Section 5.2.3 - Other comments

An industry trade organization (0111) said that the *Use of PPE* section (Section II.C) in the Federal Register Notice raises substantial questions that are much broader than the title of the section suggests. These questions include:

- What is the scope of EPA's policy? Will EPA's assumptions be limited to the use (or not) of personal protective equipment (PPE), or to the entire industrial hygiene hierarchy of controls?
- What assumptions will EPA make regarding industrial hygiene while conducting risk management rulemakings?
- How exactly will EPA consult and coordinate with OSHA during risk evaluation and risk management?
- If EPA ends up promulgating risk management requirements identical to existing OSHA requirements, how will EPA and OSHA avoid potentially divergent interpretations and duplicative enforcement?

The commenter explained that the discussion of assumptions regarding industrial hygiene are imprecise. The Federal Register Notice discussed the removal of the assumption of PPE use, but it also refers more broadly to an applicable OSHA requirement or industry practice and states that it's EPA's intent to make an unreasonable risk determination from a baseline scenario that does not assume compliance with OSHA standards. Finally, the commenter argued that EPA seemed to suggest that it will assume the use of engineering controls, but only when it is compelled to do so due to the fact that in some cases, baseline conditions reflect certain mitigation measures where monitoring data was collected at facilities that have engineering controls in place.

EPA RESPONSE

As stated in the Notice of Availability for the draft revised unreasonable risk determination for HBCD, EPA will base its risk determination on the risk characterization described in Section 4 of the risk evaluation and will not assume that workers always and appropriately wear PPE.

In accordance with TSCA section 6(a) requirements, EPA will propose risk management actions to the extent necessary so that HBCD no longer presents an unreasonable risk. The public will have an opportunity to provide comments and any additional information during the comment period of the proposed rule.

As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application for the hierarchy of controls, to the extent that the requirements, controls, and practices eliminate the identified unreasonable risks.

Consistent with TSCA section 9(d), EPA is consulting and coordinating TSCA activities with OSHA and other relevant federal agencies for the purpose of achieving the maximum enforcement of TSCA and avoiding duplicative requirements on those subject to TSCA.

With regard to risk management, the Agency might propose rules that require risk management practices that may be already common practice in many or most facilities. A goal here is the adoption of clear, comprehensive regulatory standards to foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply or may not be sufficient to address the unreasonable risk. EPA's risk evaluation in some cases may illustrate that limiting exposure to OSHA's PEL would result in risk levels below the benchmark under the TSCA standard under certain conditions of use. In these cases, TSCA risk management requirements could incorporate and reinforce requirements in OSHA standards and ensure that risks are addressed, including for circumstances where OSHA requirements are not applicable by asserting TSCA compliance/enforcement as well. EPA's risk evaluation may also find unreasonable risk under TSCA associated with some occupational conditions of use, even when the applicable OSHA requirements are being met. In these cases, EPA would need to develop risk management requirements beyond those included in OSHA's standards.

Section 5.2.4 - OSHA requirements and best practices

A couple of trade unions (0103, 0117) expressed concern that EPA plans to use so-called industry best practices to evaluate whether risk management rules are necessary to protect workers, stating that industry best practices are not relevant in determining whether mandatory regulation of exposures posing unreasonable risk is needed to protect workers, since only the best employers voluntarily use best practices. The trade union stated that voluntary efforts can disappear in an instant, in a workplace or across a whole industry, and that regulation is thus needed to protect employees. The trade union (0117) added that, nevertheless, controls that some workplaces implement voluntarily show what is feasible in all other workplaces with regulation.

An industry trade organization (0111) commented that it expects OSHA standards will apply and sufficiently address any identified unreasonable risk in many, if not most, cases. The industry trade organization encouraged EPA to coordinate and engage with OSHA at every stage of the TSCA section 6 process to inform itself about applicable OSHA standards and understand OSHA's regulations and the industrial hygiene profession in general. In addition, the commenter suggested that EPA develop a

Section 6 Memorandum of Understanding (MOU) with OSHA that addresses both the risk evaluation and risk management stages. Lastly, the commenter recommended that EPA and OSHA establish a process of consultation designed to maintain alignment on interpretive issues, so as to minimize interpretative divergence and duplicative enforcement. Similarly, a couple of other industry trade organizations (0113, 0112) encouraged EPA to continue to assess worker exposures by applying OSHA workplace requirements, stating that EPA should work with OSHA in the event that unreasonable risks are identified. The commenters suggested that if EPA is concerned about workplaces that are not subject to OSHA requirements, then adding an exposure estimate specific to that concern may be appropriate if clearly identified as such.

A couple of trade unions (0117, 0103) commented that OSHA's hazard communication standard does not protect workers from exposure to toxics, nor is OSHA's general duty clause a reliable way to protect workers from hazards. Conversely, an industry trade organization (0119) commented that all workers are protected by OSHA's general duty clause, and all workers who handle chemicals are protected by OSHA's hazard communication standard.

Similarly, an industry trade organization (0119) provided several suggestions for how EPA could address the protection of workers as a potentially exposed or susceptible subpopulation including: considering other ways to address concerns about the population of workers not covered by OSHA standards, developing risk evaluations that don't assume that PPE is either always or never used in the workplace, working with OSHA during the scoping phase and discussing improved enforcement of OSHA requirements, considering the European approach to COUs for the workplace, and more.

EPA RESPONSE

EPA agrees that for purposes of making the TSCA unreasonable risk determination, it is inappropriate to assume as a general matter that industry best practices are consistently and always properly applied or that all facilities have adopted these practices. Once EPA has determined that a chemical substance presents an unreasonable risk, EPA is required to address the identified unreasonable risk through rulemaking. EPA intends to consider current best workplace practices as it develops TSCA section 6(a) risk management action to address the unreasonable risk determined in the HBCD risk evaluation, for instance to help inform EPA's assessment of the feasibility and efficacy of different risk management options.

