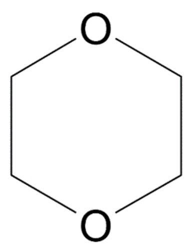
United States
Environmental Protection Agency

November 2024
Office of Chemical Safety and
Pollution Prevention

Unreasonable Risk Determination for 1,4-Dioxane

CASRN 123-91-1



November 2024

TABLE OF CONTENTS

LIST OF TABLES

6. 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. This includes an evaluation of whether a chemical substance presents an unreasonable risk to a potentially exposed or susceptible subpopulation identified by EPA as relevant to the risk evaluation, under the conditions of use.

EPA has determined that 1,4-dioxane presents an unreasonable risk of injury to health under the conditions of use. This determination is based on the information in the 2020 Risk Evaluation and the 2024 Supplement to the Risk Evaluation for 1,4-Dioxane, including the appendices and supporting documents (Refs. 1, 2). This determination was made 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.

EPA's final determination is based on cancer and non-cancer risks (from liver toxicity and effects in the olfactory epithelium) to workers and occupational non-users (ONUs) from inhalation and dermal exposures, and cancer risks to the general population, including fenceline communities, from exposures to 1,4-dioxane in drinking water sourced from surface water contaminated with industrial discharges of 1,4-dioxane (including when it is generated as a byproduct).

EPA is identifying the following conditions of use from the 2020 Risk Evaluation and the 2024 Supplement to the Risk Evaluation (Refs. 1, 2) as significantly contributing to the unreasonable risk from 1,4-dioxane:

- Manufacture (including domestic manufacture and import)
- Processing (including repackaging, recycling, non-incorporative, as a reactant, and as a byproduct, including ethoxylation processing and polyethylene terephthalate [PET] manufacturing)
- Industrial/commercial use: Intermediate
- Industrial/commercial use: Processing aid
- Industrial/commercial use: Functional fluids (open and closed system): Metalworking fluid, cutting and tapping fluid, polyalkylene glycol fluid, hydraulic fluid
- Industrial/commercial use: Laboratory chemicals
- Industrial/commercial use: Adhesives and sealants: Film cement
- Industrial/commercial use: Other uses: Spray polyurethane foam[1]
- Industrial/commercial use: Other uses: Printing and printing compositions
- Industrial/commercial use: Other uses: Dry film lubricant
- Industrial/commercial use: Other uses: Hydraulic fracturing
- Industrial/commercial use: Arts, crafts, and hobby materials: Textile dye
- Industrial/commercial use: Cleaning and furniture care products: Surface cleaner[2]
- Industrial/commercial use: Laundry and dishwashing products: Dish soap
- Industrial/commercial use: Laundry and dishwashing products: Dishwasher detergent
- Industrial/commercial use: Laundry and dishwashing products: Laundry detergent[2]

[1] Removal of the personal protective equipment assumption results in this condition of use significantly contributing to the unreasonable risk. More information on this assumption can be found in Section 6.1.2.
[2] Indicates conditions of use that did not contribute to unreasonable risk in the draft revised risk determination but were determined to significantly contribute to unreasonable risk in this final risk determination based on changes in the 2024 Supplement as a result of SACC peer review and public comments. See Sections 6.2.4.1 and 6.2.4.3.1 for more information.

- Industrial/commercial use: Paints and coatings: Paint and floor lacquer
- Consumer use: Cleaning and furniture care products: Surface cleaner[2]
- Consumer use: Laundry and dishwashing products: Dish soap[2]
- Consumer use: Laundry and dishwashing products: Dishwasher detergent[2]
- Consumer use: Laundry and dishwashing products: Laundry detergent[2]
- Consumer use: Paints and coatings: Paint and floor lacquer[2]
- Disposal

Because the risk estimates for all processing COUs identified and evaluated in the 2020 Risk Evaluation and the 2024 Supplement to the Risk Evaluation (including those where 1,4-dioxane is processed as a byproduct) significantly contribute to the unreasonable risk, EPA maintains that it is appropriate to conclude that any processing of 1,4-dioxane significantly contributes to the unreasonable risk (Refs. 1, 2). This includes circumstances described but not necessarily individually quantified in the 2020 Risk Evaluation or the 2024 Supplement to the Risk Evaluation, such as when 1,4-dioxane is generated as a byproduct during various chemical reactions, including sulfonation and sulfation, which may occur during the production of surfactants, and esterification processes, such as those used in PET manufacturing. EPA also emphasizes that this determination identifies any manufacturing, processing, or disposal of 1,4-dioxane – including as a byproduct – as significantly contributing to the unreasonable risk if the 1,4-dioxane contaminates surface water that is the source of drinking water.
This determination finds that the following conditions of use do not significantly contribute to the unreasonable risk from 1,4-dioxane:

- Distribution in commerce
- Commercial use of automobile antifreeze
- Consumer use of textile dyes
- Consumer use of automobile antifreeze
- Consumer use of spray polyurethane foam.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory action to the extent necessary so that 1,4-dioxane no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that significantly contribute to 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 significantly contribute to the 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 instance, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) that significantly contribute to the unreasonable risk, even if the upstream activities do not significantly contribute to the unreasonable risk.

As discussed in Section 6.2.4.3.1 of this document, EPA has found that exposures to the general population via drinking water sourced from surface water contaminated with 1,4-dioxane significantly contribute to the unreasonable risk presented by 1,4-dioxane. TSCA section 9(b) requires EPA to coordinate TSCA actions with actions taken under other Agency authorities. In so doing, EPA has decided that regulatory actions under both TSCA and the Safe Drinking Water Act (SDWA) may be appropriate. Under TSCA, EPA expects to apply section 6(a) requirements to the extent necessary on the manufacture, processing, commercial use, distribution in commerce, and disposal of 1,4-dioxane. These requirements may result in reduced concentrations of 1,4-dioxane in surface water. EPA recognizes that actions under TSCA may not fully eliminate releases of 1,4-dioxane to surface water, and that other sources contribute to the presence of 1,4-dioxane in surface water. These other sources may include both uses subject to regulation under TSCA and uses that are expressly excluded from regulation under TSCA due to exclusions from the definition of "chemical substance." As such, EPA will review any remaining risks following the promulgation and implementation of TSCA regulations, to determine whether additional action should be taken under SDWA.

6.1 Background

1,4-Dioxane is primarily used as a solvent in commercial and industrial applications. It can also be produced as a byproduct of several common manufacturing processes, including but not limited to ethoxylation processes used in the production of surfactants used in soaps and detergents and production of polyethylene terephthalate (PET) plastics. Even though it is not intentionally added, 1,4-dioxane produced as a byproduct may remain present in consumer and commercial products, including soaps and detergents, cleaning products, antifreeze, textile dyes, and paints/lacquers. 1,4-Dioxane is released to the environment from industrial releases and from consumer and commercial products that are washed down the drain or disposed of in landfills. People may be exposed to 1,4-dioxane through occupational exposure, consumer products, or contact with water, land, or air where 1,4-dioxane has been released to the environment.

6.1.1 Background on 2020 Risk Evaluation

In the 2020 Risk Evaluation, EPA evaluated 24 conditions of use (COUs) of 1,4-dioxane, including manufacture, processing, distribution in commerce, commercial use, and disposal, as well as consumer use of 1,4-dioxane when it is present as a byproduct in several types of consumer products (Ref. 1). For acute and chronic exposures to workers and occupational non-users, EPA evaluated risks for adverse non-cancer effects based on liver toxicity and effects in the olfactory epithelium, as well as risks of cancer from chronic exposures. For acute exposures to consumers and bystanders, EPA evaluated risks for adverse non-cancer effects based on liver toxicity. For chronic exposures to consumers, bystanders, and the general population, EPA evaluated risks of adverse non-cancer effects based on liver toxicity and effects in the olfactory epithelium, and risks of cancer.

In the unreasonable risk determination EPA published in the 2020 Risk Evaluation (Ref. 1), EPA identified no unreasonable risk to the environment for any of the 24 COUs, and also identified no unreasonable risks to consumers or bystanders from consumer use for eight COUs where 1,4-dioxane is present as a byproduct. For workers and occupational non-users, EPA identified unreasonable risk from 13 COUs, based on either worker or occupational non-user risks from acute or chronic inhalation or dermal exposures. EPA identified three occupational COUs as presenting no unreasonable risk.

Regarding the general population, in the 2020 Risk Evaluation (Ref. 1), EPA evaluated acute incidental exposures via oral and dermal routes from recreational swimming in ambient water that receives discharges from the industrial and commercial COUs for 1,4-dioxane. EPA determined that this activity presents no unreasonable risk to the general population. In addition, because 1,4-dioxane has low bioaccumulation potential, EPA determined that fish consumption does not present an unreasonable risk to the general population.

The 2020 Risk Evaluation (Ref. 1) did not evaluate risks from two critical areas: 1) fenceline or general population exposures to 1,4-dioxane in drinking water or air and 2) the full range of exposure that may result from 1,4-dioxane produced as a byproduct. The 2024 Supplement to the Risk Evaluation (Ref. 2) expands on the analysis of COUs in which 1,4-dioxane is present as a byproduct to include additional COUs for which information is reasonably available and to consider associated occupational exposures. This brings the total number of COUs evaluated to 34: 26 industrial and commercial COUs, and 8 consumer COUs. Further details of the expanded analyses are provided in Section 6.1.3.

