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Office of Chemical Safety and
Pollution Prevention

Response to SACC Recommendations and Public Comments on the Supplement to the Risk Evaluation for 1,4-Dioxane

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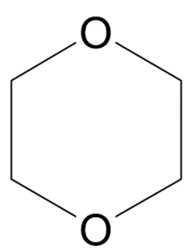

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1 INTRODUCTION

On July 10, 2023, The U.S. Environmental Protection Agency (EPA or the Agency) published a notice announcing availability of a *Draft Supplement to the Final Risk Evaluation for 1,4-Dioxane.* EPA solicited input from EPA's Science Advisory Committee on Chemicals (SACC). The SACC convened to review the draft supplement on September 12–14, 2023 (see also Appendix A). The SACC meeting minutes, and final report published November 16, 2023, presents discussion and specific recommendations from the SACC. This response to comment summary directly addresses each major (numbered) recommendation from the SACC report and summarizes other comments included in that report.

The public comment period for the draft supplement closed on September 8, 2023. A total of 33 public comment submissions were posted to the docket, as listed below in Table 1. This document numbers the public comments according to the submission numbers listed in the docket. Some numbers are skipped because not all submissions were posted to the docket (*e.g.*, duplicates, test posts, content not related to the docket). The Agency has reviewed and considered all of the comments received. This response to comment document provides a high-level summary of key themes identified in public comments and describes how EPA addressed these comments in the revised supplement. Comment summaries are organized into issue topic areas, as indicated in the TABLE OF CONTENTS.

Table 1. Index of Comment Submissions and SACC Report

Comment #	Submission Number	Link to Public Comment/SACC Report	Comment Date	Commenter/SACC Reviewers
Public Comments				
4	EPA-HQ-OPPT-2022-0905-0004	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0004	6/29/2023	Environmental Defense Fund (EDF)
33	EPA-HQ-OPPT-2022-0905-0033	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0033	6/25/2023	American Cleaning Institute (ACI)
34	EPA-HQ-OPPT-2022-0905-0034	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0034	7/28/2023	American Chemistry Council (ACC)
41	EPA-HQ-OPPT-2022-0905-0041	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0041	8/17/2023	American Petroleum Institute (API)
44	EPA-HQ-OPPT-2022-0905-0044	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0044	8/30/2023	DAK Americas LLC/Alpek Polyester
46	EPA-HQ-OPPT-2022-0905-0046	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0046	9/7/2023	Huntsman International, LLC
47	EPA-HQ-OPPT-2022-0905-0047	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0047	9/8/2023	New York State Department of Environmental Conservation (NYSDEC)
50	EPA-HQ-OPPT-2022-0905-0050	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0050	9/7/2023	American Water Works Association (AWWA), Association of Metropolitan Water Agencies (AMWA), and Association of State Drinking Water Administrators (ASDWA)
51	EPA-HQ-OPPT-2022-0905-0051	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0051	9/8/2023	Household and Commercial Products Association (HCPA)
52	EPA-HQ-OPPT-2022-0905-0052	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0052	9/8/2023	American Chemistry Council (ACC)
53	EPA-HQ-OPPT-2022-0905-0053	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0053	9/8/2023	The Procter & Gamble Company (P&G)
54	EPA-HQ-OPPT-2022-0905-0054	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0054	9/8/2023	New York State Office of the Attorney General et al.