OSHA's mission is to ensure that employees work in safe and healthful conditions. The OSH Act establishes requirements that each employer comply with the General Duty Clause of the Act (29 U.S.C. 654(a)), as well as with occupational safety and health standards issued under the Act. The General Duty Clause of the OSH Act requires employers to keep their workplace free from recognized hazards that are causing or are likely to cause death or serious physical harm to employees. The General Duty Clause is cast in general terms, and does not establish specific requirements like exposure limits, PPE, or other specific protective measures that EPA could potentially consider when developing its risk evaluations or risk management requirements. Because the requirements and application of TSCA and OSHA regulatory analyses differ, it is appropriate that EPA conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates, and it is expected that EPA's findings and requirements may sometimes diverge from OSHA's. It is appropriate, however, that EPA consider the chemical standards that OSHA has already developed, so as to limit the compliance burden to employers by aligning management approaches required by the agencies, where alignment will adequately address unreasonable risk to workers.

As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application for the

hierarchy of controls, to the extent that the requirements, controls, and practices eliminate the identified unreasonable risks. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules requiring risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers. Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management action to the extent necessary so that HBCD no longer presents an unreasonable risk. EPA will undertake a separate public notice and comment period as part of the TSCA section 6(a) risk management rulemaking for HBCD, and will consider public comments and any additional information before finalizing the rulemaking. Consistent with TSCA section 9(d), EPA is consulting and coordinating TSCA activities with OSHA and other relevant federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. Consultation with other relevant federal agencies is also required during the risk evaluation process under EPA's implementing regulations at 40 CFR 702.39.

As required by TSCA, when conducting risk evaluations, EPA identifies relevant a potentially exposed or susceptible subpopulation (PESS), and Section 4.4.1 of the HBCD Risk Evaluation describes the workers and female workers of reproductive age as PESS. Notwithstanding the analysis done for HBCD, EPA acknowledges the suggestions by several trade associations to identify workers as a potentially exposed or susceptible subpopulation for future risk evaluations and encourages the commenter to submit chemical-specific comments on PESS to assist during future risk evaluations comment periods.

EPA appreciates the suggestion to formalize a consultation process with OSHA. EPA will continue to coordinate with OSHA and other relevant federal agencies during TSCA risk evaluation and risk management activities and expects to refine its consultation process as the Agency conducts additional risk evaluations and risk management rulemakings.

Section 5.2.4.1 - Exposure limits

A couple of trade unions (0117, 0103) urged that EPA should not apply the particulates not otherwise regulated (PNOR) permissible exposure limit (PEL) to HBCD as an exposure limit reference, nor should EPA use the PNOR PEL (or any other PEL) to derive a high-end estimate of exposure. The trade unions discussed how EPA calculated the potential inhalation exposure to HBCD among workers engaged in demolition and disposal of XPS and EPS foam insulation products in buildings by multiplying the OSHA PEL for PNOR by the HBCD concentrations in XPS and EPS foam. The trade unions stated that EPA's reliance on the PNOR PEL to estimate inhalation exposure in this occupational scenario yielded an underestimate of high-end exposure and should be revised. The commenters provided a brief synopsis of the specific values that were derived from an examination of PNOR data collected by OSHA, indicating that EPA's reported high-end estimate 8-hour time weighted average exposure of 0.30 mg/m3 is an underestimate.

On the other hand, an industry trade organization (0102) expressed the belief that EPA's determined risks surrounding HBCD are mitigated through OSHA's current PNOR obligations. The commenter provided specific examples of the controls that are utilized on jobsites to comply with OSHA requirements and minimize worker exposure to dust and other particulate matter. For example, the industry trade organization stated that workers may set up zip walls, dust walls, and other barrier systems to create isolated spaces and airtight dust barrier containment. The commenter concluded that the framework to reduce injury and risk from HBCD already exists within the OSH Act and encouraged EPA to model its HBCD risk mitigation practices on OSHA's PEL levels for PNORs.

EPA RESPONSE

EPA would like to reiterate that the revised unreasonable risk determination for HBCD is based on the peer reviewed risk characterization of the September 2020 risk evaluation, which is based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science. The policy changes in the revised unreasonable risk determination do not impact the underlying data and analysis presented in the risk characterization of the risk evaluation, including how the risk estimates of non-cancer effects to workers from chronic inhalation exposures at the high-end were calculated and summarized in Table 4-27 of the final risk evaluation.

As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application for the hierarchy of controls, to the extent that the requirements, controls, and practices eliminate the identified unreasonable risks.

Section 5.2.4.2. - PPE use or respiratory protection

An industry trade organization (0102) commented that its employees typically wear PPE on a large majority of jobsites, though the variety of PPE depends on the scope of the project and whether work is performed indoors or outdoors. The industry trade organization stated that it is standard practice among its workers to wear 3-ply dust masks and gloves to reduce the risk of cuts, direct contact with electrical wires, and dermal contact with various chemicals and materials. The commenter added that the masks and gloves are mainly worn for protection from biological waste – specifically, waste from mice, squirrels, and other small rodents – which the commenter contends present a more common danger to worker health than inhalation of or contact with dust caused by foam insulation boards or similar products. The industry trade organization stated that additional requirements, such as a respirator program, would translate to unnecessary costs and burden to its businesses and other small businesses within its industry. The commenter stated that EPA's compliance cost estimates are inaccurate and present more harm to small businesses than the Agency assumes. The commenter urged EPA to recognize the benefits of alternate PPE, in combination with standard engineering controls, in providing an adequate level of worker protection and significantly limiting fiscal and physical burden on businesses in its industry.