6.1.2 Background on Policy Changes Relating to the 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 1,4-dioxane in December 2020 (Ref. 1). 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. 3, 4, 5, and 6), EPA reviewed the risk evaluations for the first ten chemical substances to ensure that the risk evaluations met the requirements of TSCA, including the requirement to use the best available science in decision-making. As a result of this review, EPA announced plans to revise specific aspects of the first ten risk evaluations to ensure that the risk evaluations appropriately identify unreasonable risks and thereby help to ensure the protection of health and the environment (Ref. 7).

EPA has also revised the regulations at 40 CFR 702 that apply to risk evaluations and risk determinations (Ref. 8). The 2024 final risk evaluation procedural rule makes several changes to the way that EPA makes unreasonable risk determinations. Consistent with the final rule, EPA has revised two key aspects of the risk determinations for 1,4-dioxane published in December 2020. First, EPA is making a single risk determination for 1,4-dioxane, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the 2020 Risk Evaluation and 2024 Supplement to the Risk Evaluation (Refs. 1, 2). Second, this risk determination does not rely on assumptions regarding the use of personal protective equipment (PPE).

Further discussion of the rationale for making a single risk determination on the chemical substance and not relying on assumptions regarding the use of PPE can be found in the final rule revising the procedures for TSCA risk evaluations (Ref. 8). For those conditions of use assessed in the 2020 Risk Evaluation for 1,4-dioxane (Ref. 1), EPA does not intend to amend, nor does a single risk determination on the chemical substance require amending, the underlying scientific analysis of the 2020 Risk Evaluation as presented in the risk characterization section of that document.

As explained in the Federal Register Notice proposing revisions to the risk determination for 1,4-dioxane (Ref. 9), the revisions to the unreasonable risk determination are based on section 4 of the 2020 Risk Evaluation and on section 5.2 of the 2024 Supplement to the Risk Evaluation) (Refs. 1, 2) and do not involve additional technical or scientific analysis beyond the 2020 Risk Evaluation and the 2024 Supplement to the Risk Evaluation. The discussion of the issues in this Final Risk Determination for 1,4-Dioxane (e.g., whether or not a condition of use or exposure pathway significantly contributes to the unreasonable risk from 1,4-dioxane) supersedes any conflicting statements in the 2020 Risk Evaluation and the Response to Public Comments document (Refs. 1, 10). In addition, in making this risk determination, EPA does not assume the use of PPE. EPA also noted in the Correction of Dermal Acute and Chronic Non-Cancer Hazard Values document, that while the corrections slightly altered occupational dermal risk estimates, the change did not appreciably impact the overall risk conclusions (Ref. 11). Because updates are not necessary for the technical analyses underlying the 2020 Risk Evaluation, EPA also views the peer reviewed hazard and exposure assessments and associated risk characterizations as robust and upholding the standards of best available science and weight of the scientific evidence, per TSCA sections 26(h) and (i).

6.1.3 The 2024 Supplement to the Risk Evaluation for 1,4-Dioxane

The 2024 Supplement to the Risk Evaluation (Ref. 2) evaluated risks to the general population—including fenceline communities and other potentially exposed or susceptible subpopulations (PESS)—

from exposure to 1,4-dioxane through drinking water or ambient air resulting from all industrial releases (including those resulting from 1,4-dioxane produced as a byproduct) as well as down-the-drain releases of consumer and commercial products. During the development of the 2020 Risk Evaluation (Ref. 1), peer reviewers and public commenters raised concerns that a failure to consider drinking water or air exposure pathways could leave portions of the population at risk. These concerns included the fact that 1,4-dioxane has been detected in drinking water and is not readily removed through typical wastewater or drinking water treatment methods. The 2024 Supplement to the Risk Evaluation includes an evaluation of 1,4-dioxane produced as a byproduct, which results in occupational exposures that were not included in the 2020 Risk Evaluation and which contributes to 1,4-dioxane in drinking water through industrial releases and down-the-drain (DTD) disposal of consumer and commercial products. Additionally, this document revises the 2020 unreasonable risk determination to incorporate the policy changes discussed in Section 6.1.2.

In evaluating risks from these additional COUs and exposure pathways, the 2024 Supplement to the Risk Evaluation relied on the hazard identification and dose-response analysis presented in the 2020 Risk Evaluation (Ref. 1). Additionally, for the 2024 Supplement to the Risk Evaluation (Ref. 2), EPA relied on the physical and chemical properties information, as well as lifecycle information, environmental fate and transport information, and hazard identification and dose-response analyses presented in the 2020 Risk Evaluation (sections 1.1, 1.4, 2.1, and 3.2 of the 2020 Risk Evaluation respectively) (Ref. 1).

The 2024 Supplement to the Risk Evaluation (Ref. 2) assessed risks for the following exposure pathways:

- Occupational exposure to:
    - 1,4-dioxane present as a byproduct in commercial products (whereas consumer products were assessed in the 2020 Risk Evaluation) (Sections 3.1, 5.2.1 of the 2024 Supplement to the Risk Evaluation) (Ref. 2)
    - 1,4-dioxane produced or present as a byproduct in industrial COUs for which information on the presence of 1,4-dioxane is reasonably available, including ethoxylation processing, PET manufacturing, and hydraulic fracturing (sections 3.1, 5.2.1 of the 2024 Supplement to the Risk Evaluation) (Ref. 2).
- General population exposures, including fenceline communities, to
    - 1,4-dioxane present in drinking water sourced from surface water as a result of all direct and indirect industrial releases and DTD releases of consumer and commercial products (sections 2.3.1, 3.2.2.1 and 5.2.2.1 of the 2024 Supplement to the Risk Evaluation) (Ref. 2);
    - 1,4-dioxane present in drinking water sourced from groundwater contaminated as a result of disposals (sections 2.3.2, 3.2.2.2 and 5.2.2.2.1.7 of the 2024 Supplement to the Risk Evaluation) (Ref. 2); and,
    - 1,4-dioxane released to air from industrial and commercial sources (sections 2.3.3, 3.2.3, and 5.2.2.3 of the 2024 Supplement to the Risk Evaluation) (Ref. 2).

The following conditions of use were added to the 2024 Supplement to the Risk Evaluation (Ref. 2):

- Processing as a byproduct (including polyethylene terephthalate (PET) byproduct and ethoxylation process byproduct)
- Industrial/commercial use: Other uses: Hydraulic fracturing
- Industrial/commercial use: Arts, crafts, and hobby materials: Textile dye
- Industrial/commercial use: Automotive care products: Antifreeze
- Industrial/commercial use: Cleaning and furniture care products: Surface cleaner

- Industrial/commercial use: Laundry and dishwashing products: Dish soap
- Industrial/commercial use: Laundry and dishwashing products: Dishwasher detergent
- Industrial/commercial use: Laundry and dishwashing products: Laundry detergent
- Industrial/commercial use: Paints and coatings: Paint and floor lacquer

6.1.4 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 must not consider costs or other non-risk 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 also takes into consideration the Agency's confidence in the data used in generating risk estimates. This includes an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimates and the risk characterization. This approach is in keeping with the Agency's final risk evaluation procedural rule (Ref. 8).

This document describes the revised unreasonable risk determination for 1,4-dioxane, under the conditions of use that are in scope for the 2020 Risk Evaluation for 1,4-Dioxane and the 2024 Supplement to the Risk Evaluation for 1,4-Dioxane (Refs. 1, 2). This revised unreasonable risk determination is based on the risk estimates in the 2020 Risk Evaluation for 1,4-Dioxane and the 2024 Supplement to the Risk Evaluation for 1,4-Dioxane, which may differ from the risk estimates in the drafts due to peer review and public comments.

6.2 Unreasonable Risk to Human Health

6.2.1 Human Health

EPA's 1,4-dioxane risk evaluation identified risks of adverse non-cancer effects from acute and chronic inhalation and dermal exposures to 1,4-dioxane, and risks of cancer from chronic inhalation and dermal exposures to 1,4-dioxane. The health risk estimates for all conditions of use are in Tables 4-23 through 4-25 of section 4.6.2 of the 2020 Risk Evaluation (Ref. 1) and in section 5.2 of the 2024 Supplement to the Risk Evaluation (Ref. 2), and in the following supplemental files of the 2024 Supplement to the Risk Evaluation:

- *Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Occupational Exposure and Risk Estimates*
- *Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Drinking Water Exposure and Risk Estimates Release to Surface Water from Individual Facilities*
- *Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Drinking Water Exposure and Risk Estimates for Surface Water Concentrations Predicted with Probabilistic Modeling*
- *Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Drinking Water Exposure and Risk Estimates for Land Releases to Landfills*
- *Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Drinking Water Exposure and Risk Estimates for Land Releases to Surface Impoundments*

- *Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Air Exposures and Risk Estimates for Single Year Analysis*
- *Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Air Exposure and Risk Estimates for Hydraulic Fracturing Operations*
- *Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Air Exposures and Risk Estimates for Industrial Laundry Operations*
- *Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Air Exposures and Risk Estimates for Multi-Year Analysis*

In developing the exposure assessment for 1,4-dioxane pursuant to 15 U.S.C. 2605(b)(4)(A), EPA analyzed reasonably available information to ascertain whether some subpopulations of people may have greater exposure or susceptibility than the general population to the hazard posed by 1,4-dioxane. Factors that may contribute to increased exposure or biological susceptibility to a chemical include lifestage, pre-existing disease, lifestyle activities, geographic factors, socio-demographic factors, nutrition, genetics, aggregate exposures, and other chemical and non-chemical stressors. For example, exposures of 1,4-dioxane would be expected to be higher amongst workers who use 1,4-dioxane on a regular basis as part of typical processes and occupational non-users (ONUs) who work near such workers.