Comment #	Submission Number	Link to Public Comment/SACC Report	Comment Date	Commenter/SACC Reviewers
55	EPA-HQ-OPPT-2022-0905-0055	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0055	9/8/2023	Environmental Defense Fund (EDF) et. al.
56	EPA-HQ-OPPT-2022-0905-0056	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0056	9/8/2023	National Tribal Toxics Council (NTTC)
57	EPA-HQ-OPPT-2022-0905-0057	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0057	9/8/2023	Union Carbide Corporation (UCC)
58	EPA-HQ-OPPT-2022-0905-0058	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0058	9/8/2023	University of California, San Francisco (UCSF)
59	EPA-HQ-OPPT-2022-0905-0059	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0059	9/8/2023	Dow Chemical
60	EPA-HQ-OPPT-2022-0905-0060	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0060	9/8/2023	Earthworks
61	EPA-HQ-OPPT-2022-0905-0061	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0061	9/8/2023	Missouri Department of Natural Resources
62	EPA-HQ-OPPT-2022-0905-0062	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0062	9/8/2023	Defend Our Health
63	EPA-HQ-OPPT-2022-0905-0063	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0063	9/8/2023	American Petroleum Institute (API)
64	EPA-HQ-OPPT-2022-0905-0064	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0064	9/8/2023	Plastics Industry Association
65	EPA-HQ-OPPT-2022-0905-0065	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0065	9/8/2023	American Coatings Association (ACA)
66	EPA-HQ-OPPT-2022-0905-0066	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0066	9/8/2023	American Cleaning Institute (ACI)
67	EPA-HQ-OPPT-2022-0905-0067	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0067	9/8/2023	American Chemistry Council (ACC)
68	EPA-HQ-OPPT-2022-0905-0068	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0068	9/8/2023	US Chamber of Commerce

Comment #	Submission Number	Link to Public Comment/SACC Report	Comment Date	Commenter/SACC Reviewers
71	EPA-HQ-OPPT-2022-0905-0071	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0071	9/12/2023	American Chemistry Council (ACC)
72	EPA-HQ-OPPT-2022-0905-0072	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0072	9/12/2023	Swati Rayasam
73	EPA-HQ-OPPT-2022-0905-0073	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0073	9/12/2023	American Cleaning Institute (ACI)
74	EPA-HQ-OPPT-2022-0905-0074	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0074	9/12/2023	Environmental Defense Fund (EDF)
75	EPA-HQ-OPPT-2022-0905-0075	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0075	9/12/2023	American Chemistry Council (ACC)
76	EPA-HQ-OPPT-2022-0905-0076	https://www.regulations.gov/comment/EPA-HQ-OPPT-2022-0905-0076	9/12/2023	Defend Our Health
SACC Recommendations				
78	EPA-HQ-OPPT-2022-0905-0078	https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0905-0078	11/16/2023	Science Advisory Committee on Chemicals (SACC)

2 SUMMARY OF COMMENTS AND EPA RESPONSES

2.1 Monte Carlo Modeling

2.1.1 Sensitivity Analysis

SUMMARY: In response to charge questions 1a, 1b, 1d, and 1e, the SACC recommended that the individual Monte Carlo model files be included in the risk evaluation as supplementary material to demonstrate the sensitivity of the model and associated parameters. The SACC also commented that a sensitivity analysis for the Monte Carlo modeling would help identify parameters driving releases/exposures and outliers that may be skewing the distribution. Public comment 63 also highlighted the lack of a sensitivity analysis for the hydraulic fracturing Monte Carlo model.

EPA RESPONSE: While EPA did not include modeling files as supplemental attachments, the aforementioned sections include sensitivity charts for some key model outputs. To demonstrate sensitivity of the modeling results, EPA added a new subsection titled "Key Strengths, Limitations, Uncertainties, and Sensitivity Analysis" at the end of each environmental release Monte Carlo modeling appendix (E.11, E.12, E.13, and E.14) and occupational inhalation exposure Monte Carlo modeling appendix (F.7, F.8, F.9, and F.10). These sections include sensitivity charts for some key model outputs.

2.1.2 Quality Ratings

SUMMARY: In response to charge questions 1a and 1c, the SACC recommended that "a more formal quality assessment process might be created and applied to the Monte Carlo modeling exercise," and that "it might be possible to derive the quality label assigned to the Monte Carlo modeling results through applying quality values to predefined model metrics."

EPA RESPONSE: Data quality ratings are provided for the sources that inform the model input parameters, as well as the sources of model equations. These ratings are available in the *Systematic Review Supplemental File: Data Quality Evaluation and Data Extraction Information for Environmental Release and Occupational Exposure*. In addition, the results of the modeling include a weight of scientific evidence rating.