EPA RESPONSE

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management action to address the unreasonable risk determined in the HBCD risk evaluation. EPA will undertake a separate public notice and comment period as part of the TSCA section 6(a) risk management rulemaking for HBCD, and will consider such public comments and any additional information before finalizing the rulemaking. EPA would encourage this commenter to submit detailed comments on the impacts of various risk management approaches during the public comment period.

As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application for the hierarchy of controls, to the extent that the requirements, controls, and practices eliminate the identified unreasonable risks.

Additionally, as required by TSCA section 6(c)(2)(A), when proposing and promulgating a TSCA section 6(a) rule for HBCD, EPA will consider and publish a statement based on reasonably available information with respect to factors including the reasonably ascertainable economic consequences of the rule. The considerations related to reasonably ascertainable economic consequences include, but are not limited to,

considerations of the costs and benefits and the cost effectiveness of the regulatory action and of the one or more primary alternative regulatory actions considered by the Administrator. In addition, pursuant to section 609(b) of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), a Panel of small businesses will be convened if certain requirements with regard to the risk management rulemaking are met in order to provide a specific opportunity for small businesses to provide feedback on potential regulatory options. The panel consultation process has convened, and EPA is working to consider potential impacts to small businesses.

Section 5.2.5 - Other comments on determination of unreasonable risk from baseline scenario

An industry trade organization (0106) suggested that the baseline scenario is improper because it causes EPA to evaluate risks without considering the actual COUs and combined the uses that do not present unreasonable risks with those that do. The commenter also compared the Baseline Scenario Approach to the Whole Chemical Approach because it causes initial risk determinations to be made on the basis of abstract hazard characteristics without considering the actual exposure risks. The commenter argued that all risk determinations should be made at the risk determination phase. The statute allows EPA only one year from the date of the risk determination to propose a final risk management rule, which allows insufficient time for EPA to identify and collect additional exposure and control information and evaluate the potential control options required by TSCA.

A couple of trade unions (0103, 0117) urged that EPA should discontinue its effort to distinguish between those who directly work with a chemical and those occupational non-user (ONU) workers who do not, stating that EPA is wrong to separately categorize these ONU workers as less exposed and less likely to use PPE without evidence that is the case. One trade union (0103) stated that grouping these workers into one COU obscures the real risks some of these workers face and that all workers exposed to a chemical at a level determined to pose an unreasonable risk should be protected, regardless of whether their job requires direct or indirect exposure to the chemical EPA is assessing. The other trade union (0117) urged that EPA does not have sufficient data on ONU workers, and its analysis of this risk is purely speculative. The commenter explained that ONU workers may be more exposed and are less likely to use PPE.

EPA RESPONSE

The revised unreasonable risk determination for HBCD is based on the peer reviewed risk characterization in the September 2020 risk evaluation, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science. The policy changes described in the Federal Register Notice announcing the availability of the draft revised risk determination for HBCD do not impact the underlying data and analysis presented in the risk characterization of the September 2020 risk evaluation.

EPA considers the risk characterization, including hazard and exposure to HBCD, described in the September 2020 risk evaluation, and is not amending the underlying scientific analysis. EPA also views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i). (86 FR 74082, 74085 (Dec. 29, 2021)). The policy changes do not impact the characterization of risk estimates by condition of use (and summarized in Section 4.5 of the final risk evaluation), or the occupational exposures to workers and ONUs (and summarized in Section 2.4 of the final risk evaluation), including an explanation of the different exposures between workers and ONUs, given the different tasks workers perform under each condition of use.

As directed by TSCA section 6(a), EPA will propose risk management requirements to the extent necessary so that HBCD no longer presents an unreasonable risk. Additionally, as noted previously, EPA identified the conditions of use that drive the unreasonable risk in the risk determination, which is part of the risk evaluation. Regulatory options are developed during the next phase of the process in which the Agency will address the unreasonable risk presented by the chemical substance. The risk management rulemaking stage is not when EPA determines which conditions of use present or drive unreasonable risk.

EPA appreciates the suggestions on how to evaluate risk to workers and ONUs, and EPA expects that the removal of the assumption that all workers always and appropriately wear PPE addresses the concerns raised. EPA intends to continue the distinction between workers and ONUs because understanding their separate risks will better inform risk management and allow EPA to consider tailored options for workers and ONUs.

Section 6 - Unreasonable risk determination

An advocacy organization (0114) said that EPA failed to consider all HBCD COUs in the Final Risk Evaluation and failed to address these flaws in the Draft Revised Risk Determination. The commenter argued that EPA failed to follow the directives of TSCA for multiple COUs, which requires EPA to identify all activities and circumstances that meet the definition of COU, take into account the duration, intensity, and frequency of exposure under each COU, and integrate the exposure assessment into its determination of unreasonable risk. Some of these COUs include the disposal of HBCD and the use and disposal of Formulated Products.

EPA RESPONSE

The revised unreasonable risk determination for HBCD is based on the peer reviewed risk characterization in the September 2020 risk evaluation, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science. Therefore, the policy changes do not impact the underlying data and analysis presented in the risk characterization of the HBCD risk evaluation.

Table 1-8 in the final risk evaluation presents the conditions of use and associated exposure scenarios that are considered within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, and consumer), distribution and disposal. Sections 2.4.2.2.6, 2.4.2, 2.3.2.1, 2.3.3.1, 2.3.3.3, and 2.4.5.3 in the final risk evaluation describe the exposures for use and disposal of Formulated Products used to determine unreasonable risk.