For the 2020 Risk Evaluation (Ref. 1), EPA identified the following groups as PESS: workers and ONUs (including men and women of reproductive age and adolescents); consumer users (including men, women, and children ages 11 and up) and bystanders of any age group (including infants, toddlers, children, and elderly) (see section 4.4, Tables 4-23 and 4-24 of the 2020 Risk Evaluation) (Ref. 1). EPA evaluated exposures to workers, occupational non-users (ONUs), consumer users, bystanders, and the general population, including people who live in fenceline communities, who are expected to be PESS due to their greater exposure, using reasonably available monitoring and modeling data for inhalation, dermal, and ingestion exposures, as applicable. The description of the data used for human health exposure is in section 2.4 of the 2020 Risk Evaluation (Ref. 1) and in section 3 of the 2024 Supplement to the Risk Evaluation (Ref. 2).

The 2024 Supplement to the Risk Evaluation (Ref. 2) considers PESS throughout the human health exposure assessment and risk characterization and incorporates all PESS considerations described previously in the 2020 Risk Evaluation (Ref. 1). The 2024 Supplement to the Risk Evaluation provides a summary of how specific factors contributing to exposure and susceptibility were addressed and identifies remaining sources of uncertainty for PESS (see section 5.2.2.43, Table 5-11) (Ref. 2).
In the 2020 Risk Evaluation (Ref. 1), EPA did not assess exposures from the ambient air, drinking water, and land/disposal pathways because these exposure pathways could fall under the jurisdiction of other environmental statutes administered by EPA, i.e., Clean Air Act (CAA), Safe Drinking Water Act (SDWA), Resource Conservation and Recovery Act (RCRA), and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). However, because EPA had not yet developed recommended recreational water quality criteria for the protection of human health for 1,4-dioxane, in the 2020 Risk Evaluation, EPA evaluated the human health risks of potential acute and chronic incidental exposures via oral and dermal routes from recreational swimming in bodies of water that receive discharges from the industrial and commercial conditions of use of 1,4-dioxane. More information on these risks can be found in sections 2.4.2.1.3, 2.4.2.1.4, and 4.2.4 of the 2020 Risk Evaluation (Ref. 1).

As a result of the policy change discussed in Section 6.1.2 of this document, in the 2024 Supplement to the Risk Evaluation (Ref. 2), EPA quantitatively evaluated inhalation and ingestion exposures for the general population, including fenceline communities, via exposure to ambient air, and oral exposures via ingestion of drinking water sourced from surface water or groundwater contaminated with 1,4-dioxane from facility-specific releases, down-the-drain releases of consumer and commercial products that contain 1,4-dioxane as a byproduct, hydraulic fracturing releases, and leaching from landfills (disposal). More information on these risks can be found in sections 2, 3.2 and 5.2.2 of the 2024 Supplement to the Risk Evaluation (Ref. 2).

6.2.2 Non-Cancer Risk Estimates

The risk estimates of non-cancer effects (expressed as margins of exposure or MOEs) refer to adverse health effects other than cancer, including effects on other organ systems and function, such as 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) or human equivalent dose (HED) for a specific health endpoint divided by the estimated exposure for the specific scenario of concern. Section 3.2.6 of the 2020 Risk Evaluation (Ref. 1) presents the PODs for acute and chronic non-cancer effects for 1,4-dioxane and section 4.2 of the 2020 Risk Evaluation (Ref. 1) presents the MOEs for acute and chronic non-cancer effects. Section 4.2 of the 2024 Supplement to the Risk Evaluation (Ref. 2) provides information on how some of the exposure scenarios included in the supplement required duration adjustments to the previously established PODs. For example, to evaluate risks from ambient air exposures for fenceline communities, EPA assumed continuous exposure to air for 24 hours/day, 7 days/week.

To characterize risk from non-cancer endpoints, the estimated endpoint-specific MOEs are compared to their respective 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 extrapolation uncertainty for specific hazard endpoints and scenarios. However, these are often not the only uncertainties in a risk evaluation. The benchmark MOE for the most robust and sensitive acute non-cancer risks for 1,4-dioxane, for systemic liver toxicity, is 300 (accounting for intraspecies, interspecies variability, and LOAEL to NOAEL variability). The benchmark MOE for the most robust and sensitive chronic non-cancer risks for 1,4-dioxane, liver toxicity and olfactory epithelium effects, is 30 (accounting for interspecies and intraspecies variability). Additional information regarding the non-cancer hazard identification is in section 3.2.3.1 and the benchmark MOE is in section 3.2.6. of the 2020 Risk Evaluation (Ref. 1). The non-cancer benchmarks are unchanged in the 2024 Supplement to the Risk Evaluation (Ref. 2).

6.2.3 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.,* 1×10^{-6} to 1×10^{-4}) depending on the subpopulation exposed. For example, in the 2020 Risk Evaluation (Ref. 1), EPA used 1×10^{-6} as the benchmark for the cancer risk to consumers and bystanders from consumer use of products containing 1,4-dioxane as a byproduct, such as dishwashing detergent and antifreeze, and used 1×10^{-4} as the benchmark for the cancer risk to individuals in industrial and commercial workplaces. These benchmarks are the same in the 2020 Risk Evaluation (Ref. 1) and the 2024 Supplement to the Risk Evaluation (Ref. 2). In the 2020 Risk Evaluation, EPA used 1×10^{-6} as the benchmark for exposures to surface water from recreational swimming. For the 2024 Supplement to the Risk Evaluation (Ref. 2), EPA presented risk estimates compared to the range of 1×10^{-6} to 1×10^{-4} for increased cancer risk for the general population, including fenceline communities, consistent with other EPA regulatory programs. Under TSCA, it is preferable for the drinking water and ambient air concentrations of 1,4-dioxane to not result in an increased cancer risk above the 1×10^{-6} benchmark. EPA has discretion to make its unreasonable risk determination for the chemical substance based on other risk-related factors as appropriate, consistent with the risk evaluation rule. Additional information regarding the cancer benchmark is in sections 3.2.6.2 and 4.2.1 of the 2020 Risk Evaluation (Ref. 1).

6.2.4 Determining Unreasonable Risk of Injury to Health

Calculated risk estimates (MOEs or cancer risk estimates) can provide a risk profile of 1,4-dioxane 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. These calculated risk estimates alone are not bright-line indicators of unreasonable risk. 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 risk characterization (section 4) of the 2020 Risk Evaluation (Ref. 1), liver toxicity, effects in the olfactory epithelium, and cancer were identified as the key endpoints for non-cancer and cancer adverse effects from acute and chronic inhalation and dermal exposures for all conditions of use. Additional risks associated with other adverse effects (e.g., kidney, lung, and brain) were identified for acute and chronic non-cancer exposures. EPA assumes that addressing unreasonable risk by using the most sensitive endpoints for acute and chronic non-cancer adverse effects (liver toxicity, olfactory epithelium) and cancer endpoints will also be protective of other adverse effects resulting from acute or chronic inhalation and dermal exposures.

When making a determination of unreasonable risk for the chemical substance, the Agency has a higher degree of confidence where uncertainty is low. The 2020 Risk Evaluation (Ref. 1) and the 2024 Supplement to the Risk Evaluation (Ref. 2) discuss major assumptions and key uncertainties by major topic: human and environmental hazards, occupational exposure, general population/consumer exposure, and environmental exposure. Important assumptions and key sources of uncertainty in the risk characterization are described in more detail in section 4.3 of the 2020 Risk Evaluation (Ref. 1) and throughout the 2024 Supplement to the Risk Evaluation (Ref. 2).

When determining the unreasonable risk for 1,4-dioxane, EPA considered the central tendency and high-end exposure levels in occupational settings and in environmental media, moderate and high intensity of use for consumer uses, and central tendency and high-end exposure levels for general population exposures, including fenceline community exposures. Risk estimates based on high-end exposure levels or high intensity use scenarios (e.g., 95^{th} 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. The revised unreasonable risk determination for 1,4-dioxane is based on the peer reviewed December 2020 Risk Evaluation and the 2024 Supplement, which were developed according to TSCA sections

26(h) and (i) requirements to make science-driven decisions, consistent with best available science. Changing the risk determination to a single-determination approach does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation. The Updated Occupational Risk Calculator for the 2024 Supplement summarizes the risk estimates with and without PPE and informed the revised unreasonable risk determination.

