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 nonrisk 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 1-bromopropane (1-BP) presents an unreasonable risk of injury to health 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 1-BP, 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 1-BP are listed in Table 1-4 of this Risk Evaluation (Ref. 1). EPA's unreasonable risk determination for 1-BP is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:

- Manufacture (domestic manufacturing)
- Manufacture (import)
- Processing: as a reactant
- Processing: incorporation into formulation, mixture or reaction product
- Processing: incorporation into articles
- Processing: repackaging
- Processing: recycling
- Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser – open-top, inline vapor degreaser)
- Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser – closed-loop)
- Industrial and commercial use as solvent for cleaning and degreasing in cold cleaners
- Industrial and commercial use as solvent in aerosol spray degreaser/cleaner
- Industrial and commercial use in adhesives and sealants
- Industrial and commercial use in dry cleaning solvents, spot cleaners and stain removers
- Industrial and commercial use in liquid cleaners (e.g., coin and scissor cleaner) and liquid spray/aerosol cleaners
- Other industrial and commercial uses: arts, crafts, hobby materials (adhesives accelerant); automotive care products (engine degrease, brake cleaner, refrigerant flush); anti-adhesive agents (mold cleaning and release product); electronic and electronic products and metal products; functional fluids (close/open-systems) – refrigerant/cutting oils; asphalt extraction; laboratory chemicals; and temperature indicator – coatings
- Consumer use as solvent in aerosol spray degreasers/cleaners
- Consumer use in spot cleaners and stain removers
- Consumer use in liquid cleaners (e.g., coin and scissor cleaners)

- Consumer use in liquid spray/aerosol cleaners
- Consumer use in arts, crafts, hobby materials (adhesive accelerant)
- Consumer use in automotive care products (refrigerant flush)
- Consumer use in anti-adhesives agents (mold cleaning and release product)
- Disposal

The following conditions of use do not drive EPA's unreasonable risk determination for 1-BP:

- Distribution in commerce
- Commercial and consumer uses of building/construction materials (insulation)

EPA is not making condition of use-specific risk determinations for these conditions of use, is not issuing a final order under TSCA section 6(i)(1) for the conditions of use that do not drive the unreasonable risk, and does not consider the revised risk determination for 1-BP to constitute a final agency action at this point in time.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory action to the extent necessary so that 1-BP no longer presents an unreasonable risk. EPA expects to focus its risk management action 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. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) driving unreasonable risk, even if the upstream activities do not drive the 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 1-BP. 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. 2, 3, 4, and 5), 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 and weight of the scientific evidence.

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 (Ref. 6). To that end, EPA has reconsidered two key aspects of the risk determinations for 1-BP published in August 2020. First, EPA has determined that the appropriate approach to these determinations is to make an unreasonable risk determination for 1-BP 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 has determined that the risk determination explicitly state 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 will be considered during risk management. Making unreasonable risk determinations based on the baseline scenario without assuming 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 noncompliance with applicable OSHA standards. EPA understands that there could be occupational safety protections in place at workplace locations; however, not assuming use of PPE 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 their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health,"[1] or because OSHA has not issued a chemical specific permissible exposure limit (PEL) (as is the case for 1-BP), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

Separately, EPA is conducting a screening approach to assess risks from pathways excluded from evaluation for several of the first 10 chemicals, including this chemical. For 1-BP, the air exposure pathway was not fully assessed in the final risk evaluation (see Sections 1.4.2 and 4.5.2.3 of the August 2020 1-BP risk evaluation). The goal of the recently-developed screening approach is to remedy this exclusion and to determine if there may be risks that were unaccounted for in the 1-BP risk evaluation. The screening-level approach has gone through public comment and independent external peer review through the SACC. The Agency received the final peer review report on May 18, 2022, and has reviewed public comments and SACC comments. EPA expects to describe its findings regarding the chemical-specific application of this screening-level approach in the forthcoming proposed rule under TSCA section 6(a) for 1-BP.

