

5. UNREASONABLE RISK DETERMINATION

TSCA section 6(b)(4) requires EPA to conduct a risk evaluation to 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 by EPA as relevant to this Risk Evaluation, under the conditions of use.

EPA has determined that HBCD presents an unreasonable risk of injury to health and the environment under the conditions of use. This determination is based on the information in previous sections of this Risk Evaluation, the appendices and supporting documents of Cyclic Aliphatic Bromide Cluster (HBCD), in accordance with TSCA section 6(b), as well as TSCA's best available science (TSCA section 26(h)) and weight of scientific evidence standards (TSCA section 26(i)), and relevant implementing regulations in 40 CFR part 702.

The full list of conditions of use evaluated for the HBCD TSCA risk evaluation are listed in Table 8-1 of the risk evaluation: 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. EPA's unreasonable risk determination for HBCD is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:

- Import
- Processing: Incorporated into a Formulation, Mixture, or Reaction Products
- Processing: Incorporation into Article
- Processing: Recycling (of XPS and EPS foam, resin, and panels containing HBCD)
- Commercial/Consumer Use:¹ Building/Construction Materials (Installation)
- Disposal (Demolition)

EPA will initiate risk management for HBCD by applying one or more of the requirements under TSCA section 6(a) 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., use) even if the upstream activities are not unreasonable risk drivers.

¹Note: Commercial and consumer use was assessed as part of the same exposure scenario, but risks were quantified separately and commercial use is a driver for unreasonable risk.

5.1 Background

5.1.1 Background on Policy Changes Relating to the Whole Chemical Risk Determination and Assumption of PPE Use by Workers

From June 2020 to January 2021, EPA published risk evaluations on the first ten chemical substances, including for HBCD in September 2020. The risk evaluations included individual unreasonable risk determinations for each condition of use evaluated. The determinations that particular conditions of use did not present an unreasonable risk were issued by order under TSCA section 6(i)(1).

In accordance with Executive Order 13990 (“Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis”) and other Administration priorities (Refs. 1, 2, 3, and 4), EPA reviewed the risk evaluations for the first ten chemical substances to ensure that they meet the requirements of TSCA, including conducting decision-making in a manner that is consistent with the best available science.

As a result of this review, EPA announced plans to revise specific aspects of certain of the first ten risk evaluations in order to ensure that the risk evaluations appropriately identify unreasonable risks and thereby can help ensure the protection of health and the environment (<https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>). To that end, EPA is reconsidering two key aspects of the risk determinations for HBCD published in September 2020. First, EPA proposes that the appropriate approach to these determinations is to make an unreasonable risk determination for HBCD as a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation. Second, EPA proposes that the risk determination should be explicit that it does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6; rather, the use of PPE would be considered during risk management. Further discussion of the rationale for the whole chemical approach is found in the Federal Register notice in the docket accompanying this revised HBCD unreasonable risk determination and further discussion of the proposed decision to not rely on assumptions regarding the use of PPE is provided in the Federal Register Notice and in section 5.1.1.3 below. With respect to the HBCD risk evaluation, EPA does not intend to amend, nor does a whole chemical approach require amending, the underlying scientific analysis of the risk evaluation in the risk characterization section of the risk evaluation.

With regard to the specific circumstances of HBCD, as further explained below, EPA proposes that a whole chemical approach better aligns with TSCA’s objective of protecting health and the environment. For HBCD, EPA favors the whole chemical approach based in part on the benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle—from manufacturing (import), processing, commercial and consumer use, and disposal) for both health and the environment and considering the physical-chemical properties of HBCD as a persistent, bioaccumulative and toxic substance, and the irreversible health effects associated with HBCD exposures. Since the chemical-specific properties cut across