Section 7 - Conditions of Use (COUs) that drive the unreasonable risk determination

Comments associated with this issue are summarized below.

Section 7.1 - Import

An industry trade organization (0100) said that EPA's revised risk determination may lead to unwarranted impacts on importers of articles containing HBCD. The commenter explained that in the September 2020 Risk Evaluation, EPA concluded that the consumer/commercial use of HBCD in articles does not pose an unreasonable risk, but by taking a whole chemical approach, EPA may influence a public perception that these COUs present an unreasonable risk. Also, the whole chemical approach may increase the likelihood that EPA will regulate the use of HBCD in articles that were previously deemed to not present an

unreasonable risk, specifically because EPA views TSCA section 6(a) as permitting EPA to regulate upstream activities in order to address downstream activities driving unreasonable risk even if those upstream activities do not drive the unreasonable risk.

EPA RESPONSE

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management requirements to the extent necessary so that HBCD no longer presents an unreasonable risk. Under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, commercial use, and disposal in order to address the unreasonable risk. For instance, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities driving unreasonable risk (e.g., consumer use) even if the upstream activities do not drive the unreasonable risk. EPA's authority under TSCA section 6(a) is not affected by the change to a whole chemical risk determination for HBCD.

Processing: Incorporation into Articles is one of the conditions of use that drives the HBCD unreasonable risk and will be subject to risk management action. EPA will undertake a separate public notice and solicit public comments as part of the TSCA section 6(a) risk management rulemaking for HBCD, and will consider such public comments and any additional information before finalizing the rulemaking. EPA acknowledges the commenter's suggestions related to risk management of HBCD and encourages the commenter to submit specific comments along these lines during the future public comment period for the HBCD risk management rule.

Section 7.2 - Processing: incorporation into articles

An industry trade organization (0108) provided a suggestion for the risk management of all processing COUs that drive unreasonable risk. The commenter said that EPA should use a Significant New Use Rule (SNUR) to confirm cessation of current use and prevent new uses of HBCD without review and assent by the EPA.

EPA RESPONSE

EPA will propose a TSCA section 6(a) risk management rulemaking to address the unreasonable risk determined in the final HBCD risk determination section of the TSCA section 6(b) risk evaluation. EPA will undertake a separate public notice and solicit public comments as part of the TSCA section 6(a) risk management rulemaking for HBCD, and will consider such public comments and any additional information before finalizing the rulemaking.

EPA appreciates the suggestion to promulgate a SNUR to confirm cessation of current uses and prevent new uses of HBCD from commencing without notification to and review by the Agency; however, given international commitments and anticipated impacts of TSCA section 6(a) risk management rulemaking for HBCD, it is unlikely that past practices or new uses of HBCD would be initiated.

Section 7.3 - Processing: recycling (of XPS and EPS foam, resin, panels containing HBCD)

An industry trade organization (0101) stated that EPA's draft revision implementing the whole chemical approach is inconsistent with EPA's scoping document regarding the COUs of HBCD, specifically the determination of unreasonable risks for the COUs of recycling of old expanded polystyrene (EPS) building and construction insulation and the demolition of buildings containing EPS building insulation. The commenter said that data on the recycling of old EPS building insulation indicates that it is not being recycled in a manner that would result in a finding of unreasonable risk.

Another industry trade organization (0108) provided a suggestion for the risk management of recycling and reuse. The commenter suggested that EPA isolate materials and direct them to proper disposal.

EPA RESPONSE

The revised unreasonable risk determination for HBCD is based on the peer reviewed risk characterization in the September 2020 risk evaluation, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science. EPA does not intend to amend, nor does a whole chemical approach require amending, the underlying scientific analysis of the September 2020 risk evaluation. In the September 2020 risk evaluation for HBCD, EPA determined that processing: recycling (of XPS and EPS foam, resin, and panels containing HBCD); commercial and consumer use of building and construction materials containing HBCD; and disposal/demolition present unreasonable risk. EPA's revised determination that HCBD presents unreasonable risk is driven, in part, by the risks identified in the September 2020 risk evaluation for the recycling (of XPS and EPS foam, resin, and panels containing HBCD) and the disposal (demolition) and installation of XPS and EPS foam insulation products in buildings. EPA originally proposed the underlying scientific analysis in the draft risk evaluation published on July 1, 2019. The comment period lasted 60 days from July 1, 2019. Based on public comments and peer review comments received, EPA revised and issued the risk evaluation in September 2020. Since changing the risk determination to a whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation, information provided by the commentors that was not provided during the draft risk evaluation and not considered in the risk characterization, will be considered during risk management. This action amends the risk evaluation by making a determination that HBCD presents unreasonable risk to health and the environment as a whole chemical, rather than condition of use-specific determinations and withdrawing previously-issued determinations of no unreasonable risk under section 6(i).

Once EPA finalizes the risk determination for HBCD, EPA will propose a TSCA section 6(a) risk management rulemaking to address the unreasonable risk determined in the final HBCD risk determination section of the TSCA section 6(b) risk evaluation. EPA will undertake a separate public notice and comment period as part of the TSCA section 6(a) risk management rulemaking for HBCD, and will consider such public comments and any additional information before finalizing the rulemaking. EPA acknowledges the commenter's suggestions related to risk management of HBCD and encourages the commenter to submit specific comments along these lines during the future public comment period for the HBCD risk management rule.