6.2.4.1 Occupational Settings

As shown in section 4 of the 2020 Risk Evaluation (Ref. 1) and section 5 of the 2024 Supplement to the Risk Evaluation (Ref. 2), and consistent with the final risk evaluation rule amendments (Ref. 8), EPA has evaluated the levels of risk present in baseline scenarios where no mitigation measures are assumed to be in place.[3] This approach considers the risk to potentially exposed or susceptible subpopulations of workers 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. Mitigation scenarios included in the 2020 Risk Evaluation (Ref. 1) (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 unreasonable risk determination. EPA's 2024 revisions to the framework rule for TSCA risk evaluations also explained why EPA will "not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination" (89 FR 37028). As commenters on that rule observed, both OSHA and NIOSH have been supportive on this point, emphasizing the importance of the hierarchy of controls (see, e.g., EPA-HQ-OPPT-2023-0496-0215). 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," (Ref. 12) or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

For most of the conditions of use with occupational exposures in the 2020 Risk Evaluation (Ref. 1) and the 2024 Supplement to the Risk Evaluation (Ref. 2), high-end cancer risk estimates were above 1 in 10,000 (1×10^{-4}). Cancer risk estimates for both central tendency and high-end dermal and inhalation exposures exceeded cancer risk benchmarks and were greater than 1 in 10,000 (1×10^{-4}) for occupational exposures associated with numerous conditions of use (COUs), including manufacturing, processing (including repackaging, recycling, processing as a reactant, non-incorporative processing, processing as a byproduct), industrial use as an intermediate, industrial use as a processing aid, industrial/commercial use in adhesives and sealants (film cement), and disposal. For some conditions of use, cancer risk estimates exceeded cancer risk benchmarks only for dermal exposures, such as for industrial use as a functional fluid in metalworking fluid, cutting and tapping fluid, polyalkane glycol fluid (high end and central tendency risk estimates); industrial use in spray polyurethane foam (high end and central tendency risk estimates); and commercial use in laundry and dishwashing products – dish soap and laundry detergent (high end risk estimates).

[3] 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.

For non-cancer risks, for numerous COUs, calculated acute and/or chronic central tendency and high-end MOEs are less than the benchmark MOE for inhalation and dermal exposures (indicating risk), including manufacturing (including importing), processing (including repackaging, recycling, processing as a reactant, and non-incorporative processing), industrial use as an intermediate, industrial use as a processing aid, industrial/commercial use in adhesives and sealants (film cement) and disposal. For some conditions of use, non-cancer risk estimates are less than the benchmark MOE only for dermal exposures, such as industrial use in printing and printing compositions (acute and chronic non-cancer high end and central tendency risk estimates); and commercial use in paints and coatings – paint and floor lacquer (acute and chronic non-cancer high end risk estimates).

More information on occupational risk estimates is in section 4.2.2 of the 2020 Risk Evaluation (Ref. 1) and section 5.2.1 of the 2024 Supplement to the Risk Evaluation (Ref. 2). Complete risk calculations and results for occupational COUs from the 2020 Risk Evaluation and the 2024 Supplement to the Risk Evaluation are in *Supplement to the Risk Evaluation for 1,4-Dioxane – Supplemental Information File: Occupational Exposure and Risk Estimates mentioned in Section 6.2.1.*

As discussed in Appendix K to the 2024 Supplement to the Risk Evaluation, several changes were made in response to peer review and public comment on the 2023 Draft Supplement (Refs. 2, 10, 14). Incorporation of Monte Carlo modeling into the inhalation exposure estimates decreased the exposure estimates for the industrial or commercial use of 1,4-dioxane as a byproduct in dish soap and dishwasher detergent. Monte Carlo simulation allows for variation in the model input data, thus increasing the representativeness of the approach. Updates to the Monte Carlo modeling that had previously been done for industrial or commercial use of 1,4-dioxane as a byproduct in laundry detergent increased the exposure estimates. Incorporation of product concentration data from New York State Department of Environmental Conservation (NYDEC) approved waivers for 1,4-dioxane in consumer products resulted in increased dermal exposures estimates for the industrial or commercial use of 1,4-dioxane as a byproduct in surface cleaner, dishwasher detergent, and laundry detergent.

With respect to EPA's confidence in the occupational risk estimates, EPA has moderate to high confidence in the worker estimates from the 2020 Risk Evaluation (Ref. 1). EPA used monitoring data to assess inhalation exposures and modeled dermal exposures. EPA has moderate confidence in the dermal exposure estimates, and low confidence in the occupational non-user (ONU) inhalation estimates, which were based on central tendency parameters for worker inhalation exposure estimates. Uncertainties include the representativeness of the monitoring data for all of the industries within the particular occupational exposure scenario (OES), and the extent to which the modeled dermal exposures represent actual exposures. With respect to health endpoints, as discussed in section 3.2.7 of the 2020 Risk Evaluation (Ref. 1), EPA has medium confidence in the PODs for acute exposure scenarios, high confidence in the non-cancer PODs chronic exposure scenarios, high confidence in the cancer inhalation unit risk, and medium to high confidence in the oral and dermal cancer slope factors. More information on EPA's confidence in these estimates and the uncertainties associated with them is in section 4.3 of the 2020 Risk Evaluation (Ref. 1).

EPA has similar confidence in the occupational risk estimates in the 2024 Supplement. Inhalation monitoring data were available for most of the occupational exposure scenarios, which were used to derive the worker risk estimates for each condition of use. For three of the occupational exposure scenarios (antifreeze, laundry detergent, and hydraulic fracturing), EPA did not find reasonably available monitoring data, so inhalation exposures were modeled. In addition, as discussed previously, modeling was incorporated into the dish soap and dishwasher detergent exposure scenarios. However, EPA was unable to develop distributions for all input parameters, increasing the uncertainty in the parameterization and applicability. More information on EPA's confidence in these estimates and the uncertainties associated with them can be found in section 3.1.2.4 and 5.2.2.6.1 of the 2024 Supplement to the Risk Evaluation (Ref. 2).

Based on the occupational risk estimates and EPA's confidence in them, EPA finds that risks to workers and ONUs from all but four occupational conditions of use significantly contribute to the unreasonable risk from 1,4-dioxane. (The four exceptions are distribution in commerce, antifreeze, surface cleaner, and dishwasher detergent), More details are in Table 6-1 of this document.

6.2.4.2 Consumer Uses

In the 2020 Risk Evaluation (Ref. 1), EPA evaluated eight consumer uses of products that contain 1,4-dioxane as a byproduct. For each of the eight conditions of use, EPA evaluated non-cancer effects to consumers and bystanders from acute inhalation and dermal exposures (for consumer users). For four of the conditions of use, based on the exposure assessment, EPA also evaluated cancer risks to consumers from chronic inhalation and dermal exposures, because the products involved (surface cleaner, dish soap, dishwasher detergent, laundry detergent) are likely to be used on a regular basis. EPA did not estimate chronic inhalation exposures to bystanders because bystanders would be exposed to lower levels than the users based on the model bystander placement in the home during the product's use. EPA also did not evaluate non-cancer effects from dermal exposures to bystanders because bystanders are not dermally exposed to 1,4-dioxane. EPA's overall confidence in the consumer inhalation exposure estimates ranges from moderate to high, while confidence in the consumer dermal exposure estimates ranges from low to moderate. More information on the consumer and bystander analysis can be found in sections 2.4.3.4, 4.2.3, and 4.3.2.1 of the 2020 Risk Evaluation (Ref. 1). Based on the consumer and bystander risk estimates, which do not exceed applicable benchmarks, and EPA's confidence in them, EPA finds that exposures to consumers and bystanders resulting from consumer use of products that contain 1,4-dioxane do not significantly contribute to the unreasonable risk.

6.2.4.3 General Population Including Fenceline Communities

6.2.4.3.1 Drinking Water

In the 2024 Supplement to the Risk Evaluation (Ref. 2), EPA evaluated oral exposures via ingestion of drinking water sourced from surface water or groundwater contaminated with 1,4-dioxane from facility-specific releases, down-the-drain (DTD) releases of consumer and commercial products that contain 1,4-dioxane as a byproduct, hydraulic fracturing releases, and leaching from landfills. 1,4-Dioxane is not readily removed through typical wastewater or drinking water treatment processes.

EPA considered risks from these sources of 1,4-dioxane individually and in aggregate. The relative contribution from different sources varies under different conditions and is likely to be driven by site-specific factors including the amounts released from each source, flow rates of receiving water bodies, and proximity of releases to drinking water intakes. In general, risk estimates for 1,4-dioxane in drinking water related to surface water are highest where there are high releases (whether from industrial facilities or large populations [DTD]) into a low flow waterbody. Similarly, EPA's drinking water risk estimates associated with 1,4-dioxane in groundwater indicate that higher hydraulic fracturing releases or landfill leachate concentrations and loadings are associated with higher risks.

For facility-specific releases to surface water, EPA used release data reported to the Toxics Release Inventory (TRI) and the Discharge Monitoring Report (DMR) and modeled hydrologic flow (stream flow) data associated with the receiving water body from the National Hydrography Dataset Plus (NHDPlus, V2.1 dataset) as model inputs to estimate concentrations in receiving waterbodies for manufacturing, processing, disposal, and most industrial COUs. See Section 2.3.1.2.1 of the 2024 Supplement for more information. EPA estimated 1,4-dioxane concentrations in a receiving waterbody following release. In this approach, EPA considers mixing and dilution that occurs at the point of release, but there is uncertainty and site-specific variability in the amount of additional dilution that occurs between the point of release and the location of known drinking water intakes. EPA used three approaches to estimate the potential impact of downstream dilution on concentrations:

- EPA looked to see if there are drinking water intakes downstream of 1,4-dioxane release sites.
- EPA completed a national scale assessment to estimate 1,4-dioxane risk based on a range of dilution scenarios. EPA used an average dilution (i.e., dilution to 1% of the original concentration) and no dilution in these calculations. These dilution values are based on the full distribution of available site-specific data (i.e., flow, distance, and releases).
- EPA estimated water concentrations and risks that may occur at specific drinking water intakes downstream of 1,4-dioxane releasing facilities where EPA had sufficient location-specific data.