82 the conditions of use within the scope of the risk evaluation, the Agency’s risk findings and
83 conclusions encompass the majority of those conditions of use, and the Agency is better
84 positioned to achieve its TSCA objectives for HBCD when issuing a whole chemical
85 determination for HBCD, EPA concludes that the Agency’s risk determination for HBCD is
86 better characterized as a whole chemical risk determination rather than condition-of-use-specific
87 risk determinations. As explained in the Federal Register Notice, the revisions to the
88 unreasonable risk determination (section 5 of the risk evaluation) would be based on the existing
89 risk characterization section of the risk evaluation (section 4 of the risk evaluation) and would
90 not involve additional technical or scientific analysis. The discussion of the issues in this draft
91 revision to the risk determination would supersede any conflicting statements in the prior HBCD
92 risk evaluation and the response to comments document (Summary of External Peer Review and
93 Public Comments and Disposition for Cyclic Aliphatic Bromide Cluster (HBCD), September
94 2020). In addition, in making this risk determination, EPA does not assume the use of PPE. EPA
95 also views the peer reviewed hazard and exposure assessments and associated risk
96 characterization as robust and upholding the standards of best available science and weight of the
97 scientific evidence, per TSCA sections 26(h) and (i).
98

99 **5.1.2 Background on Unreasonable Risk Determination**

100 In each Risk Evaluation under TSCA section 6(b), EPA determines whether a chemical
101 substance presents an unreasonable risk of injury to health or the environment, under the
102 conditions of use. The unreasonable risk determination does not consider costs or other non-risk
103 factors. In making the unreasonable risk determination, EPA considers relevant risk-related
104 factors, including, but not limited to: the effects of the chemical substance on health and human
105 exposure to such substance under the conditions of use (including cancer and non-cancer risks);
106 the effects of the chemical substance on the environment and environmental exposure under the
107 conditions of use; the population exposed (including any potentially exposed or susceptible
108 subpopulations (PESS)); the severity of hazard (including the nature of the hazard, the
109 irreversibility of the hazard); and uncertainties. EPA takes into consideration the Agency’s
110 confidence in the data used in the risk estimate. This includes an evaluation of the strengths,
111 limitations, and uncertainties associated with the information used to inform the risk estimate and
112 the risk characterization. This approach is in keeping with the Agency’s final rule, *Procedures*
113 *for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726,
114 July 20, 2017).²
115

116 This section describes the draft revised unreasonable risk determination for HBCD, under the
117 conditions of use in the scope of the Risk Evaluation for the cyclic aliphatic bromide cluster
118 chemicals. EPA evaluated two of the three chemicals in the cluster: CASRN 25637-99-4 and
119 CASRN 3194-55-6. In this document, the use of “HBCD” refers to either or both chemicals. No
120 conditions of use were identified for the third chemical, CASRN 3194-57-8. This draft revised

² This risk determination is being issued under TSCA section 6(b) and the terms used, such as unreasonable risk, and the considerations discussed are specific to TSCA. Other EPA programs have different statutory authorities and mandates and may involve risk considerations other than those discussed here.

121 unreasonable risk determination is based on the risk estimates in the final Risk Evaluation, which
122 may differ from the risk estimates in the draft Risk Evaluation due to peer review and public
123 comments.
124

125 **5.2 Unreasonable Risk to Human Health**

126 **5.2.1 Human Health**

127
128 EPA's HBCD risk evaluation identified non-cancer adverse effects from acute and chronic
129 inhalation and dermal exposures to HBCD. The most sensitive and robust endpoint for acute
130 exposure is offspring loss, and for chronic exposure, it is thyroid effects. Risks were estimated
131 for all human receptors following both acute and chronic exposure for representative endpoints
132 from every hazard domain carried through to dose-response analysis. The health risk estimates
133 for all conditions of use are in Tables 4-14 through 4-24 of this Risk Evaluation.
134

135 EPA accounted for PESS in risk estimation by providing risk conclusions based on the most
136 sensitive receptor or lifestage (*i.e.*, female workers of reproductive age for occupational risk, the
137 youngest relevant lifestage for general population and consumer risk) and consideration of high
138 end exposures (Section 4.5.2 and Table 4-11 of this Risk Evaluation).
139

140 EPA evaluated exposures to workers, occupational non-users (ONUs)³, consumer users, and the
141 general population using reasonably available monitoring and modeling data for inhalation,
142 dermal, and ingestion exposures, as applicable. The description of the data used for human health
143 exposure is in Section 4.2 of this Risk Evaluation. Uncertainties in the analysis are discussed in
144 Section 4.3.2 of this Risk Evaluation and are considered in the unreasonable risk determination
145 including that EPA was unable to model the potential effects of bioaccumulation in human tissues
146 over time, EPA was unable to quantify ONU exposure due to lack of adequate data or relevant
147 models, and estimated fish ingestion exposure is highly dependent on the selected Bioaccumulation
148 Factor (BAF) value.
149