Section 7.4 - Commercial/consumer use: building/construction materials (installation)

An industry trade organization (0101) stated that the Risk Determination finding demolition of EPS insulation to present an unreasonable risk is based on inaccurate assumptions. The commenter explained

that 40% of the EPS from the HBCD era is fully or partially encapsulated and isolated, which is an effective engineering control to protect workers. For the other 60% of EPS insulation with HBCD, the Risk Determination grossly overestimated the amount of HBCD contained within those boards. Similarly, another industry trade organization (0108) said that the Agency has significantly overestimated the rate at which residential construction workers are exposed to HBCD. For example, foam insulation boards, which account for 95% of all HBCD applications, are rarely used in residential remodeling. The commenter also said that there is not an effective testing method or process to determine the presence of HBCD in foam insulation boards. The commenter urged EPA to recognize the low rate of interaction with foam insulation boards in its final risk evaluation and create separate standards that distinguish industries with infrequent interaction with HBCD and engineering controls in place, such as the remodeling and construction industries, from industries that frequently interact with HBCD when EPA moves forward with creating a risk management standard. Finally, the commenter requested that the EPA evaluate the potential implications of its proposal options on small remodeling firms.

An industry trade organization (0108) summarized a letter titled the N*AMBA letter to Director Collazo-Reyes dated May 6, 2021 RE: Final Risk Evaluation for HBCD*. The letter explained that the EPA overestimated the amount of HBCD that XPS and EPS boards contain, assumed that HBCD would be fully released from PS foam matrix during certain COUs, and incorrectly assumed that XPS and EPS boards would release a significant amount of dust during the installation, among other assumptions. The letter also said that PS foam boards provide environmental benefits such as saving energy and reducing carbon emissions.

An industry trade organization (0102) stated that EPA must address whether existing stormwater control requirements are sufficient in order to mitigate the potential environmental risks associated with disturbing HBCD containing material during remodeling projects. The commenter cautioned against EPA imposing additional duplicative requirements or regulatory burdens.

EPA RESPONSE

The revised unreasonable risk determination for HBCD is based on the peer reviewed risk characterization in the September 2020 risk evaluation, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science. EPA does not intend to amend, nor does a whole chemical approach require amending, the underlying scientific analysis of the September 2020 risk evaluation. EPA originally proposed the underlying scientific analysis in the draft risk evaluation published on July 1, 2019. The comment period lasted 60 days from July 1, 2019. Based on public comments and peer review comments received, including comments linked to the amount of HBCD in construction boards and exposures that may follow from HBCD containing boards, EPA finalized the risk evaluation in September 2020.

EPA will propose a TSCA section 6(a) risk management rulemaking to address the unreasonable risk determined in the final HBCD risk determination section of the TSCA section 6(b) risk evaluation. As required by TSCA section 6(c)(2)(A), when proposing and promulgating a TSCA section 6(a) rule for HBCD, EPA will consider and publish a statement based on reasonably available information with respect to factors including the reasonably ascertainable economic consequences of the rule. The considerations related to reasonably ascertainable economic consequences include, but are not limited to, considerations of the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health. EPA will undertake a separate public notice and comment

period as part of the TSCA section 6(a) risk management rulemaking for HBCD, and will consider such public comments and any additional information before finalizing the rulemaking.

EPA acknowledges the commenter's suggestions related to storm water control requirements and risk management of HBCD, and encourages the commenter to submit specific comments along these lines during the future public comment period for the HBCD risk management rule. Consistent with TSCA section 9(d), EPA will consult and coordinate TSCA activities with relevant federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements.

Section 7.5 - Disposal (demolition)

An industry trade organization (0101) said that EPA should rely on Section 2.3.1 of the 2014 Design for the Environment report on HBCD which describes the potential movement of HBCD particles during demolition or disposal. The commenter also said that the models used to support the unreasonable risk determination for demolition of buildings with HBCD era EPS over-estimated the amount of HBCD by a factor of 12. Similarly, an industry trade organization (0108) said that the assumptions made by EPA regarding demolition are not science based. These assumptions include that all dust generated by XPS and EPS at demolition sites would be small enough to remain airborne, and that all dust generated at demolition sites is from HBCD-containing XPS and EPS foam despite the fact that only 1% of construction waste is from XPS and EPS boards. The commenter provided recommendations for the risk management of disposal, such as requiring workers on demolition sites to be protected from dust exposure from all sources and require that contractors comply with existing fugitive air emissions and stormwater runoff control measures.

Conversely, an environmental advocacy group (0114) stated that EPA ignored the risk caused by the disposal of HBCD, particularly the vast quantities of insulation sent to landfills and incinerators, which resulted in an underestimation of the risk HBCD poses to human health. The commenter said that building demolition and remodeling generate insulation waste containing 1,000,000 pounds of HBCD per year, and with over 100 million pounds of HBCD in insulation currently in buildings, this would result in many years of continued disposal. During incineration, the burning of insulation could result in the creation of dioxins and furans, which are toxic chemicals formed from the burning of substances such as HBCD. Insulation in landfills could result in particles of HBCD blown off in the wind or leached out of the landfill through water.

EPA RESPONSE

The revised unreasonable risk determination for HBCD is based on the peer reviewed risk characterization in the September 2020 risk evaluation, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science. EPA does not intend to amend, nor does a whole chemical approach require amending, the underlying scientific analysis of the September 2020 risk evaluation. EPA originally proposed the underlying scientific analysis in the draft risk evaluation published on July 1, 2019. The comment period lasted 60 days from July 1, 2019. Based on public comments peer reviews received, EPA finalized the risk evaluation in September 2020.

As previously addressed by the Agency in the SACC response to public comments for the draft risk evaluation, the OSHA PNOR PEL model was used in the absence of relevant data for the Demolition and Disposal of XPS and EPS Foam Insulation in Residential, Public, and Commercial Buildings, and Other

Structures. In addition, EPA performed a limited supplemental data search for surrogate data on occupational exposures during demolition. EPA was not able to identify reasonably available data that was similar to the conditions expected during demolition of insulation materials. EPA estimated inhalation exposure concentrations to be equal to OSHA PNOR PEL multiplied by the HBCD concentrations in XPS and EPS foam. EPA determined that Disposal—land disposal of XPS and EPS foam insulation was a condition of use driving unreasonable risk to the environment, workers and ONUs.