Further discussion of the rationale for the whole chemical approach is found in the Federal Register Notice in the docket accompanying this revised 1-BP unreasonable risk determination and further discussion of the decision to not rely on assumptions regarding the use of PPE is provided in the Federal Register Notice and in Section 5.2.4 below. With respect to the 1-BP risk evaluation, EPA did not amend, nor does a whole chemical approach or change in assumptions

[1] As noted on OSHA's Annotated Table of Permissible Exposure Limits: "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time" (Ref. 7).

regarding PPE 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 1-BP, as further explained below, EPA has determined that a whole chemical approach is appropriate in order to protect health and the environment. The whole chemical approach is appropriate for 1-BP because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (including import), processing, industrial and commercial use, consumer use, and disposal) for health and the risk of health effects (specifically developmental toxicity and cancer) associated with 1-BP exposures are irreversible. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, and a substantial amount of the conditions of use drive the unreasonable risk, it is therefore appropriate for the Agency to make a determination that the whole chemical presents an unreasonable risk. In addition, as discussed below in Section 5.2.4, in making this risk determination, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. EPA is revising the assumption for 1-BP that workers always and properly use PPE, although it does not question the public comments received regarding the occupational safety practices often followed by industry respondents. PPE use will be considered during risk management.

As explained in the Federal Register Notice, the revisions to the unreasonable risk determination (Section 5 of this Risk Evaluation) follow the issuance of a draft revision to the TSCA 1-BP unreasonable risk determination (87 FR 43265, July 20, 2022) (Ref. 8) and the receipt of public comment. A response to comments document is also being issued with this final revised unreasonable risk determination for 1-BP (Ref. 9). As noted in the Federal Register Notice, the revisions to the unreasonable risk determination are based on the existing risk characterization section of this Risk Evaluation (Section 4), and do not involve additional technical or scientific analysis. The discussion of the issues in this revision to the risk determination supersedes any conflicting statements in the prior 1-BP risk evaluation (August 2020) and the response to comments document (*Summary of External Peer Review and Public Comments and Disposition for 1-Bromopropane (1-BP), August 2020).* 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).

5.1.2 Background on Unreasonable Risk Determination

In each risk evaluation under TSCA section 6(b), EPA determines whether a chemical substance presents an unreasonable risk of injury to health or the environment, under the conditions of use. 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 potentially exposed or susceptible subpopulations

(PESS)); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties. EPA also 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. This approach is in keeping with the Agency's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017).[2]

This section describes the revised unreasonable risk determination for 1-BP, under the conditions of use in the scope of the Risk Evaluation for 1-BP. This revised unreasonable risk determination is based on the risk estimates in the final Risk Evaluation, which may differ from the risk estimates in the draft Risk Evaluation due to peer review and public comments.

5.2 Unreasonable Risk to Human Health

5.2.1 Human Health

EPA's 1-BP risk evaluation identified risks for non-cancer adverse effects from acute and chronic inhalation and dermal exposures to 1-BP, and cancer from chronic inhalation and dermal exposures to 1-BP. The health risk estimates for all conditions of use are in Tables 4-58 and 4-59 of Section 4.5 of this Risk Evaluation.

In developing the exposure assessment for 1-BP, EPA identified the following groups as Potentially Exposed or Susceptible Subpopulations (PESS): workers and occupational non-users (ONUs)[3] (including men and women of reproductive age, and adolescents); consumer users (female and male youth (between 11 and 21 years of age) and female and male adults (21 years of age and greater)) and bystanders (of any age group, including infants, toddlers, children, and elderly) (Section 4.4.1 and Tables 4-3, 4-4, and 4-5 of this Risk Evaluation).

EPA evaluated exposures to workers, occupational non-users (ONUs), consumer users, and bystanders using reasonably available monitoring and modeling data for inhalation and dermal exposures, as applicable. For example, EPA assumed that ONUs and bystanders do not have direct contact with 1-BP; therefore, non-cancer effects and cancer from dermal exposures to 1-BP are not expected and were not evaluated for these groups. The description of the data used for human health exposure is in Section 2.3 of the Risk Evaluation. Uncertainties in the analysis are discussed in Section 4.3 of the Risk Evaluation and are considered in the unreasonable risk determination presented below, including the fact that the dermal model used does not address variability in exposure duration and frequency.

[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.

[3] ONUs are workers who do not directly handle 1-BP but perform work in an area where 1-BP is present. (Executive Summary of this Risk Evaluation).