150 EPA quantitatively evaluated inhalation, ingestion and dermal exposures to the general
151 population via exposure to indoor and ambient air; dermal contact with soil and dust; and oral
152 exposures via ingestion of food, breast milk, soil, dust and fish. While HBCD is released to
153 surface water, EPA determined during problem formulation that no further analysis beyond what
154 was presented in the problem formulation document would be done for the drinking water
155 exposure pathway in this Risk Evaluation. While this exposure pathway remains in the scope of
156 this Risk Evaluation, EPA does not find the unreasonable risk determination for HBCD to be
157 driven by general population exposure to HBCD in drinking water, based on a qualitative
158 assessment of the physical chemical properties and fate of HBCD in the environment as well as

³ ONUs are workers who do not directly handle HBCD but perform work in an area where HBCD is present. (Executive Summary of this Risk Evaluation).

159 the absence of any detection of HBCD in monitored water samples (Section 2.3.5.3 of the
160 Problem Formulation; Section 4.2.3.1 of this Risk Evaluation).

161 **5.2.1.1 Non-Cancer Risk Estimates**

162
163 The risk estimates of non-cancer effects (expressed as margins of exposure or MOEs) refer to
164 adverse health effects associated with health endpoints other than cancer, including to the body's
165 organ systems, such as thyroid effects, liver effects, and reproductive/developmental effects. The
166 MOE is the point of departure (POD) (an approximation of the no-observed adverse effect level
167 (NOAEL) or benchmark dose level (BMDL)) and the corresponding human equivalent
168 concentration (HEC) for a specific health endpoint divided by the exposure concentration for the
169 specific scenario of concern. Section 3.2.5 presents the PODs for acute and chronic non-cancer
170 effects for HBCD and Section 4.2 presents the MOEs for acute and chronic non-cancer effects.

171
172 The MOEs are compared to a benchmark MOE. The benchmark MOE accounts for the total
173 uncertainty in a POD, including, as appropriate: (1) the variation in sensitivity among the
174 members of the human population (*i.e.*, intrahuman/intraspecies variability); (2) the uncertainty
175 in extrapolating animal data to humans (*i.e.*, interspecies variability); (3) the uncertainty in
176 extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure
177 (*i.e.*, extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating
178 from a lowest observed adverse effect level (LOAEL) rather than from a NOAEL. A lower
179 benchmark MOE (*e.g.*, 30) indicates greater certainty in the data (because fewer of the default
180 uncertainty factors (UFs) relevant to a given POD as described above were applied). A higher
181 benchmark MOE (*e.g.*, 1000) would indicate more uncertainty for specific endpoints and
182 scenarios. However, these are often not the only uncertainties in a risk evaluation. The
183 benchmark MOE for the most robust and sensitive acute non-cancer risks for HBCD is 100
184 (accounting for intraspecies and interspecies variability). The benchmark MOE for the most
185 robust and sensitive chronic non-cancer risks for HBCD is 300 (accounting for interspecies and
186 intraspecies variability as well as subchronic to chronic extrapolation). Additional information
187 regarding the benchmark MOE is in Section 3.2.6.

188

5.2.1.2 Cancer Risk Estimates

189
190
191 Usually, EPA determines cancer risk estimates to represent the incremental increase in
192 probability of an individual in an exposed population developing cancer over a lifetime (excess
193 lifetime cancer risk (ELCR)) following exposure to the chemical. EPA did not evaluate cancer
194 risk from exposure to HBCD because there is indeterminate evidence to make a conclusion of
195 genotoxicity of HBCD and therefore inadequate information to assess the carcinogenic potential
196 of HBCD. The only experimental animal study to examine cancer endpoints concluded that
197 HBCD was not carcinogenic, however, this study was only available as an incomplete report
198 (Kurokawa et al. 1984). Therefore, according to the U.S. EPA Guidelines for Carcinogen Risk
199 Assessment (U.S. EPA 2005), there is “inadequate information to assess the carcinogenic
200 potential” of HBCD. Despite the limited evidence, it is unlikely that the results of any potential
201 additional studies would significantly alter the conclusions about the hazard due to the mixed results
202 and the negative incomplete report. As a result, this hazard was not carried forward for dose-
203 response analysis or risk estimation (Section 3.2.4.2 of this Risk Evaluation).