2.1.3 Outliers

SUMMARY: In response to Charge questions 1b, 1d, and 1e, the SACC stated, "Monte Carlo simulation results may be very sensitive to how outliers in associated data are handled," and that outliers "may represent real exposures, for example from process upsets and spills." The SACC recommended that EPA explain "how the modeling team handled outliers in determining the appropriate distribution (triangular, for most variables) and in computing the calculating emissions, exposure, and risk distributions."

EPA RESPONSE: In general, scenarios are modeled such that the output distributions will be representative of real exposures. Use of the high-end and central tendency values from these distributions provides characteristic exposures, inclusive of outliers in the distribution, sufficient for risk evaluation. Process upsets and spills are included in the Generic Scenarios/Emission Scenario Documents (GS/ESD) that form the basis of the model equations, where data was available during the development of the GS/ESD to inform such releases within the subject industry. For example, the ESD that informed the modeling for the Hydraulic Fracturing occupational exposure scenario (OES) was updated in 2023 to include environmental releases from spills. EPA therefore updated the modeling in the revised supplement (Appendix E.13) to incorporate this spill release per the Emission Scenario Document (ESD).

2.1.4 Granularity of Scenarios Modeled

SUMMARY: In response to Charge question 1d, the SACC made the recommendation to perform Monte Carlo analysis on more granular scenarios, such as for different sized sites or sites located at different locations in the country, as opposed to one run that covers the entirety of the OES, which may over or underestimate exposures. The SACC also outlined two methods for how to generate nationally generalizable results.

***EPA RESPONSE*:** The limitations of reasonably available data do not provide the level of granularity needed to generate separate scenarios for the modeled OES by factors such as facility sizes or location. Additionally, the foreseeable utility and feasibility of modeling more granular scenarios may be limited and may have only marginal impact on the final risk conclusions. However, running these more specific scenarios may be useful for risk management. Therefore, EPA may consider more granular assessment for other chemicals in the future where data availability permits.

2.1.5 Transparency around Model Inputs and Assumptions

SUMMARY: In response to charge question 1f, the SACC recommended that EPA, "provide explicit and clear statements for all the decisions/selections utilized when implementing a Monte Carlo approach so to ensure and enhance reproducibility." Specifically, the SACC recommended stating all assumptions undertaken within the modeling, providing rationale for decisions regarding model parameters, and elaborating on distributions adopted to represent uncertainty. Public comment 63 also mentioned that some distribution definitions are confusing.

EPA RESPONSE: EPA made clarifying edits to Monte Carlo input parameter discussions in each environmental release Monte Carlo modeling appendix (E.11, E.12, E.13, and E.14) and occupational inhalation exposure Monte Carlo modeling appendix (F.7, F.8, F.9, and F.10). In addition, EPA added a new subsection titled "Key Strengths, Limitations, Uncertainties, and Sensitivity Analysis" at the end of each Monte Carlo modeling appendix mentioned above. These sections include discussion of uncertainties associated with the model and sensitivity charts for some key model outputs.

2.1.6 Model Validation

SUMMARY: In response to charge question 1f, the SACC recommended that EPA, "validate the results obtained via Monte Carlo methods to guarantee that the model formulation, parameter choices, etc. lead to valid, plausible results."

EPA RESPONSE: In general, data are not reasonably available to support the type of validation suggested. In this case, EPA was unable to compare the modeling results to measured data because measured data are not available. However, the deterministic forms of these models have been utilized in previous risk evaluations with some comparable results to existing monitoring data.

2.1.7 Uncertainties

SUMMARY: In response to charge question 1a, the SACC recommended that EPA, "address the uncertainty in the deterministic model formulation on which the Monte Carlo approach is currently being applied." Specifically, the SACC states that the Monte Carlo Appendices focus on input uncertainty, not mathematical formulation uncertainties. Therefore, it isn't clear how to interpret the outputs of the model.