5.2.2 Non-Cancer Risk Estimates

The risk estimates for non-cancer effects (expressed as margins of exposure or MOEs) refer to adverse health effects associated with health endpoints other than cancer, including to the body's organ systems, such as developmental effects, cardiac and lung effects, and kidney and liver effects. The MOE is the point of departure (POD) (an approximation of the no-observed adverse effect level (NOAEL) or benchmark dose level (BMDL)) and the corresponding human equivalent concentration (HEC) for a specific health endpoint divided by the exposure concentration for the specific scenario of concern. Section 3.2.8 of this Risk Evaluation presents the PODs for acute and chronic non-cancer effects for 1-BP and Section 4.2 of this Risk Evaluation presents the MOEs for acute and chronic non-cancer effects.

The MOEs are compared to a benchmark MOE. The benchmark MOE accounts for the total uncertainty in a POD, including, as appropriate: (1) the variation in sensitivity among the members of the human population (i.e., intrahuman/intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (i.e., interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating from a lowest observed adverse effect level (LOAEL) rather than from a NOAEL. A lower benchmark MOE (e.g., 30) indicates greater certainty in the data (because fewer of the default uncertainty factors (UFs) relevant to a given POD as described above were applied). A higher benchmark MOE (e.g., 1000) would indicate more uncertainty for specific endpoints and scenarios. However, these are often not the only uncertainties in a risk evaluation. The benchmark MOE for acute and chronic non-cancer risks for 1-BP is 100 (accounting for interspecies and intraspecies variability). Additional information regarding the non-cancer hazard identification is in Section 3.2.4.1 and the benchmark MOE is in Section 4.2.1. of this Risk Evaluation.

5.2.3 Cancer Risk Estimates

Cancer risk estimates represent the incremental increase in probability of an individual in an exposed population developing cancer over a lifetime (excess lifetime cancer risk (ELCR)) following exposure to the chemical. Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (i.e., $1x10^{-6}$ to $1x10^{-4}$) depending on the subpopulation exposed. For example, in this risk evaluation, EPA used $1x10^{-6}$ as the benchmark for the cancer risk to consumers and bystanders from consumer use of insulation, and used $1x10^{-4}$ as the benchmark for the cancer risk to individuals in industrial and commercial workplaces. The $1x10^{-4}$ value is not a bright line and EPA has discretion to make an unreasonable risk determination for the chemical substance based on other benchmarks as appropriate. Additional information regarding the cancer benchmark is in Section 4.2.4. of this Risk Evaluation, with a discussion of uncertainties in Section 4.3.4.2.

5.2.4 Determining Unreasonable Risk of Injury to Health

Calculated risk estimates (MOEs or cancer risk estimates) can provide a risk profile of 1-BP by presenting a range of estimates for different health effects for different conditions of use. A calculated MOE that is less than the benchmark MOE supports a determination of unreasonable risk of injury to health, based on noncancer effects. Similarly, a calculated cancer risk estimate

that is greater than the cancer benchmark supports a determination of unreasonable risk of injury to health from cancer. Whether EPA makes a determination of unreasonable risk for the chemical substance depends upon other risk-related factors, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values.

In the 1-BP risk characterization, developmental toxicity (i.e., post-implantation loss) was identified as the most sensitive endpoint for non-cancer adverse effects from acute and chronic inhalation and dermal exposures for all conditions of use. However, additional risks associated with other adverse effects (e.g., additional developmental toxicity, reproductive toxicity, liver toxicity, kidney toxicity, neurotoxicity) were identified for acute and chronic inhalation and dermal exposures. Addressing unreasonable risk by using the developmental toxicity endpoint will also address the risk from other endpoints resulting from acute or chronic inhalation or dermal exposures.

In accordance with EPA's Guidelines for Carcinogen Risk Assessment, in this risk evaluation EPA concluded that 1-BP may be considered "likely to be carcinogenic in humans" based on the positive findings for carcinogenicity in more than one test species together with positive findings for the direct reactivity of 1-BP with DNA and suggestive but inconclusive evidence for genetic toxicity. EPA calculated cancer risk estimates using a linear model and cancer slope factors based on the endpoints described in Section 3.2.2. EPA calculated cancer risk estimates for all occupational conditions of use for workers for chronic inhalation and dermal exposures and for ONUs for chronic inhalation exposures. For consumers and bystanders, EPA calculated cancer risks from insulation (off-gassing) of 1-BP following installation of insulation (described in Sections 2.3.2.4, with modeling intensities described in 2.3.2.1). EPA assumed that all other consumer use exposures would be acute, rather than chronic.