EPA will propose a TSCA section 6(a) risk management rulemaking to address the unreasonable risk determined in the final HBCD risk determination section of the TSCA section 6(b) risk evaluation. EPA will undertake a separate public notice and comment period as part of the TSCA section 6(a) risk management rulemaking for HBCD, and will consider such public comments and any additional information before finalizing the rulemaking. EPA acknowledges the commenter's suggestions related to risk management of HBCD, and encourages the commenter to submit specific comments along these lines during the future public comment period for the HBCD risk management rule.

Section 8 - Comments regarding the COUs that do not drive the revised unreasonable risk determination

A few commenters (0112, 0113) provided feedback regarding the COUs that do not drive the revised unreasonable risk determination. The commenters recommended that EPA reaffirm the exemption from regulation for replacement parts and exempt such parts from risk mitigation measures. An industry trade association (0117) noted that, due to the highly regulated nature of HBCD on the international level, the chemical has been phased out of new production or manufacture of new replacement parts and additional regulation would be duplicative. One commenter (0112) stated that as legacy replacement parts are phased out of the automobile sector, HBCD will be cleared from trade channels and pose very little risk to workers and the general population.

An advocacy organization (0115) expressed support for EPA's approach, in that the Agency is not limited to regulating the precise activities that drive unreasonable risk and for example, may choose to regulate HBCD upstream COUs such as processing and distribution in commerce to avoid downstream unreasonable risk drivers, even if the upstream activities are not unreasonable risk drivers.

EPA RESPONSE

There is no change in the underlying scientific analysis of the September 2020 risk evaluation with regard to COUs that may relate to replacement parts. The revised risk determination identifies COUs that drive unreasonable risk from HBCD, which may include COUs that relate to replacement parts or articles. Under TSCA section 6(c)(2)(D), the consideration of replacement parts will take place during the risk management rulemaking stage, based on the risk evaluation findings.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management action to the extent necessary so that HBCD no longer presents an unreasonable risk. EPA will undertake a separate public notice and comment period as part of the TSCA section 6(a) risk management rulemaking for HBCD, and will consider such public comments and any additional information before finalizing the rulemaking, including comments related to the use of HBCD in replacement automobile parts, plastics and other articles, and formulated products and articles.

Section 9 - Comments regarding EPA's withdrawal of the associated orders

A few commenters (0112, 0113) provided feedback regarding EPA's withdrawal of the associated orders. Multiple industry trade organizations (0099, 0112, 0113) requested that EPA not withdraw the order for the six uses of HBCD that were found not to present an unreasonable risk. Two of these commenters requested that EPA not withdraw the existing associated orders to avoid regulatory issues in which states promulgate risk management rules before EPA finalizes their federal rule and create preemption concerns over state and federal requirements.

One industry trade organization stated that as the revised draft risk assessment did not reassess the six uses, there is no basis for withdrawal of the associated orders (0099). Another commenter requested that EPA keep the associated orders in place until a second round of risk evaluations for the 10 Work Plan chemicals have been completed to provide additional certainty throughout the process and until new risk management rules are in place (0112).

EPA RESPONSE

The revised unreasonable risk determination for HBCD is based on the peer reviewed risk characterization in the September 2020 risk evaluation, based on reasonably available information pursuant to TSCA section 26(k) and 40 CFR 702.33, and developed in accordance with TSCA section 26(h) to make decisions under TSCA section 6 in a manner consistent with the best available science. EPA does not intend to amend, nor does a whole chemical approach require amending, the underlying scientific analysis of the September 2020 risk evaluation. As explained in the Notice of Availability, these actions are specific to HBCD. While EPA intends to consider, and may take additional similar actions on other of the first ten chemicals, EPA is taking a chemical-specific approach to reviewing the unreasonable risk determinations and is incorporating new policy direction in a surgical manner, while being mindful of Congressional direction on the need to complete risk evaluations and move toward any associated risk management activities.

EPA is issuing a final revised unreasonable risk determination for the HBCD risk evaluation after consideration of the public comments received on the draft. For purposes of TSCA section 6(i), EPA is making a risk determination on HBCD as a whole chemical. Under the revised approach, the "whole chemical" risk determination for HBCD supersedes the no unreasonable risk determinations for HBCD that were premised on a condition-of-use-specific approach to determining unreasonable risk and also contains an order withdrawing the TSCA section 6(i)(1) order in section 5.4.1 of the September 2020 HBCD risk evaluation.

Consistent with the statutory requirements of TSCA section 6(a), the Agency will propose risk management actions to the extent necessary to address the unreasonable risk presented by HBCD. EPA does not plan to conduct a second risk evaluation on HBCD.

TSCA section 18(c)(3) defines the scope of federal preemption with respect to any final rule EPA issues under TSCA section 6(a). That provision provides that federal preemption of statutes, criminal penalties, and administrative actions applies to the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to [TSCA section 6(a)]. EPA reads this to mean that states are preempted from imposing requirements through statutes, criminal penalties, and administrative actions relating to any hazards, exposures, risks, and uses or conditions of use evaluated in the final risk evaluation and informing the risk determination that EPA addresses in the TSCA section 6(a) rulemaking. For example, federal preemption applies even if EPA does not regulate in that final rule a particular COU, but that COU was evaluated in the final risk evaluation.