EPA RESPONSE: EPA added language on these uncertainties to the new subsections titled "Key Strengths, Limitations, Uncertainties, and Sensitivity Analysis" at the end of each environmental release Monte Carlo modeling appendix (E.11, E.12, E.13, and E.14) and occupational inhalation exposure Monte Carlo modeling appendix (F.7, F.8, F.9, and F.10).

2.1.8 Interpretation of Sensitivity Analysis

SUMMARY: In response to charge question 1d, the SACC recommended that EPA, "more fully describe how the sensitivity analysis informed modeling decisions."

EPA RESPONSE: EPA added discussion on sensitivity to the new subsections titled "Key Strengths, Limitations, Uncertainties, and Sensitivity Analysis" at the end of each environmental release Monte Carlo modeling appendix (E.11, E.12, E.13, and E.14) and occupational inhalation exposure Monte Carlo modeling appendix (F.7, F.8, F.9, and F.10). These discussions show identification of the input parameters with the greatest impact on the magnitude of the model output estimates and are ranked accordingly. EPA has updated the general Monte Carlo methodology appendix (E.10) with additional discussion on the use of sensitivity analysis for decision-making in future risk evaluations.

2.1.9 Rationale for Input Parameters

SUMMARY: In response to charge question 1b, the SACC recommended that, "additional description and justification should be provided in Section E.11 (Textile Dye Modeling Approach and Parameters for Estimating Environmental Releases) for the distribution assignments for: the daily use rate of detergent, container residual fraction of totes, drums, and pails, mass fraction of the dye formulation in the dyebath, fraction of dye product, and operating days."

EPA RESPONSE: EPA revised the parameter rationales in each environmental release Monte Carlo modeling appendix (E.11, E.12, E.13, and E.14) and occupational inhalation exposure Monte Carlo modeling appendix (F.7, F.8, F.9, and F.10) to state where chemical-specific information was not found, and generic information from ESDs, GSs, standard models, and other sources were used.

2.1.10 Model Distributions

SUMMARY: In response to charge questions 1b and 1c, the SACC stated that all the container residual models used to inform distributions are based on a 1988 study. The SACC recommended, "reviewing this study and the data therein, [as] they may indicate another choice of distributional form rather than the default triangular."

EPA RESPONSE: EPA added explanation for each of the container residual parameters in the environmental release Monte Carlo modeling appendices (E.11, E.12, E.13, and E.14), citing the underlying data sources. A triangular distribution was determined as the most representative distribution based on the available data.

2.2 Occupational Exposure

2.2.1 1,4-Dioxane Concentrations in Products

SUMMARY: In response to charge question 2.2, the SACC provided a link to a database containing concentrations of 1,4-dioxane in dish soap, detergent, and surface cleaners, stating that, "Additional sources of data that EPA might use include the New York State Department of Conservation, which has a 1,4-dioxane limit of 2 ppm for 2022, and 1 ppm for 2023 for cleaning products that becomes effective at the end of 2023. The New York State Department of Environmental Conservation (NYSDEC) also has a waiver process for products that do not meet the 2 ppm or 1 ppm requirements. A list of over 1000 products is available at the provided link that should assist the Agency in determining concentrations reflective of the current market." In addition, the SACC stated that manufacturers of dyes, soaps, and detergents can provide 1,4-dioxane concentrations of their products. Public comments 47, 51, 52, 53, 54, 55, 66, 67, 71, 73, and 75 either recommended EPA utilize the NYSDEC database, or use the limits of 2 ppm limit to inform exposure estimates.

EPA RESPONSE: EPA compiled 1,4-dioxane concentration data from NYSDEC's waiver database and incorporated the relevant data into the 1,4-dioxane concentration data already used in the Draft Supplement. EPA used the updated 1,4-dioxane concentration data to update the environmental release and occupational exposure estimates, where appropriate (Appendices E.14, F.4.3, F.4.4, F.4.5, F.4.6). EPA did not use the New York limit to 2 ppm to inform exposure estimates as suggested by some commenters because it may not be representative of product concentrations nationally.