When making a determination of unreasonable risk for the chemical substance, the Agency has a higher degree of confidence where uncertainty is low. For example, EPA has high confidence in the hazard and exposure characterizations when the basis for characterizations is measured data or monitoring data or a robust model and the hazards identified for risk estimation are relevant for conditions of use. This Risk Evaluation discusses major assumptions and key uncertainties. The 1-BP risk determination considers the uncertainties associated with the reasonably available information to justify the linear cancer dose-response model when compared to other available models. The cancer analysis is described in Section 3.2.2. EPA considered cancer risks estimates from chronic dermal or inhalation exposures in the unreasonable risk determination. Important assumptions and key sources of uncertainty in the risk characterization are described in more detail in Sections 4.2.5 and 4.3.4 of this Risk Evaluation.

When determining the unreasonable risk for a chemical substance, EPA considers the central tendency and high-end exposure levels in occupational settings, and low, moderate and high intensity of use for consumer uses. Risk estimates based on high-end exposure levels or high intensity use scenarios (e.g., 95th percentile) are generally intended to cover individuals or sub-populations with greater exposure (PESS) as well as to capture individuals with sentinel exposure, and risk estimates at the central tendency exposure are generally estimates of average

or typical exposure (Section 4.4 of this Risk Evaluation).

As shown in Section 4 of this Risk Evaluation, when characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. 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. This approach of not assuming PPE use by workers considers the risk to potentially exposed or susceptible subpopulations (workers and ONUs) who may not be covered by Occupational Safety and Health Administration (OSHA) standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. In addition, EPA risk evaluations may characterize the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific PELs and/or chemical-specific health standards with PELs and additional ancillary provisions), as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. EPA's evaluation of risk under scenarios that, for example, incorporate use of engineering or administrative controls, or personal protective equipment, serves to inform its risk management efforts. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform potential risk management actions by providing information that could be used to tailor risk mitigation appropriately to address worker exposures where the Agency has found unreasonable risk. In particular, EPA can use the information developed during its risk evaluation to determine whether alignment of EPA's risk management requirements with existing OSHA requirements or industry best practices will adequately address unreasonable risk as required by TSCA.

When undertaking unreasonable risk determinations as part of TSCA risk evaluations, EPA cannot assume as a general matter that an applicable OSHA requirement or industry practice is consistently and always properly applied. Mitigation scenarios included in the 1-BP risk evaluation (e.g., scenarios considering use of various personal protective equipment (PPE)) likely represent what is happening already in some facilities. However, the Agency cannot assume that all facilities will have adopted these practices for the purposes of making the TSCA risk determination.

Therefore, EPA conducts baseline assessments of risk and makes its determination of unreasonable risk from a baseline scenario that is not based on an assumption of compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on the baseline scenario 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 noncompliance with applicable OSHA standards. Rather, it 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, 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 because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker

health,"[4] or because OSHA has not issued a chemical specific permissible exposure limit (PEL) (as is the case for 1-BP), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

The revised unreasonable risk determination for 1-BP is based on the peer reviewed risk characterization of the August 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. Section 4.5.2 and Tables 4-58 and 4-59 of this Risk Evaluation summarize the risk estimates with and without PPE, and informed the revised unreasonable risk determination.

5.3 Unreasonable Risk to the Environment

5.3.1 Environment

EPA calculated a risk quotient (RQ) to compare environmental concentrations against an effect level. The environmental concentration is determined based on the levels of the chemical released to the environment (*e.g.,* surface water, sediment, soil, biota) under the conditions of use, based on the fate properties, release potential, and reasonably available environmental monitoring data. The effect level is calculated using concentrations of concern that represent hazard data for aquatic, sediment-dwelling, and terrestrial organisms. Section 4.1 of this Risk Evaluation provides more detail regarding the environmental risk characterization for 1-BP.