Section 10 - EPA's decision to not conduct a peer review for the draft revised unreasonable risk determination

A chemical manufacturer (0107) stated that it is imperative for the EPA to conduct another peer-review on the risk characterization section of the risk determination so that the lack of PPE use in the future can be thoroughly reviewed and assessed.

EPA RESPONSE

The removal of PPE assumptions from the HBCD risk determination reflects a change in policy direction affecting the risk determination alone and does not result in changes to the underlying risk assessments and risk characterization in the 2020 risk evaluation. The revised unreasonable risk determination for HBCD is based on the underlying risk assessments and risk characterization, in which EPA evaluated worker risk with and without PPE, and which were peer-reviewed by the SACC. Section 4.5.1 and Table 4-27 of the final risk evaluation summarizes the peer reviewed risk estimates without PPE and informed the revised unreasonable risk determination. No changes have been made to the peer reviewed risk assessments or risk characterization as a result of revisions to the risk determination for HBCD, and therefore EPA does not plan to conduct another round of peer review.

Section 11 - Other comments related to the draft revision to the risk determination

Section 11.1 - Comments discussing the scientific analysis

An advocacy organization (0116) stated that though EPA has revised Section 5 of the Risk Evaluation for HBCD, which is the unreasonable risk determination, it has not modified Section 4 which is where EPA undertakes risk characterization based on exposures and hazards. The commenter expressed concern for this, as the risk characterization did not adequately quantify HBCD's potential to harm children's brains. The commenter said that under the Lautenberg Act, EPA is obligated to thoroughly assess HBCD's impact on human health, including children's health. The commenter went on to state that this failure also raises environmental justice concerns, specifically for Alaska Native and Arctic Indigenous pregnant women and children who are more exposed to HBCD through traditional foods.

Similarly, another advocacy organization (0114) also said that EPA's decision not to amend the underlying scientific analysis violated TSCA. The commenter went on to state that the Final Risk Evaluation did not address the risk to PESS, including Alaska Indigenous Peoples, firefighters, and infants. The commenter argued that since the Revised Risk Determination did not to amend these flaws, the Final Risk Determination continues to violate TSCA. The commenter stated that though EPA evaluated the risks to the broader group of subsistence fishers, they concluded that this subpopulation did not face unreasonable risk, and applied this conclusion to all Indigenous subsistence fishers, including Alaska Indigenous Peoples, who are exposed to greater amounts of HBCD than subsistence fishers. Similarly, EPA did not identify firefighters as a relevant subpopulation and evaluate the risks they face, according to the commenter. The commenter noted that firefighters respond to fires where HBCD insulation and other products containing HBCD are burning, therefore they face greater exposure to HBCD than the general population. Finally, the commenter noted that EPA did not evaluate the potential harm HBCD poses to Infants' developing brains. Citing studies, the commenter suggested that even small amounts of HBCD can harm developing brains.

A tribal organization (0104) said that because EPA did not amend the underlying scientific analysis of the HBCD risk evaluation, they have the following concerns:

- Tribal risks remain unevaluated.
- Disposal, other than demolition on-site, remains unconsidered.
- Legacy Use and associated disposal remain unconsidered.
- Fenceline communities living near disposal sites were not considered as potentially exposed and susceptible subpopulations (PESS).
- Any risk management actions cannot be considered to be protective of Native Americans and other populations not considered in the original analysis, with the exception of a full ban.
- Even with a full ban on HBCD, risk management actions cannot be considered to be protective of risks from legacy use and associated disposal.

The commenter expressed concern that without additional scientific or technical analyses, the revised risk determination and risk management actions will not be protective of tribal people. The commenter recommended that EPA utilize its authority under TSCA to ban HBCD imports and use, as well as regulate consumer product disposal.

EPA RESPONSE

EPA considers the risk characterization, including hazard and exposure to HBCD, included in the September 2020 risk evaluation to account for reasonably available information for HBCD, and does not intend to amend the underlying scientific analysis in the risk characterization section of the risk evaluation. EPA also views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i). (86 FR 74082, 74085 (Dec. 29, 2021)). In the final risk evaluation, EPA considered both infants and subsistence fishers as PESS. EPA acknowledged that breast milk concentrations may be higher in women who consume more fish. EPA did an infant sensitivity analysis to capture high-end exposure up to and exceeding the 99th percentile, which would account for very high-end breast milk exposure. EPA excluded the direct consumption of fish for infants, with the assumption that breast milk is the main dietary source of HBCD for infants. Sections 2.4.2.5 and 4.2.3.2 of the final risk evaluation include EPA risk estimates for subsistence fishers based on monitored fish concentrations and estimated increased fish ingestion rates.

As explained in the *Summary of External Peer Review and Public Comments and Disposition for Cyclic Aliphatic Bromide Cluster (HBCD)*,[12] EPA incorporated aggregate exposures covering all potential exposure routes for the general population and consumers in the final risk evaluation and has similarly accounted for those aggregate exposures in the revised unreasonable risk determination. Sections 2.4.2 to 2.4.8 of the final risk evaluation detail the exposures to the general population and consumers from 12 conditions of use. EPA further explained in this summary that no study examining developmental neurotoxicity containing adequate dose-response information exists, so EPA did not evaluate potential harm to infants' developing brain. In the absence of a study examining developmental neurotoxicity containing adequate dose-response information, EPA used a POD for acute thyroid hormone changes to serve as a surrogate because thyroid hormones changes are an early molecular event leading to

[12] Summary of External Peer Review and Public Comments and Disposition for Cyclic Aliphatic Bromide Cluster (HBCD) Response to Support Risk Evaluation of Cyclic Aliphatic Bromide Cluster (HBCD) https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0237-0069

downstream effects on neurological development. Additionally, the application of acute exposures to the developmental endpoints is a conservative assumption that is also expected to be protective of neurological outcomes. EPA believes it had sufficient information to complete the risk evaluation using a weight-of-scientific evidence approach.