Risk estimates were also compared to available drinking water monitoring data and, where monitoring data are available near release sites, the comparisons demonstrate general agreement between modeled concentrations and monitoring data where available. The facility-specific analysis supports the unreasonable risk finding for 1,4-dioxane because the median lifetime cancer risk estimate is 2.32×10^{-6} and the 95th percentile risk estimate is 4.92×10^{-3} (Ref. 2). For nearly all COUs, the mean cancer risk estimates exceed 1×10^{-6} (Ref. 2, *1,4-Dioxane Supplemental Information File: Drinking Water Exposure and Risk Estimates Release to Surface Water from Individual Facilities*).

These risk estimates rely on the assumption that concentrations at drinking water intakes are the same as concentrations estimated near the point of release. While this is a conservative assumption for most water systems, EPA believes that it accurately reflects the situation for some water systems. To refine this assumption, EPA considered the proximity of release sites to downstream drinking water intake locations for community and non-community non-transient public water systems. Of the 69 facilities with cancer risks greater than 1×10^{-6}, 4 have a downstream drinking water intake within 10 kilometers (Ref. 2). As discussed in section 5.2.2.1.2 of the 2024 Supplement to the Risk Evaluation (Ref. 2), based on available site-specific information for each facility, the mean modeled dilution predicted at downstream drinking water intakes is one percent of original concentrations estimated in receiving water bodies near the point of release. Assuming that drinking water intake concentrations were diluted to 1% of initial receiving water body concentrations, the median lifetime cancer risk estimate is 8.51×10^{-9} and the 95th percentile cancer risk estimate is 4.92×10^{-5} (Ref. 2).

Even when accounting for site-specific influences on downstream dilution, EPA modeled concentrations that would result in adult lifetime cancer risk in excess of 1×10^{-6} at intakes for 20 of the PWSs identified through this assessment, serving a combined population of 2,124,000 people. Adult lifetime cancer risk estimates were greater than 1×10^{-5} for 5 of these public water systems, serving a combined population of 834,000 people. Overall confidence in the distribution of risk estimates for drinking water exposures resulting from facility releases is medium to high. Based on this analysis, EPA finds that general population risks due to exposure to drinking water sourced from surface water that is contaminated by 1,4-dioxane released from industrial facilities significantly contributes to the unreasonable risk from 1,4-dioxane.

EPA's analysis indicates that other sources of 1,4-dioxane in surface water contribute less to drinking water exposure and risk than facility-specific releases, although the other sources may still significantly contribute to the unreasonable risk presented by 1,4-dioxane. For example, EPA evaluated the potential contribution to drinking water exposure and risk of DTD releases of consumer and commercial products that contain 1,4-dioxane as a byproduct and that were evaluated for occupational and consumer exposures. EPA's drinking water exposure estimates correspond to surface water concentrations estimated by probabilistic modeling of DTD releases under varying population and stream flow conditions. EPA determined surface water concentrations at the point of DTD releases via publicly-owned treatment works primarily by the size of the population contributing to DTD releases and the flow rates of receiving water bodies. Assuming no additional dilution *(i.e.*, beyond the mixing with the receiving water body that occurs at the point of release) between the point of release and the drinking water intake, the estimated risks range from 2.04×10^{-11} to 6.11×10^{-5} (Ref. 2), with the risks increasing as population increases and stream flow decreases (Ref. 2, Table 5-4).

EPA considered the impact of exposure factors assumptions on drinking water risk estimates. As explained in the 2024 Supplement to the Risk Evaluation (Ref. 2), EPA applied a mean drinking water ingestion rate for the lifetime drinking water exposure scenarios. In addition, EPA's risk estimates in the 2023 Draft Supplement assumed an exposure duration of 33 years over a lifetime, representing the 95th percentile of the expected duration at a single residence (Ref. 13). The peer reviewers of the 2023 Draft Supplement recommended that EPA consider both higher drinking water ingestion rates and a full lifetime of exposure for assessing lifetime exposure and cancer risks for environmental justice and fenceline communities. EPA agrees with these recommendations. A review of the 95th percentile reported drinking water ingestion rates shows that, while there is variation by age group, an increased ingestion rate could result in risks up to 3 to 4 times greater than those estimated with the mean ingestion rate, or lifetime cancer risk estimates as high as 2.3×10^{-4} for the combinations of population size and stream flow considered (Ref. 2). Similarly, lifetime cancer risk estimates for a full lifetime of exposure (78 years) would be 2.26 times greater, accounting for ingestion rate differences across ages, resulting in risk estimates as high as 1.4×10^{-4} for the combinations of population size and stream flow considered (Ref. 2).

Overall confidence in risk estimates for drinking water exposures resulting from DTD releases is medium. As noted in section 5.2.2.1.3. of the 2024 Supplement, these risk estimates are not tied to known releases at specific locations; rather, the analysis defines the conditions under which modeled DTD releases would result in varying levels of risk (Ref. 2). For this reason, there is uncertainty around the proximity of releases to drinking water intake locations and the extent to which 1,4-dioxane is further diluted prior to reaching intake locations. However, based on this analysis, and the increase in risk estimates that results from the consideration of either or both recommended exposure factors, EPA finds that general population exposures to drinking water contaminated with 1,4-dioxane from DTD releases of commercial and consumer products that contain 1,4-dioxane as a byproduct significantly contribute to the unreasonable risk from 1,4-dioxane.

EPA also evaluated the contribution of 1,4-dioxane to risks from surface water by hydraulic fracturing. EPA incorporated information from reports on 1,4-dioxane use reported by hydraulic fracturing wells and reasonably available hydrologic information to generate a distribution of modeled releases and pair them with hydrologic flows, resulting in a distribution of possible surface water concentrations. See section 2.3.1.2.3 of the 2024 Supplement. Water concentrations of 1,4-dioxane resulting from disposal of hydraulic fracturing produced water vary substantially across sites. The median lifetime cancer risk estimate is 3.85×10^{-8} and the 95th percentile lifetime cancer risk estimate is 1.52×10^{-6} (Ref. 2). Overall confidence in risk estimates for drinking water exposures resulting from hydraulic fracturing releases is medium. Applying the recommended additional exposure factor assumptions discussed above could result in risks as high as 1.37×10^{-5}. As with the DTD analysis, the modeled exposure estimates are not directly tied to specific releases at known locations, decreasing the strength of the evidence related to the representativeness of the exposure estimates for actual exposures. There is also some uncertainty around the proximity of releases to drinking water intake locations and the extent to which 1,4-dioxane is further diluted prior to reaching intake locations. In addition, while hydraulic fracturing produced water continues to be returned throughout the life of the well, the percentage of produced water drops off after the first few weeks or months and is replaced by produced oil or gas (Ref. 14). Further, while estimated well life ranges from 5 to 70 years, because the current hydraulic fracturing-led production surge is somewhat recent, it is not known how much and for how long these wells will ultimately produce (Ref. 14). Therefore, it is unlikely that there will be exposures that result in the 95% percentile lifetime cancer risks, whether based on 33 years or a full lifetime. Based on this analysis, EPA has found that general population exposures to drinking water contaminated with 1,4-dioxane from hydraulic fracturing do not contribute to the unreasonable risk from 1,4-dioxane.

EPA estimated risks from general population exposures that could occur if groundwater containing 1,4-dioxane is used as a source of drinking water. These risk estimates are not tied to known releases at specific locations. Rather, the analysis defines the conditions under which 1,4-dioxane disposal to landfills or from hydraulic fracturing operations could result in varying levels of risk based on concentrations of 1,4-dioxane in groundwater.

For potential groundwater concentrations resulting from landfill leachate, EPA estimated risks under varying combinations of leachate concentrations and landfill loading rates. While estimated risks exceed 1×10^{-6} at the highest leachate concentrations and loading rates, the overall confidence in these risk estimates is low to medium (Ref. 2). Model inputs include chemical properties of 1,4-dioxane that are well-defined and reviewed and therefore supported by robust evidence. However, model inputs for leachate concentrations and loading rates are more uncertain. EPA does not have reasonably available information on actual concentrations of 1,4-dioxane in leachate for most landfills. Therefore, EPA selected a range of landfill leachate concentrations to evaluate the potential for risk to human health. Loading rates are based on the range reported in TRI for RCRA subtitle C landfills and therefore may not be representative of loading to all nonhazardous RCRA subtitle D landfills evaluated in this analysis. The drinking water exposure scenario relies on the assumption that modeled groundwater concentrations reflect the actual groundwater concentrations that occur at well locations.