5.3.2 Determining Unreasonable Risk of Injury to the Environment

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

EPA considered the effects on the aquatic, sediment dwelling, and terrestrial organisms. EPA found that there were no exceedances of benchmarks to aquatic organisms from exposures to 1-BP. The RQ values associated with acute and chronic exposures are <0.01 and 0.12, respectively, based on the best available science (Table 4-2 of this Risk Evaluation). In the case of 1-BP, one

[4] As noted on OSHA's Annotated Table of Permissible Exposure Limits: "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time" (Ref. 7).

single study was used to characterize the environmental hazards; however, the study was of high quality, based on EPA's systematic review, and the analysis was complemented with modeling. The experimental procedures used in this effort represent the best practices for conducting acute toxicity testing with fathead minnows and are consistent with the test guidelines currently recommended by EPA and international regulatory partner organizations for purposes of conducting ecological risk assessment purposes for fish. The confidence in the available data to characterize the environmental hazards of 1-BP is bolstered by the use of the QSAR modeling program ECOSAR (v2.0) lending greater confidence to the risk estimates. The high volatility, high water solubility and low Log Koc of 1-BP suggest that 1-BP will only be present at low concentrations in the sediment and terrestrial environmental compartments. EPA provides estimates for environmental risk in Section 4.4.2 and Table 4-2 of this Risk Evaluation.

When making a determination of unreasonable risk, EPA has a higher degree of confidence where uncertainty is low. For example, EPA has high confidence in the hazard and exposure characterizations when the basis for the characterizations is measured or representative monitoring data or a robust model and the hazards identified for risk estimation are relevant for conditions of use. Where EPA has made assumptions in the scientific evaluation, the degree to which these assumptions are conservative (i.e., more protective) is also a consideration. Additionally, EPA considers the central tendency and high-end scenarios when determining the unreasonable risk. High-end risk estimates (*e.g.*, 90th percentile) are generally intended to cover organisms or populations with greater exposure (those inhabiting ecosystems near industries) and central tendency risk estimates are generally estimates of average or typical exposure.

EPA considered uncertainties in its determination of unreasonable risk for 1-BP. While EPA has determined that sufficient data are reasonably available to characterize the overall environmental hazards of 1-BP under the conditions of use of this evaluation, there are uncertainties regarding the available environmental hazard data for 1-BP. High volatility (Vapor Pressure= 110 mm Hg and Henry's Law constant of 7.3×10^{-3} atm-m^3/mole), and a consideration of the conditions of use of the chemical, indicates that 1-BP will only be present in terrestrial environmental compartments as a transient vapor. No specific conditions of use were identified that resulted in systematic, significant airborne exposures that overlap with terrestrial habitats, so this is not a relevant route of exposure for 1-BP under the conditions of use of this risk evaluation. Additionally, 1-BP is not expected to bioaccumulate and therefore, exposure to terrestrial species through ingestion of prey is negligible. Assumptions and key sources of uncertainty in the risk characterization are detailed in Section 4.3.4. of this Risk Evaluation.

Therefore, based on this Risk Evaluation, including the risk estimates, the environmental effects of 1-BP, the exposures, physical-chemical properties of 1-BP, and consideration of uncertainties, EPA did not identify risk of injury to the environment that drives the unreasonable risk determination for 1-BP.

5.4 Additional Information Regarding the Basis for the Unreasonable Risk Determination

Table 5-1 and Table 5-2 summarize the basis for the revised determination of unreasonable risk of injury to health presented by 1-BP. In these tables, a checkmark indicates the risk of the type of effect and the exposure route to the population evaluated for each condition of use that drives the unreasonable risk determination. As explained in Section 5.2, for the revised unreasonable risk determination, EPA considered the effects on human health of exposure to 1-BP at the central tendency and high-end, the exposures from the condition of use, the risk estimates, and the uncertainties in the analysis. See Section 4.5.2 of the Risk Evaluation for a summary of risk estimates.