2.2.2 Available Monitoring and Model Input Data

SUMMARY: In response to charge questions 1a, 1c, 1d, 1e, and 1f, the SACC noted that, "the use of distributions is based on 'old' data or in some cases no data. Instead, some input data are based on questionable expert advice or questionable assumptions." The SACC recommended that EPA request information from manufacturers as an additional source of refined data. Public comment 66 referenced the presence of outdated information and recommended EPA work with the American Cleaning Institute to develop a harmonized survey form to collect occupational exposure data. Public comments 44, 46, 53, and 59 provided occupational exposure data for EPA to use in place of the data used in the Draft Supplemental.

EPA RESPONSE: EPA encouraged stakeholders to submit additional available exposure data through the public comment period. EPA incorporated exposure data provided through public comment into the revised exposure assessment. For example, inhalation monitoring data for the PET [polyethylene terephthalate] Manufacturing OES (Appendix F.4.9) was incorporated from public comment 44. Process descriptions, PPE information, dermal concentrations, and monitoring data PET Manufacturing OES were incorporated from public comment 46. Process descriptions, PPE, and engineering controls for the Dish Soap and Dishwasher Detergent OES (Appendices F.4.4, F.4.5) were incorporated from public comment 53. Monitoring data, process descriptions, product concentrations for the Ethoxylation OES (Appendix F.4.10) were incorporated from public comment 59.

2.2.3 Preference of Monitoring Data over Modeling Based on Default Assumptions

SUMMARY: In response to charge questions 1c, 1d, and 1e, the SACC commented that exposure monitoring data often misrepresents actual exposures and is often biased and not representative of all worker tasks. Therefore, the SACC recommended that EPA, "default to the use of Monte Carlo modeling as the first and dominant approach with available monitoring as a support piece."

EPA RESPONSE: The use of monitoring data directly applicable to users of 1,4-dioxane was preferred over modeling with generic input parameters. Therefore, EPA did not perform Monte Carlo modeling for all OES exposures. EPA updated exposure estimates where new monitoring data were available in public comments and made text edits to the Analysis of Inhalation Exposure Monitoring Data section (3.1.2.4.2) to ensure that the uncertainties highlighted by the SACC were presented.

2.2.4 Dermal Exposure Model

SUMMARY: In response to charge question 1e, the SACC made the recommendation that "Monte Carlo could have been applied to variables of the [dermal] absorption model used. For example, single values were assigned to the CT and HE for the model variables S, Q_u, and Y_{derm}." Public comment 51 mentioned that "the dermal exposure model used by the EPA does not factor in typical use parameters and practices." Public comment 52 provided additional values for Q_u from a clinical trial of sunscreens and a floor fragrance study. Public comment 66 questions the validity of the default value for Q_u, stating that this parameter is surrogate data from a cooking oil study, and that 1,4-dioxane is vastly different than cooking oil both in viscosity and vapor pressure.

EPA RESPONSE: EPA applied the existing deterministic dermal model used for all risk evaluations to date. However, EPA is currently exploring methods and approaches to Monte Carlo modeling of dermal exposure in the context of TSCA risk evaluations and will consider those Monte Carlo methods for application and peer review in future assessments for other chemicals. For the default value for Q_u, EPA does not have more representative data to use for this parameter. EPA considered all available and readily applicable dermal assessment options when determining the most appropriate method, while acknowledging that advancement in this area is ongoing and will continue to improve the representativeness of future dermal exposure estimates.

2.2.5 Products Diluted During Use

SUMMARY: Public comment 52 made the recommendation that "for products that are diluted during use, such as dish soap, EPA should apply a dilution factor to the 1,4-dioxane concentration consistent with the extent to which the product is diluted with water during use, and a rinse-off factor (*i.e.*, including hand washing practices as a removal mechanism during the workday)." Public comment 53 echoes this statement and suggests a dilution factor of 0.156%.
EPA RESPONSE: EPA recognizes that dish soap may be diluted during use, but consumers and workers may also come into contact with the soap prior to dilution, washing, and rinsing. Therefore, no dilution factor was applied.