5.2.1.3 Determining Unreasonable Risk of Injury to Health

204
205
206 Calculated non-cancer risk estimates (MOEs) can provide a risk profile of HBCD by presenting a
207 range of estimates for different health effects for different conditions of use. A calculated MOE
208 that is less than the benchmark MOE supports a determination of unreasonable risk of injury to
209 health, based on noncancer effects. These calculated risk estimates alone are not bright-line
210 indicators of unreasonable risk. Whether EPA makes a determination of unreasonable risk for the
211 chemical substance depends upon other risk-related factors, such as the endpoint under
212 consideration, the reversibility of effect, exposure-related considerations (*e.g.*, duration,
213 magnitude, or frequency of exposure, or population exposed), and the confidence in the
214 information used to inform the hazard and exposure values.

215
216 In the HBCD risk characterization, offspring loss was identified as the most robust and sensitive
217 endpoint for non-cancer adverse effects from acute exposures for all conditions of use. For
218 chronic exposures, thyroid effects were identified as the most robust and sensitive endpoint for
219 noncancer adverse effects for all conditions of use. However, additional risks associated with
220 other adverse effects (*e.g.*, liver effects, reproductive effects, and other developmental effects)
221 were also identified for acute and chronic exposures. The HBCD unreasonable risk
222 determination uses offspring loss and thyroid effects as driving endpoints.

223
224 When making a determination of unreasonable risk for the chemical substance, the Agency has a
225 higher degree of confidence where uncertainty is low. For example, EPA has high confidence in
226 the hazard and exposure characterizations when the basis for characterizations is measured or
227 monitoring data or a robust model and the hazards identified for risk estimation are relevant for
228 conditions of use. This Risk Evaluation discusses the major assumptions and key uncertainties by
229 major topic: physical-chemical properties and toxicokinetics, hazard, occupational exposure,
230 general population/consumer exposure, and historical production volumes and activities. For the

231 human health risk estimation, key assumptions and uncertainties are related to the toxicokinetics
232 of HBCD, including high-end assumptions about dermal absorption and uncertainty whether
233 existing UFs sufficiently account for bioaccumulation in human tissues. Additional sources of
234 uncertainty related to human health hazard include the application of adult rodent thyroid
235 hormone changes to humans in a developmental context and the absence of reliable dose-
236 response information for developmental neurotoxicity endpoints. Important assumptions and key
237 sources of uncertainty in the risk characterization are described in more detail in Section 4.3.2 of
238 this Risk Evaluation.

239
240 When determining the unreasonable risk for a chemical substance, EPA considers the central
241 tendency and high-end exposure levels in occupational settings and in environmental media.
242 Risk estimates based on high-end exposure level scenarios (e.g., 95th percentile) are generally
243 intended to cover individuals or sub-populations with greater exposure (i.e., PESS) as well as to
244 capture individuals with sentinel exposure, and risk estimates at the central tendency exposure
245 levels are generally estimates of average or typical exposure (p. 38).

246
247 As shown in Section 4 of this Risk Evaluation, when characterizing the risk to human health
248 from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate
249 to evaluate the levels of risk present in baseline scenarios where no mitigation measures are
250 assumed to be in place.⁴ This approach considers the risk to potentially exposed or susceptible
251 subpopulations of workers who may not be covered by Occupational Safety and Health
252 Administration (OSHA) standards, such as self-employed individuals and public sector workers
253 who are not covered by a State Plan. In addition, EPA believes it is appropriate to evaluate the
254 levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-
255 specific permissible exposure limits (PELs) and/or chemical-specific PELs with additional
256 substance-specific standards) as well as scenarios considering industry or sector best practices
257 for industrial hygiene that are clearly articulated to the Agency. By characterizing risks using
258 scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform
259 potential risk management actions by providing information that could be used during risk
260 management to tailor risk mitigation appropriately to address any unreasonable risk identified.