Table 5-1. Supporting Basis for the Revised Unreasonable Risk Determination for Human Health (Occupational Conditions of Use)[5]

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Manufacture	Domestic Manufacture	Domestic Manufacture	Worker	Inhalation	✓		✓		✓	✓
				Dermal					✓	
			ONU	Inhalation	–					
Manufacture	Import	Import	Worker	Inhalation						
				Dermal					✓	
			ONU	Inhalation						
Processing	Processing – as a reactant	Intermediate in all other basic inorganic chemical manufacturing, all other basic organic chemical manufacturing, and pesticide, fertilizer and other agricultural chemical manufacturing	Worker	Inhalation						
				Dermal					✓	
			ONU	Inhalation						
Processing	Processing – incorporation into formulation, mixture or reaction products	Solvents for cleaning or degreasing in manufacturing of: - all other chemical product and preparation - computer and electronic product	Worker	Inhalation	N/A	✓	N/A	✓	N/A	✓
				Dermal					✓	

[5] The checkmarks indicate the risk of the type of effect and the exposure route to the population evaluated for each condition of use that supports the revised unreasonable risk determination for 1-BP. This table is based on Tables 4-58 and 4-59 of this Risk Evaluation.

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
		- electrical equipment, appliance and component - soap, cleaning compound and toilet preparation - services	ONU	Inhalation	✓		✓		✓	✓
Processing	Processing – incorporation into articles	Solvents (becomes part of product formulation or mixture) in construction	Worker	Inhalation						
				Dermal					✓	
			ONU	Inhalation						
Processing	Repackaging	Solvents (cleaning or degreasing in all other basic organic chemical manufacturing)	Worker	Inhalation						
				Dermal					✓	
			ONU	Inhalation						
Processing	Recycling	Recycling	Worker	Inhalation						
				Dermal					✓	
			ONU	Inhalation						
Industrial/ Commercial use	Solvent (for cleaning or degreasing)	Batch vapor degreaser (open-top) and In-line vapor degreaser (*e.g.,* conveyorized, web cleaner)	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal					✓	
			ONU	Inhalation	✓	✓	✓	✓	✓	✓

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Industrial/ Commercial use	Solvent (for cleaning or degreasing)	Batch vapor degreaser (closed-loop)	Worker	Inhalation	✓		✓		✓	
				Dermal					✓	
			ONU	Inhalation	✓		✓		✓	
Industrial/ Commercial use	Solvent (for cleaning or degreasing)	Cold cleaner	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal					✓	
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ Commercial use	Solvent (for cleaning or degreasing)	Aerosol spray degreaser/cleaner	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal					✓	
			ONU	Inhalation	✓		✓		✓	✓
Industrial/ Commercial use	Adhesives and sealants	Adhesive chemicals - spray adhesive for foam cushion manufacturing and other uses	Sprayer	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal					✓	
			Non-sprayer	Inhalation	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ Commercial use	Cleaning and furniture care products	Dry cleaning solvent, spot cleaner, and stain remover	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal					✓	
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ Commercial use	Cleaning and furniture care products	Liquid cleaner (*e.g.,* coin and scissor cleaner) and liquid spray/aerosol cleaner [c]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal					✓	
			ONU	Inhalation	✓		✓		✓	✓

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Industrial/ Commercial use	Other uses	Arts, crafts, and hobby materials (adhesive accelerant); automotive care products (engine degreaser, brake cleaner); anti-adhesive agents (mold cleaning and release product); electronic and electronic products and metal products; functional fluids – closed systems (refrigerant) and open-systems (cutting oils); asphalt extraction; laboratory chemicals; and temperature indicator (coatings) [d]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal					✓	
			ONU	Inhalation	✓		✓		✓	✓
Commercial and consumer use [e]	Insulation	Building/construction materials not covered elsewhere	Worker	Inhalation						
				Dermal						
			ONU	Inhalation						
			Consumer	Inhalation						
				Dermal						
			Bystander	Inhalation						
Disposal	Disposal	Municipal waste incinerator Off-site waste transfer	Worker	Inhalation						
				Dermal					✓	
			ONU	Inhalation						

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency

[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 1-BP.
[b] These subcategories reflect more specific information regarding the conditions of use of 1-BP.
[c] EPA has not identified exposure data associated with these conditions of use. The worker activity, use pattern, and associated exposure will vary for each condition of use. For conditions of use where 1-BP is used in an aerosol application, the exposure levels may be as high as those presented in Section 2.3.1.15 of the Risk Evaluation. Actual exposure levels for each condition of use will likely vary depending on the use volume, engineering control, and PPE.
[d] *Ibid.*
[e] The information pertaining to this condition of use of 1-BP is presented in the "Consumer Risk Summary" (Table 4-59) of the August 2020 Risk Evaluation. It is presented here with the other occupational conditions of use of 1-BP to show more clearly the chronic and cancer risks to consumers.