As part of this analysis, EPA reviewed direct groundwater monitoring results stored in the Water Quality Portal. While EPA's modeled data are within the range of groundwater monitoring data that have been evaluated at the national scale, the modeled results may not represent the current condition of waste management units. For example, some of the available groundwater monitoring data are from Superfund sites where historical groundwater contamination is being managed. In addition, as explained in Section 2.3.2.1. of the Supplement, samples collected prior to 2000 tended to be substantially higher in concentration relative to those collected later. This may indicate that changes in industrial practices related to 1,4-dioxane, including changes in disposal practices possibly resulting from land disposal restrictions under RCRA, are having a beneficial effect on groundwater concentrations. Although several post-2003 samples are still above 10 µg/L, particularly in 2007, the bulk of the more recent data tend to fall between 1 and 10 µg/L. Further, the models EPA used to estimate groundwater concentrations are based on a 1988 survey of drinking water wells located downgradient from a waste management unit, and, due to the age of the survey, it is not clear how well the survey represents current conditions and proximity of drinking water wells to disposal units. Based on this analysis, and the substantial uncertainty around the extent to which the modeled data represent actual exposures, EPA finds that general population exposures to drinking water sourced from groundwater contaminated with 1,4-dioxane from landfill leachate do not significantly contribute to the unreasonable risk from 1,4-dioxane. EPA also calculated risks for groundwater concentrations resulting from disposal of hydraulic fracturing produced water. Options for these produced waters after use include underground injection, treatment and subsequent use, treatment and discharge, or evaporation in surface impoundments. According to EPA's analysis, up to 3% of produced waters are released to surface impoundments, and unlined surface impoundments can potentially contaminate groundwater.

The estimated risks range from 1.1×10^{-5} to 2.5×10^{-10}, and the mean estimated risk is 4.0×10^{-7} (Ref. 2). Overall confidence in the risk estimates is low to medium. The modeling methodology is robust and the release information relied on as model input data is supported by moderate evidence, this exposure scenario relies on the assumption that modeled groundwater concentrations reflect the actual groundwater concentrations that occur at well locations. However, in the absence of specific data to characterize exposure scenarios and populations impacted, many conservative assumptions have been made to estimate potential risks from these operations.

Available groundwater monitoring data are not located near hydraulic fracturing operations and do not provide information about the potential for hydraulic fracturing operations to contribute to groundwater contamination. Further, as discussed above, while hydraulic fracturing produced water continues to be returned throughout the life of the well, the percentage of produced water (and thus 1,4-dioxane) drops off after the first few weeks or months and is replaced by produced oil or gas (Ref. 14). While estimated well life ranges from 5 to 70 years, because the current hydraulic fracturing-led production surge is somewhat recent, it is not known how much and for how long these wells will ultimately produce (Ref. 14). Therefore, it is very unlikely that there will be exposures that result in the 95% percentile lifetime cancer risks. Based on the uncertainty as to whether the modeled data represents actual exposures and whether 95th percentile lifetime cancer risks will actually ever occur, and the fact that the maximum estimated lifetime cancer risk is 1.1×10^{-5} while the mean is 4.0×10^{-7}, EPA finds that general population exposures to drinking water sourced from groundwater contaminated with 1,4-dioxane from the disposal of hydraulic fracturing produced water do not significantly contribute to the unreasonable risk from 1,4-dioxane.

In summary, EPA has determined that exposure to drinking water sourced from surface water that is potentially contaminated by 1,4-dioxane released from industrial facilities and DTD releases significantly contributes to the unreasonable risk from 1,4-dioxane. EPA has determined that other exposures to drinking water potentially contaminated with 1,4-dioxane do not significantly contribute to the unreasonable risk for 1,4-dioxane such as drinking water sourced from groundwater that is potentially contaminated with landfill leachate or releases from hydraulic fracturing. EPA's determination is based primarily on the risk estimates for facility-specific and DTD releases of 1,4-dioxane, the extent to which those high-end risk estimates exceed applicable benchmarks, and EPA's higher confidence in the facility-specific and DTD risk estimates versus other drinking water risk estimates.

6.2.4.3.2 Ambient Air

EPA estimated risks from fenceline community exposures to 1,4-dioxane released to air. Risks were evaluated for air releases from industrial COUs, hydraulic fracturing operations, and industrial and institutional laundry facilities. EPA estimated risks from fenceline exposures that could occur in communities immediately neighboring releases from industrial COUs by modeling either facility-specific chemical releases reported to TRI or, when TRI data were not available, alternative release estimates representing a generic facility. Cancer and non-cancer risk estimates for fenceline exposures within 10,000 meters of industrial releases were calculated for the modeled exposure concentrations. Acute and chronic non-cancer risk estimates do not indicate risk relative to the benchmark MOEs for any of the estimated exposure concentrations at any facilities evaluated. Cancer risk estimates for 95th percentile exposure concentrations within 1,000 meters of the point of release from facilities with the greatest risk in each COU ranged from 1.05×10^{-10} to 9.21×10^{-5}.[4] The COUs with estimated risks exceeding 1×10^{-6} include domestic manufacturing, processing (including non-incorporative, as a reactant, and as a byproduct, including during the ethoxylation process and during polyethlene terephthalate production), industrial use of 1,4-dioxane as an intermediate, industrial and commercial use of 1,4-dioxane as a laboratory chemical, and disposal.

EPA evaluated the land use patterns to determine whether residences, businesses, or other public spaces were present within the area where the lifetime cancer risk was estimated to be greater than 1×10^{-6} assuming 33 years of continuous exposure to 95th percentile modeled air concentrations. Based on this evaluation, fenceline community exposures are reasonably anticipated at 50 percent of facilities where cancer risk exceeds 1.0×10^{-6}. However, in most cases, the anticipated exposures are for workers who work at other nearby industrial facilities and not for fenceline community residents (Ref. Fenceline Deeper Dive memo), and therefore, the exposures are not expected to be continuous.

As discussed earlier in this section, EPA's risk estimates in the 2023 Draft Supplement assumed an exposure duration of 33 years, but the peer reviewers of the 2023 Draft Supplement recommended that EPA consider a full lifetime (78 years) of exposure for assessing lifetime exposure and cancer risks for environmental justice and fenceline communities (Ref. 13). EPA agrees with this recommendation. Lifetime cancer risk estimates for a full lifetime (78 years) of inhalation exposure would be 2.36 times greater, resulting in lifetime cancer risk estimates as high as 2.6×10^{-4} for domestic manufacturing (Ref. 2). However, most of the lifetime cancer risk estimates that exceed 1.0×10^{-6} are for distances that are very close to the releasing facilities, i.e., at 100 meters or less. The highest risk estimates for a full lifetime for four COUs, domestic manufacturing (2.3×10^{-6}), ethoxylation byproduct processing (6.1×10^{-6}), PET manufacturing (1.7×10^{-6}), and industrial use as an intermediate (1.1×10^{-6}), would exceed 1×10^{-6} only at distances of 100 meters to 1000 meters (Ref. 2). Facilities that are releasing 1,4-dioxane as a result of these COUs are chemical manufacturing companies, many of them are large facilities. For these facilities, even 1000 meters from the point of release is more likely to be a point within the same facility or another nearby industrial facility, rather than a fenceline community. As noted in Section 5.2.2.3.1 of the 2024 Supplement (Ref. 2), the exposure scenarios that EPA considered are those most relevant to long-term residents in fenceline communities. There is uncertainty around the extent to which people spend a lifetime living that close to the specific facilities where risks are highest, which decreases overall confidence in the exposure scenario, particularly at distances within 1000 meters of release sites.

EPA's confidence in the risk estimates for ambient air exposures for those COUs identified in the previous two paragraphs is medium to high, except for industrial and commercial use of 1,4-dioxane as a laboratory chemical. The modeling methodology used for this analysis is robust and relied primarily on release data reported to TRI via Form R. Because the laboratory chemical analysis relied on surrogate or modeled release data, EPA's confidence in those risk estimates is low to medium. For most COUs, the analysis is limited to facilities that report to TRI, so other sources of 1,4-dioxane releases are not directly captured.

EPA also evaluated potential risks from aggregate ambient air exposures from multiple neighboring facilities in these COUs using a conservative screening methodology. EPA identified five groups of two to four facilities reporting 1,4-dioxane releases in proximity to each other, *i.e.*, within 10 km. Aggregated risks estimated for these groups of facilities were generally dominated by the facility with the greatest risk. This aggregate analysis did not identify locations with cancer risk greater than 1×10^{-6} that did not already have cancer risk estimates above that level from an individual facility.

[4] A higher risk estimate (1.1×10^{-4}) was associated with a facility that ceased manufacture of 1,4-dioxane in 2018.

For two COUs without site-specific data, modeling was used to estimate high-end and central tendency 1,4-dioxane concentrations in ambient air at three distance zones from an emitting facility (100, 100 to 1,000, and 1,000 meters). This methodology was applied for hydraulic fracturing and for industrial and institutional laundry facilities. Environmental releases (fugitive and stack) along with other data (like days of release) for these COUs were estimated using Monte Carlo modeling. These release estimates were then used to estimate ambient air concentrations.

Lifetime cancer risk estimates for distances within 1,000 meters of hydraulic fracturing operations range from 3.9×10^{-7} to 7.1×10^{-5} for high end release estimates and 2.2×10^{-8} to 4.1×10^{-6} for central tendency release estimates across a range of model scenarios (Ref. 2). Acute and chronic non-cancer risk estimates do not indicate risk relative to benchmark MOEs for any exposure concentrations estimated for hydraulic fracturing operations.

While applying the 2.36 multiplier for a full lifetime (78 years) of exposure to the high end release estimates would result in lifetime cancer risks as high as 1.7×10^{-4}, it is unlikely that hydraulic fracturing would occur in approximately the same location resulting in daily exposures for a full lifetime. As previously noted, while hydraulic fracturing fluids continue to be returned throughout the life of the well, the percentage of those fluids drops off after the first few weeks or months and is replaced by produced oil or gas (Ref. 14). Further, while estimated well life ranges from 5 to 70 years, because the current hydraulic fracturing-led production surge is somewhat recent, it is not known how much and for how long these wells will ultimately produce (Ref. 14). Therefore, it is unlikely that there will be daily residential exposures that result in the 95% percentile lifetime cancer risks, whether based on 33 years or a full lifetime.