Finally, the potential exposures for firefighters are discussed in Section 2.4.1.15 Assumptions and Key Sources of Uncertainty for Occupational Exposures of the risk evaluation. EPA did not identify data specific to firefighters' potential exposure to HBCD through the initial systematic review. EPA performed a limited supplemental data search to find information on firefighter exposure to HBCD. EPA only found one source that sampled for HBCD in settled dust on PPE, but the study did not detect HBCD. EPA provides a discussion of other identified literature in Section 2.4.1.15.5 Firefighter Potential Occupational Exposures of the risk evaluation, finding that firefighters may be exposed to flame retardants and combustion by-products. EPA acknowledges that firefighter exposure to HBCD is an uncertainty in the risk evaluation.

Fenceline communities living near disposal sites were included as part of all potential exposure routes for the general population. Sections 2.4.2 to 2.4.8 of the final risk evaluation detail the exposures to the general population from twelve conditions of use. As part of risk management for HBCD, EPA intends to conduct required environmental justice analysis to identify and address, as appropriate, disproportionately high and adverse health or environmental effects of their programs, policies and activities on minority populations and low-income populations in the U.S., as required by Executive Order 12898.

In 2019, the Ninth Circuit Court of Appeals ruled that EPA cannot categorically exclude legacy use and associated disposal from the definition of conditions of use (*Safer Chemicals, Healthy Families v. U.S. Envtl. Prot. Agency*).[13] Due to the court ruling in *Safer Chemicals,* EPA added conditions of use for the activities it had excluded as legacy uses and associated disposals in the risk evaluation for HBCD. Exposure to HBCD from use, reuse, recycling, or disposal of discontinued products and articles is not excluded from the final risk evaluation. In the final risk evaluation, EPA discusses these legacy uses of HBCD in products and articles, and disposal of those products and articles, in Section 1.2.8 of the final risk evaluation.[14]

With respect to impacts from this revised unreasonable risk determination on risk management of HBCD, EPA will be proposing a regulatory action with requirements under TSCA section 6(a) to the extent necessary so that HBCD would no longer present unreasonable risk. Such proposed regulatory action will be subject to public comments, and EPA would consider such public comments and any additional information before finalizing the rulemaking. EPA acknowledges the commenter's suggestions related to risk management of HBCD, and encourages the commenter to submit specific comments along these lines during the future public comment period for the HBCD risk management rule.

[13] *Safer Chemicals v. EPA*. 943 F.3d 397, 413 (9th Cir. 2019)
[14] Final Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. Federal Register (82 FR 33726, July 20, 2017) (FRL-9964-38).

Section 11.2 - Other comments

An advocacy organization (0120) commented that EPA should approach worker protection broadly when it considers how to regulate HBCD and should adhere to the hierarchy of controls in addressing workplace unreasonable risks. The advocacy organization urged that the industrial hygiene hierarchy of controls is a well-established and widely-accepted approach to effectively mitigate workplace hazards and is a foundational element of OSHA's workplace safety policy. The advocacy organization stated that EPA must consider all protective measures and assess the regulatory options in light of the fact that certain populations may be more harmed because of their greater exposure or susceptibility.

An individual commenter (0098) said that the Federal Register Notice does not clearly identify the chemicals in HBCD which could cause future regulatory confusion when applying the whole chemical risk determination. The commenter suggested that text be added to Section II (D) to clearly define the chemical entities and mixtures that are included in HBCD.

An industry trade association (0108) expressed support for the comments submitted by the American Chemistry Council (ACC). ACC's comments (0119) have already been summarized throughout this document.

EPA RESPONSE

When undertaking risk management actions, EPA intends to develop occupational risk mitigation measures to address unreasonable risk identified by EPA, and when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application for the hierarchy of controls, to the extent that the requirements, controls, and practices eliminate the identified unreasonable risks.

Responding to the question of HBCD composition, the Executive Summary in the final risk evaluation states that HBCD is often characterized as a mixture of mainly three diastereomers, which differ only in the spatial disposition of the atoms: Hexabromocyclododecane (CASRN 25637-99-4), 1,2,5,6,9,10-hexabromocyclododecane (CASRN 3194-55-6); and, 1,2,5,6-tetrabromocyclooctane (CASRN 3194-57-8). The revised unreasonable risk determination for HBCD applies to the cyclic aliphatic bromide cluster (HBCD) (that includes all three chemicals). Any future TSCA section 6(a) proposed and final rule to address the unreasonable risk presented by HBCD will be for the HBCD cluster: Hexabromocyclododecane (CASRN 25637-99-4), 1,2,5,6,9,10-hexabromocyclododecane (CASRN 3194-55-6); and, 1,2,5,6-tetrabromocyclooctane (CASRN 3194-57-8).

Section 12 - Comments on potential revisions to other risk determinations for the first ten chemicals

An advocacy organization (0118) said that in order to achieve the public health goals, EPA should make holistic risk determinations for all the initial 10 risk evaluations and apply the whole chemical approach to all future risk evaluations.

EPA RESPONSE

While EPA intends to consider and may take additional similar actions on other of the first ten chemicals, EPA is taking a chemical-specific approach to reviewing the unreasonable risk determinations and is incorporating new policy direction in a surgical manner, while being mindful of Congressional direction on the need to complete risk evaluations and move toward any associated risk management activities. To the extent the Agency deems appropriate, additional actions may follow that are specific to each of the other chemical substances for which EPA has issued completed risk evaluations under TSCA section 6.