Table 5-2. Supporting Basis for the Revised Unreasonable Risk Determination for Human Health (Consumer Conditions of Use)[6]

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health		
					Acute Non-cancer		
					High Intensity Use	Moderate Intensity Use	Low Intensity Use
Consumer use	Solvent (cleaning or degreasing)	Aerosol spray degreaser/cleaner	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	✓
Consumer use	Cleaning and furniture care products	Spot cleaner, stain remover	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal	✓		
			Bystander	Inhalation	✓	✓	
Consumer use	Cleaning and furniture care products	Liquid cleaner (*e.g.,* coin and scissor cleaner)	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal			
			Bystander	Inhalation	✓	✓	✓
Consumer use	Cleaning and furniture care products	Liquid spray/aerosol cleaner	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	✓
Consumer use	Other uses	Arts, crafts and hobby materials - adhesive accelerant	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal			
			Bystander	Inhalation	✓	✓	

[6] The checkmarks indicate the risk of the type of effect and the exposure route to the population evaluated for each condition of use that support the revised unreasonable risk determination for 1-BP. This table is based on Table 4-59 of this Risk Evaluation.

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health		
					Acute Non-cancer		
					High Intensity Use	Moderate Intensity Use	Low Intensity Use
Consumer use	Other uses	Automotive care products – refrigerant flush	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal	✓	✓	✓
			Bystander	Inhalation	✓	✓	✓
Consumer use	Other uses	Anti-adhesive agents - mold cleaning and release product	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal			
			Bystander	Inhalation	✓	✓	
Consumer use	Insulation	Building/ construction materials[c]	Consumer user and bystander	Information displayed alongside worker information in Table 5-1			

[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 1-BP.

[b] These subcategories reflect more specific information regarding the conditions of use of 1-BP.

[c] The information pertaining to this condition of use of 1-BP is presented in the "Consumer Risk Summary" (Table 4-59) of the August 2020 Risk Evaluation. It is presented in Table 5-1 alongside the other occupational conditions of use of 1-BP to show more clearly the chronic and cancer risks to consumers.

5.5 Order Withdrawing TSCA Section 6(i)(1) Order

The August 2020 risk evaluation for 1-BP included individual risk determinations for each condition of use evaluated. The determinations that particular conditions of use did not present unreasonable risk were issued by order under TSCA section 6(i)(1). Section 5.4.1 of the August 2020 Risk Evaluation stated: "This subsection of the final Risk Evaluation … constitutes the order required under TSCA section 6(i)(1), and the 'no unreasonable risk' determinations in this subsection are considered to be final agency action effective on the date of issuance of this order."

In this revised risk determination, EPA has determined that 1-BP as a whole chemical substance presents an unreasonable risk of injury to health under the conditions of use. This revised risk determination supersedes the no unreasonable risk determinations in the August 2020 Risk Evaluation that were premised on a condition of use-specific approach to determining unreasonable risk. This subsection of the revised risk determination also constitutes an order withdrawing the TSCA section 6(i)(1) order in the August 2020 Risk Evaluation. 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 explanation and justification for this action can be found in the Federal Register Notice announcing the availability of the draft revised risk determination for 1-BP, 87 Fed. Reg. 43265 (July 20, 2022) (Ref. 8), and in the Federal Register Notice accompanying this revised risk determination.

5.6 References

1. EPA. Risk Evaluation for 1-Bromopropane (1-BP). August 2020. *https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0235-0085*.

2. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register* (86 FR 7009, January 25, 2021).

3. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register* (86 FR 7037, January 25, 2021).

4. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal Register* (86 FR 7619, February 1, 2021).

5. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. *Federal Register* (86 FR 8845, February 10, 2021).

6. EPA Press Release. EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 30, 2021. *https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations.*

7. Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. *https://www.osha.gov/annotated-pels.*

8. Notice. 1-Bromopropane (1-BP); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment. *Federal Register* (87 FR 43265, July 20, 2022).

9. EPA. Response to Public Comments to the Revised Unreasonable Risk Determination; 1-Bromopropane (1-BP). December 2022.