Lifetime cancer risk estimates for distances within 1,000 meters of industrial and institutional laundry facilities range from 1.5×10^{-11} to 3.8×10^{-8} across a range of high end and central tendency exposure scenarios (Ref. 2). While EPA revised the release assessment for industrial and institutional laundries in response to peer review comments, and considered a full lifetime of exposure, the shift in release estimates did not affect EPA's risk conclusions. (See section 5.2.2.3.3. of the 2024 Supplement for more information (Ref. 2)) Acute and chronic non-cancer risk estimates do not indicate risk relative to benchmark MOEs for any exposure concentrations estimated for industrial and institutional laundry facilities.

Overall confidence in risk estimates from inhalation exposures resulting from hydraulic fracturing and industrial and institutional laundries is medium. The modeling methodologies are robust. The distribution of air releases used as model input data were estimated using Monte Carlo modeling and rely on conservative assumptions. No air monitoring data were reasonably available to determine whether 1,4-dioxane is detected near hydraulic fracturing operations or industrial and institutional laundry facilities. Because the air concentrations underlying this analysis are based on probabilistic modeling, the values are not tied to specific locations that can be evaluated for land use patterns. Based on the risk estimates for cancer, acute effects, and non-cancer chronic effects and factoring in the uncertainty of a lifetime of exposure in proximity of a releasing facility, the extent to which the risk estimates do not exceed the applicable benchmarks, the land use analysis, and EPA's confidence in the risk estimates, EPA does not find that fenceline community exposure to 1,4-dioxane in ambient air from releases from TSCA conditions of use significantly contributes to the unreasonable risk from 1,4-dioxane.

6.3 Unreasonable Risk to the Environment

6.3.1 Environment

EPA used environmental fate parameters, physical-chemical properties, modelling, and monitoring data to assess ambient water exposure to aquatic organisms. Following a qualitative assessment of the physical-chemical properties and fate of 1,4-dioxane in the environment, further analysis was not conducted for biosolids, soil and sediment pathways. However, a quantitative comparison of hazards and exposures for aquatic organisms in surface water was evaluated. EPA calculated a risk quotient (RQ) to compare environmental concentrations against an effect level in surface water for the most biological relevant species. Exposures of 1,4-dioxane to aquatic organisms from surface water were assessed and presented in the 2020 Risk Evaluation and used to inform the risk determination (Ref. 1). These analyses are described in sections 2.1, 2.3, and 4.1 of the 2020 Risk Evaluation (Ref. 1). Uncertainties in the analysis are discussed in section 4.3.4 of the 2020 Risk Evaluation (Ref. 1).

6.3.2 Determining Unreasonable Risk of Injury to the Environment

Calculated risk quotient (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 and terrestrial organisms. In the 2020 Risk Evaluation, EPA found that there were no exceedances of benchmarks to aquatic organisms from exposures to 1,4-dioxane (Ref. 1). The RQ values for acute and chronic risks are 0.2 and 0.397, respectively, based on the best available science in the 2020 Risk Evaluation. The high volatility, high water solubility and low Log Koc of 1,4-dioxane suggest that 1,4-dioxane will only be present at low concentrations in sediment and land-applied biosolids.

EPA considered uncertainties in its determination of unreasonable risk for 1,4-dioxane. Key assumptions and uncertainties in the environmental risk estimation are related to data used for the characterization of environmental exposure (e.g., model input parameters, inability to directly relate monitoring sites to conditions of use) and environmental hazard (e.g., selection of representative organisms, allometric-scaling to estimate hazard thresholds for other organisms). Additionally, the reasonably available environmental monitoring data was limited temporally and geographically. Assumptions and key sources of uncertainty in the risk characterization are detailed in section 4.3.1. of the 2020 Risk Evaluation (Ref. 1).

Therefore, based on the 2020 Risk Evaluation, EPA did not identify risk of injury to the environment that would significantly contribute to the unreasonable risk from 1,4-dioxane.

6.4 Additional Information Regarding the Basis for the Unreasonable Risk Determination

Table 6-1 and Table 6-2 summarize the basis for the revised determination of unreasonable risk of injury to health presented by 1,4-dioxane (Ref. 1). In these tables, a checkmark indicates the type of effect and the exposure route to the population evaluated for each condition of use that significantly contributes to the unreasonable risk determination. As explained in Section 6.2, for the revised unreasonable risk determination, EPA considered the effects on human health and the environment of exposure to 1,4-dioxane at the central tendency and high-end (or moderate and high intensity use), the exposures from the condition of use, the risk estimates, and the uncertainties in the analysis. See section 4.6 of the 2020 Risk Evaluation and sections 5.2.1 and 5.2.2 of the 2024 Supplement to the Risk Evaluation for summaries of risk estimates (Refs. 1, 2).

Table 6-1. Supporting Basis for the Unreasonable Risk Determination for Human Health (Occupational Conditions of Use Including Releases)[5]

Life Cycle Stage	Category[a]	Subcategory[b]	Population	Exposure Route	Human Health Effects							
					Acute Non-cancer		Chronic Non-cancer		Cancer		General Population/ Fenceline Communities	
					High-End	Central Tendency	High-End	Central Tendency	High End	Central Tendency	Ambient Air[c]	Drinking Water[d]
Manufacture	Domestic manufacture	Domestic manufacture	Worker	Inhalation	✓		✓		✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation						✓		
Manufacture	Import	Import/ Repackaging (Bottle and Drum)	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		
Processing	Repackaging	Repackaging (Bottle and Drum)	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		
Processing	Recycling	Recycling	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		
Processing	Non-incorporative	Basic organic chemical manufacturing (process solvent)	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		
Processing	Processing as a reactant	Polymerization catalyst	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		

[5] The checkmarks indicate the type of effect and the exposure route to the population evaluated for each condition of use that significantly contributes to the draft revised unreasonable risk from 1,4-dioxane. If a check mark is not noted that effect or exposure route does not significantly contribute to the unreasonable risk.

Life Cycle Stage	Category[a]	Subcategory[b]	Population	Exposure Route	Human Health Effects							
					Acute Non-cancer		Chronic Non-cancer		Cancer		General Population/ Fenceline Communities	
					High-End	Central Tendency	High-End	Central Tendency	High End	Central Tendency	Ambient Air [c]	Drinking Water [d]
Processing	Byproduct	Polyethylene terephthalate (PET) byproduct	Worker	Inhalation	✓		✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU[e]	Inhalation								
Processing	Byproduct	Ethoxylation process byproduct	Worker	Inhalation	✓		✓	✓	✓	✓		✓
				Dermal			✓		✓	✓		
			ONU[e]	Inhalation								
Distribution in Commerce												
Industrial Use	Intermediate use	Agricultural chemical and plasticizer intermediate; Catalysts and reagents for anhydrous acid reactions, brominations and sulfonations	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		
Industrial Use	Processing aids, not otherwise listed	Wood pulping, extraction of animal and vegetable oils, wetting and dispersing agent in textile processing, purification of process intermediates, and etching of fluoropolymers	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		
Industrial Use	Functional Fluids	Metalworking fluid, cutting and tapping fluid, polyalkalene glycol fluid, hydraulic fluid	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		General Population/ Fenceline Communities	
					High-End	Central Tendency	High-End	Central Tendency	High End	Central Tendency	Ambient Air [c]	Drinking Water [d]
Industrial Use and Commercial Use	Laboratory Use	Chemical reagent, Reference material, spectroscopic and photometric measurement, liquid scintillation counting medium, stable reaction medium, cryoscopic solvent for molecular mass determination, preparation of histological sections for microscopic examination	Worker	Inhalation	✓		✓		✓			
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU[e]	Inhalation								
Industrial and Commercial Use	Adhesives and Sealants	Film cement	Worker	Inhalation	✓	✓	✓	✓	✓	✓		
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation								
Industrial Use	Other uses	Spray polyurethane foam	Worker	Inhalation								
				Dermal					✓	✓		
			ONU	Inhalation								
Industrial Use	Other uses	Printing and printing compositions	Worker	Inhalation								
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU[e]	Inhalation								
Industrial Use	Other uses	Dry film lubricant	Worker	Inhalation	✓				✓			
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU[e]	Inhalation								

Life Cycle Stage	Category[a]	Subcategory[b]	Population	Exposure Route	Human Health Effects: Acute Non-cancer High-End	Acute Non-cancer Central Tendency	Chronic Non-cancer High-End	Chronic Non-cancer Central Tendency	Cancer High End	Cancer Central Tendency	General Population/ Fenceline Communities: Ambient Air [c]	Drinking Water [d]
Industrial Use	Other uses	Hydraulic fracturing	Worker	Inhalation	✓		✓		✓			
				Dermal	✓	✓	✓		✓	✓		
			ONU[e]	Inhalation								
Commercial Use	Arts, crafts, and hobby materials	Textile dye	Worker	Inhalation	✓		✓	✓	✓	✓		
				Dermal								
			ONU[e]	Inhalation								
Commercial Use	Automotive care products	Antifreeze	Worker	Inhalation								
				Dermal								
			ONU[e]	Inhalation								
Commercial Use	Cleaning and furniture care products	Surface cleaner	Worker	Inhalation								
				Dermal								✓
			ONU[e]	Inhalation								
Commercial Use	Laundry and dishwashing products	Dish soap	Worker	Inhalation								
				Dermal					✓			✓
			ONU[e]	Inhalation								
Commercial Use	Laundry and dishwashing products	Dishwasher detergent	Worker	Inhalation								
				Dermal								✓
			ONU[e]	Inhalation								
Commercial Use	Laundry and dishwashing products	Laundry detergent (industrial) (institutional)	Worker	Inhalation								
				Dermal					✓			✓
			ONU[e]	Inhalation								