261
262 When undertaking unreasonable risk determinations as part of TSCA risk evaluations, EPA
263 cannot assume as a general matter that an applicable OSHA requirement or industry practice is
264 consistently and always properly applied or would automatically lead EPA to conclude that any
265 unreasonable risk for a chemical substance is not driven by occupational scenarios. Mitigation
266 scenarios included in the HBCD risk evaluation (e.g., scenarios considering use of various
267 personal protective equipment (PPE)) likely represent what is happening already in some
268 facilities. However, the Agency cannot assume that all facilities will have adopted these practices
269 for the purposes of making the TSCA risk determination.

270
271 Therefore, EPA conducts baseline assessments of risk and makes its determination of
272 unreasonable risk from a baseline scenario that does not assume compliance with OSHA

⁴ It should be noted that, 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.

273 standards, including any applicable exposure limits or requirements for use of respiratory
274 protection or other PPE. Making unreasonable risk determinations based on the baseline scenario
275 should not be viewed as an indication that EPA believes there are no occupational safety
276 protections in place at any location or that there is widespread non-compliance with applicable
277 OSHA standards. Rather, it reflects EPA’s recognition that unreasonable risk may exist for
278 subpopulations of workers that may be highly exposed because they are not covered by OSHA
279 standards, such as self-employed individuals and public sector workers who are not covered by a
280 State Plan, or because their employer is out of compliance with OSHA standards, or because
281 EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA
282 requirements.
283

284 **5.3 Unreasonable Risk to the Environment**

285
286 EPA’s Risk Evaluation identified adverse effects resulting from acute and chronic exposures to
287 HBCD for both aquatic and terrestrial organisms for all conditions of use, as summarized in
288 Section 3.1. The environmental hazard threshold is calculated for both aquatic and terrestrial
289 organisms. The hazard threshold for aquatic organisms takes into account an assessment factor
290 that represents uncertainties explained in Section 3.1.5, therefore allowing a concentration of
291 concern (COC) to be derived. Limitations in data availability regarding HBCD toxicity to
292 terrestrial organisms do not allow for an assessment factor to be used to derive a COC, therefore
293 the hazard threshold is based on reported hazard effect concentrations reported by key studies
294 summarized in Section 3.1.5. The description of the data used for environmental exposure is in
295 Section 2.3. The environmental concentration is determined based on the levels of the chemical
296 released to the environment (*e.g.*, surface water, sediment, soil, biota) under the conditions of
297 use, based on the fate properties, release potential, and reasonably available environmental
298 monitoring data. Section 4.1. provides more detail regarding the risk quotient derivations for
299 HBCD.

300
301 EPA calculated a risk quotient (RQ) to compare environmental concentrations against an effect
302 level. The environmental risk quotient from exposure to HBCD via water (*e.g.*, surface water and
303 sediment) and air (*e.g.*, soil) releases are characterized in Section 4.1 (Table 4-3 through Table 4-
304 7). Uncertainties in the analysis are discussed in Section 4.3 and considered in the risk
305 determination below, including the fact that despite HBCD being a PBT, exposure to HBCD
306 across and within media types were not aggregated to estimate risk (as explained in Section
307 4.1.3), therefore environmental risk may be underestimated for aquatic and terrestrial organisms.
308

309 **5.3.1 Determining Unreasonable Risk of Injury to the Environment**

310

311 Calculated risk quotient (RQs) can provide a risk profile by presenting a range of estimates for
312 different environmental hazard effects for different conditions of use. An RQ equal to 1 indicates
313 that the exposures are the same as the concentration that causes effects. An RQ less than 1, when
314 the exposure is less than the effect concentration, generally indicates that there is not risk of
315 injury to the environment that would support a determination of unreasonable risk for the
316 chemical substance. An RQ greater than 1, when the exposure is greater than the effect
317 concentration, generally indicates that there is risk of injury to the environment that would
318 support a determination of unreasonable risk for the chemical substance. Consistent with EPA's
319 human health evaluations, the RQ is not treated as a bright line and other risk-based factors may
320 be considered (e.g., confidence in the hazard and exposure characterization, duration, magnitude,
321 uncertainty) for purposes of making an unreasonable risk determination.