Life Cycle Stage	Category[a]	Subcategory[b]	Population	Exposure Route	Human Health Effects							
					Acute Non-cancer		Chronic Non-cancer		Cancer		General Population/ Fenceline Communities	
					High-End	Central Tendency	High-End	Central Tendency	High End	Central Tendency	Ambient Air[c]	Drinking Water[d]
Commercial Use	Paints and coatings	Paint and floor lacquer	Worker	Inhalation	✓		✓		✓			✓[f]
				Dermal								
			ONU[e]	Inhalation								
Disposal	Disposal	Wastewater, underground injection, landfill, recycling, incineration	Worker	Inhalation	✓	✓	✓	✓	✓	✓		✓
				Dermal	✓	✓	✓	✓	✓	✓		
			ONU	Inhalation		✓		✓		✓		

[a.] These categories of conditions of use appear in the Life Cycle Diagrams in the 2020 Risk Evaluation and the 2024 Supplement to the Risk Evaluation, reflect CDR codes, and broadly represent additional information regarding all conditions of use of 1,4-dioxane.

[b.] These subcategories reflect more specific information regarding the conditions of use of 1,4-dioxane.

[c.] The general population cancer risks from chronic inhalation exposures associated with the listed conditions of use are highly dependent on release amounts, stack heights, topography, and meteorological conditions as discussed further in section 5.2.2.3.1 in the 2024 Supplement to the Risk Evaluation.

[d.] The general population cancer risks from chronic exposures to drinking water sourced from surface water associated with the listed conditions of use are highly dependent on the amount of 1,4-dioxane released and the flow of the receiving water body. Exposure and risk estimates are also influenced by whether there is a drinking water intake downstream of a release and the degree of dilution that occurs between the point of release and the drinking water intake. See sections 3.2.2 and 5.2.2.1 in the 2024 Supplement to the Risk Evaluation. Similarly, as discussed in section 5.2.2.2 in the 2024 Supplement to the Risk Evaluation, EPA's drinking water risk estimates associated with groundwater indicate that higher hydraulic fracturing releases or landfill leachate concentrations and loadings are associated with higher risks. As noted in section 5.2.2.1 of the 2024 Supplement to the Risk Evaluation, cancer risk is the primary risk driver in most exposure scenarios.

[e.] Monitoring data and modeling approaches were not available to estimate occupational inhalation exposures for ONUs. The ONU exposures are anticipated to be lower than worker exposures since ONUs do not typically directly handle the chemical.

[f.] The 2024 Supplement to the Risk Evaluation evaluates paints and floor lacquers under the Paints and Coatings COU. For the general population, EPA has determined that paints do contribute to the unreasonable risk from 1,4-dioxane through down-the-drain releases to surface water, while floor lacquers do not (Table appendix G-4 of the 2024 Supplement).

Table 6-2. Supporting Basis for the Unreasonable Risk Determination for Human Health (Consumer Conditions of Use Including Releases)

Lifecycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects				
					Acute Non-cancer		Chronic Cancer		General Population/ Fenceline Communities
					Moderate Intensity Use	High Intensity Use	Moderate Intensity Use	High Intensity Use	Drinking Water [c]
Consumer use	Arts, crafts, and hobby materials	Textile dye	Adult ≥21 years	Inhalation					
				Dermal					
			Child 16-20 years	Inhalation					
				Dermal					
			Child 11-15 years	Inhalation					
				Dermal					
			Bystander	Inhalation					
Consumer use	Automotive care products	Antifreeze	Adult ≥21 years	Inhalation					
				Dermal					
			Child 16-20 years	Inhalation					
				Dermal					
			Child 11-15 years	Inhalation					
				Dermal					
			Bystander	Inhalation					
Consumer use	Cleaning and furniture care products	Surface cleaner	Adult ≥21 years	Inhalation					✓
				Dermal					
			Child 16-20 years	Inhalation					
				Dermal					
			Child 11-15 years	Inhalation					
				Dermal					
			Bystander	Inhalation					

Lifecycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects				
					Acute Non-cancer		Chronic Cancer		General Population/ Fenceline Communities
					Moderate Intensity Use	High Intensity Use	Moderate Intensity Use	High Intensity Use	Drinking Water [c]
Consumer use	Laundry and dishwashing products	Dish soap	Adult ≥21 years	Inhalation					✓
				Dermal					
			Child 16-20 years	Inhalation					
				Dermal					
			Child 11-15 years	Inhalation					
				Dermal					
			Bystander	Inhalation					
Consumer use	Laundry and dishwashing products	Dishwasher detergent	Adult ≥21 years	Inhalation					✓
				Dermal					
			Child 16-20 years	Inhalation					
				Dermal					
			Child 11-15 years	Inhalation					
				Dermal					
			Bystander	Inhalation					
Consumer use	Laundry and dishwashing products	Laundry detergent	Adult ≥21 years	Inhalation					✓
				Dermal					
			Child 16-20 years	Inhalation					
				Dermal					
			Child 11-15 years	Inhalation					
				Dermal					
			Bystander	Inhalation					
Consumer use	Paints and coatings	Paint and floor lacquer	Adult ≥21 years	Inhalation					✓[d]
				Dermal					
			Child 16-20 years	Inhalation					
				Dermal					
			Child 11-15 years	Inhalation					
				Dermal					
			Bystander	Inhalation					

Lifecycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects				
					Acute Non-cancer		Chronic Cancer		General Population/ Fenceline Communities
					Moderate Intensity Use	High Intensity Use	Moderate Intensity Use	High Intensity Use	Drinking Water [c]
Consumer use	Other consumer uses	Spray polyurethane foam	Adult ≥21 years	Inhalation					
				Dermal					
			Child 16-20 years	Inhalation					
				Dermal					
			Child 11-15 years	Inhalation					
				Dermal					
			Bystander	Inhalation					

[a.] These categories of conditions of use appear in the Life Cycle Diagrams in the 2020 Risk Evaluation and the 2024 Supplement to the Risk Evaluation, reflect CDR codes, and broadly represent additional information regarding all conditions of use of 1,4-dioxane.
[b.] These subcategories reflect more specific information regarding the conditions of use of 1,4-dioxane.
[c.] The general population cancer risks from chronic exposures to drinking water sourced from surface water associated with the listed conditions of use are highly dependent on the amount of 1,4-dioxane released and the flow of the receiving water body. Exposure and risk estimates are also influenced by whether there is a drinking water intake downstream of a release and the degree of dilution that occurs between the point of release and the drinking water intake. See sections 3.2.2 and 5.2.2.1 in the 2024 Supplement to the Risk Evaluation. As noted in section 5.2.2.1, cancer risk is the primary risk driver in most exposure scenarios.
[d.] The 2024 Supplement to the Risk Evaluation evaluates paints and floor lacquers under the Paints and Coatings COU. For the general population, EPA has determined that paints do contribute to the unreasonable risk from 1,4-dioxane through down-the-drain releases to surface water, while floor lacquers do not (Table appendix G-4 of the 2024 Supplement).

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

The December 2020 Risk Evaluation for 1,4-dioxane 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 December 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, singular risk determination, EPA determined that the chemical substance 1,4-dioxane presents an unreasonable risk of injury to health and the environment under the conditions of use. This revised risk determination supersedes the no unreasonable risk determinations in the December 2020 Risk Evaluation that were premised on a condition-of-use-specific and assumed-use-of-PPE 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 December 2020 Risk Evaluation. EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision 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 2023 Draft Revised Risk Determination for 1,4-dioxane (88 FR 48249, July 26, 2023) (Ref. 9), and in the Federal Register Notice accompanying this revised risk determination.

6.6 References

1. EPA. Risk Evaluation for 1,4-Dioxane. December 2020. EPA-HQ-OPPT-2019-0238-0092.
2. 1,4-Dioxane Supplement to the Risk Evaluation. Nov-2024. EPA-740-R-24-013.
3. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Federal Register (86 FR 7009, January 25, 2021).
4. 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).
5. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. Federal Register (86 FR 7619, February 1, 2021).
6. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. Federal Register (86 FR 8845, February 10, 2021).
7. 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
8. Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 89 FR 37028, May 3, 2024.
9. EPA. 1,4-Dioxane; Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment. September 8, 2023. 88 FR 48249, July 26, 2023. https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0723-0095.
10. EPA. Summary of External Peer Review and Public Comments and Disposition for 1,4-Dioxane. December 2020.
11. EPA. Correction of Dermal Acute and Chronic Non-Cancer Hazard Values Used to Evaluate Risks from Occupational Exposures in the Final Risk Evaluation for 1,4-dioxane. June 26, 2023.
12. Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. https://www.osha.gov/annotated-pels

13. EPA. Draft Supplement Risk Evaluation. July 2023. https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0723-0103.
14. EPA, Office of Research and Development, Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States. December 2016.