322
323 EPA evaluated the effects of exposure to HBCD on aquatic and terrestrial organisms. HBCD is a
324 persistent, bioaccumulative, and toxic (PBT) substance. EPA found that there were exceedances
325 of benchmarks for pelagic and benthic aquatic organisms (Section 4.5.1.1 of this Risk
326 Evaluation). There were no exceedances of benchmarks for terrestrial organisms (Section 4.5.1.2
327 of this Risk Evaluation). In the HBCD risk characterization, delayed hatching and reduced
328 growth of offspring were identified as the most robust and sensitive endpoints for pelagic
329 organisms due to acute and chronic exposures of HBCD, respectively. EPA evaluated algae risk
330 separately from the categorization of an acute or chronic exposure, and risk of reduced algae
331 growth was evaluated. The most robust and sensitive endpoint identified for benthic organisms
332 due to chronic HBCD exposure was reduced reproduction. EPA also identified reduced
333 reproduction and survival of soil organisms due to chronic exposure to HBCD as being the most
334 robust and sensitive endpoint. EPA provides estimates for environmental risk in Section 4.5.1 of
335 this Risk Evaluation.

336
337 EPA may make an unreasonable risk determination when the risk affects organisms that are
338 identified as being relevant (Section 3.1). Based on the available hazard data for aquatic and
339 terrestrial organisms, EPA based environmental risk for conditions of use on predicted media-
340 specific HBCD concentrations. Although EPA acknowledges that due to the physical-chemical
341 properties of HBCD that dietary exposure is likely, HBCD release information cannot be directly
342 used to extrapolate tissue concentrations of prey of either aquatic or terrestrial organisms;
343 monitoring data was primarily used for the trophic transfer estimation of HBCD (Section 3.1.3),
344 and that is used to evaluate the potential for HBCD to undergo trophic transfer due to all
345 activities and releases that likely contribute to HBCD background exposures. Due to the lack of
346 HBCD hazard information regarding terrestrial organism exposure, terrestrial organism risk
347 resulting from HBCD exposure is limited to that for soil organisms (e.g., earthworms), and EPA
348 acknowledges this uncertainty (Section 4.3.1).

349
350 When making a determination of unreasonable risk, EPA has a higher degree of confidence
351 where uncertainty is low. For example, EPA has high confidence in the hazard and exposure
352 characterizations when the basis for the characterizations is measured or monitoring data or a
353 robust model and the hazards identified for risk estimation are relevant for conditions of use.
354 Where EPA has made assumptions in the scientific evaluation, whether or not those assumptions

355 are protective is also a consideration. Additionally, EPA considers the central tendency and high-
356 end scenarios when determining the unreasonable risk. High-end risk estimates (*e.g.*, 90th
357 percentile) are generally intended to cover organisms or populations with greater exposure (those
358 inhabiting ecosystems near industries) and central tendency risk estimates are generally estimates
359 of average or typical exposure.

360
361 EPA considered uncertainties in its determination of unreasonable risk for HBCD. Key
362 assumptions and uncertainties in the environmental risk estimation are related to data used for
363 the characterization of environmental exposure (*e.g.*, model input parameters, inability to directly
364 relate monitoring sites to conditions of use) and environmental hazard (*e.g.*, selection of
365 representative organisms, allometric-scaling to estimate hazard thresholds for other organisms).
366 Additionally, the reasonably available environmental monitoring data was limited temporally
367 and geographically. Assumptions and key sources of uncertainty in the risk characterization are
368 detailed in Section 4.3.1. of this Risk Evaluation.

369

370 **5.4 Additional Information regarding the Basis for the Unreasonable Risk** 371 **Determination**

372

373 Tables 5-1 and 5-2 summarize the basis for the draft revised determination of unreasonable risk
374 of injury to health and the environment presented by HBCD. In both tables, a checkmark
375 indicates the type of effect and the exposure route to the population evaluated for each condition
376 of use that support the unreasonable risk determination for HBCD. As explained in Section 5.1,
377 for the draft revised unreasonable risk determination, EPA considered the effects on human
378 health and the environment of exposure to HBCD at the central tendency and high-end, the
379 exposures from the condition of use, the risk estimates, and the uncertainties in the analysis. See
380 Sections 4.5.1 and 4.5.2 of this Risk Evaluation for a summary of risk estimates.

Table 5-1. Supporting Bases for the Draft Revised Unreasonable Risk Determination for Human Health⁵

Life Cycle Stage	Category ^a	Subcategory ^b	Population	Exposure Route	Human Health Risk			
					Acute Non-cancer		Chronic Non-cancer	
					High End	Central Tendency	High End	Central Tendency
Manufacture	Import	Import	Worker	Inhalation and Dermal	✓	✓	✓	✓
Processing	Incorporated into formulation, mixture or reaction product	Flame retardants used in custom compounding of resin (e.g., compounding in XPS masterbatch) and in solder paste	Worker	Inhalation and Dermal	✓	✓	✓	✓
Processing	Processing – incorporation into article	Flame retardants used in plastics product manufacturing (manufacture of XPS and EPS foam; manufacture of structural insulated panels (SIPS) and automobile replacement parts from XPS and EPS foam)	Worker	Inhalation & Dermal	✓	✓	✓	✓
Processing	Recycling	Recycling of XPS and EPS foam, resin, panels containing HBCD	Worker	Inhalation			✓	

⁵ The checkmarks indicate the type of effect and the exposure route to the population evaluated for each condition of use that support the draft revised unreasonable risk determination for HBCD. This table is based on Table 4-27 of this Risk Evaluation.

Commercial/ consumer use	Building/ construction materials	Plastic articles (hard): construction and building materials covering large surface areas (<i>e.g.</i> , XPS/EPS foam insulation in residential, public and commercial buildings, and other structures) and solder paste	Worker & ONU	Inhalation & Dermal			✓	
Disposal	Disposal	Land disposal (<i>e.g.</i> , EPS and XPS foam insulation)	Worker & ONU	Inhalation			✓	

^a These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent additional information regarding all conditions of use of HBCD.

^b These subcategories reflect more specific information regarding the conditions of use of HBCD.

Table 5-2. Supporting Bases for the Draft Revised Unreasonable Risk Determination for the Environment⁶

Life Cycle Stage	Category a	Subcategory b	Population	Exposure Route	Environmental Risk			
					Acute		Chronic	
					High End	Central Tendency	High End	Central Tendency
Manufacture	Import	Import	Aquatic Organisms	Surface Water and Sediment	✓	✓	✓	✓
Processing	Incorporated into formulation, mixture or reaction product	Flame retardants used in custom compounding of resin (<i>e.g.</i> , compounding in XPS masterbatch) and in solder paste	Aquatic Organisms	Surface Water and Sediment	✓	✓	✓	

⁶ The checkmarks indicate the type of effect and the exposure route to the population evaluated for each condition of use that support the draft revised unreasonable risk determination for HBCD. This table is based on Table 26 of this Risk Evaluation.

Processing	Processing – incorporation into article	Flame retardants used in plastics product manufacturing (manufacture of XPS and EPS foam; manufacture of structural insulated panels (SIPS) and automobile replacement parts from XPS and EPS foam)	Aquatic Organisms	Surface Water and Sediment	✓	✓	✓	✓
Processing	Recycling	Recycling of XPS and EPS foam, resin, panels containing HBCD	Aquatic Organisms	Surface Water and Sediment	✓	✓	✓	
Commercial/consumer use	Building/construction materials	Plastic articles (hard): construction and building materials covering large surface areas (e.g., XPS/EPS foam insulation in residential, public and commercial buildings, and other structures) and solder paste	Aquatic Organisms	Surface Water and Sediment	✓	✓		
Disposal	Disposal	Land disposal (e.g., EPS and XPS foam insulation)	Aquatic Organisms	Surface Water	✓	✓	✓	

^a These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent additional information regarding all conditions of use of HBCD.

^b These subcategories reflect more specific information regarding the conditions of use of HBCD.

5.3 References

1. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register* (86 FR 7009, January 25, 2021).
2. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register* (86 FR 7037, of January 25, 2021).
3. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal Register* (86 FR 7619, February 1, 2021).
4. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. *Federal Register* (86 FR 8845, February 10, 2021).