2.2.6 Hydraulic Fracturing Modeling

SUMMARY: With respect to exposure modeling for the Hydraulic Fracturing OES, public comment 63 stated that, "While a probabilistic modeling approach is performed, almost half of the input variables are defined using a single value. This negates the usefulness of the probabilistic model." The comment also suggested EPA, "provide either the SQL code used in evaluating the FracFocus data or, at a minimum, enough identifying information such that those records selected for use (*i.e.*, the 411 referenced [in the risk evaluation]) can be easily identified for review."
EPA RESPONSE: EPA updated the Monte Carlo modeling parameter descriptions in the Hydraulic Fracturing environmental release and occupational exposure modeling appendices (E.13 and F.9) with additional clarification on parameters and results. EPA also added language to parameter descriptions in Appendices E.13 and F.9 to clarify that only one source of data was available for some parameters, which is why EPA only referenced one source.

2.3 Environmental Releases

2.3.1 Down-the-Drain Releases

SUMMARY: In response to charge questions 2.2 and 2.3a, the SACC stated that "the way the SHEDS-HT loadings were used are not clearly explained, assumptions are not well supported, and there appear to be inconsistencies in approach between the case studies and the probabilistic model," and that the use of SHEDs-HT for industrial/commercial releases without TRI/DMR may not be appropriate since it is unclear where all the assumptions in SHEDs for commercial uses come from. The SACC suggested checking consumer vs. commercial inputs. The SACC also stated that assumption of scalability between consumer and commercial dish products may be flawed and recommended that the DTD releases of dish soap should be validated with data on product use rates. Public comments 47, 51, 53, 66, and 73 recommended using Monte Carlo modeling for releases and exposures during the Dish Soap and Dishwasher Detergent OES as opposed to SHEDS-HT and outdated monitoring data from a soap formulation plant.
EPA RESPONSE: As suggested by SACC and public comments, EPA updated the assessment of environmental releases and occupational exposures for the Dish Soap and Dishwasher Detergent OESs using Monte Carlo modeling. Additionally, EPA clarified how SHEDS-HT was used for commercial environmental release assessment in the revised supplement, specifically in the Water Release Estimates section (2.1.1.2) as well as in the Strengths, Limitations, Assumptions, and Uncertainty for Environmental Release Assessment sections (2.2.1.3 and E.7.). For the Surface Cleaner OES, an environmental release model and associated input parameters were not reasonably available; therefore, the assessment is still based on SHEDS-HT. Furthermore, EPA expanded on the uncertainties of this

approach in the Strengths, Limitations, Assumptions, and Uncertainty for Environmental Release Assessment sections (2.2.1.3 and E.7.) of the revised supplement.

2.3.2 Hydraulic Fracturing Releases

SUMMARY: In response to charge question 1d, with respect to the Hydraulic Fracturing OES, the SACC made the recommendation for, "modeling specific scenarios, where possible, beyond the single drilling scenario assessed in the report." The SACC made this recommendation due to variability between sites for parameters such as the number of wells per fracturing site, control processes, and handling of produced water.
EPA RESPONSE: EPA was unable to break up the hydraulic fracturing modeling into individual scenarios, as the available data does not suggest discrete sets of common facility sizes or other meaningful ways to identify individual scenarios.

SUMMARY: In response to charge question 1e, the SACC made the recommendation that "a more detailed analysis of the OESs modeling assessment from Hydraulic Fracturing should be done by a modeler with experience with the Near-Field/Far-Field Model (that has Monte Carlo capabilities) in the American Industrial Hygiene Association Model Suite IHMOD. The Agency should also initiate on-site visits to perform monitoring and ascertain reasonable modeling inputs." Public comments 63 and 66 also stated that the Draft ESD on Chemicals Used in Hydraulic Fracturing had not been peer reviewed and questioned the use of this reference.
EPA RESPONSE: EPA updated the hydraulic fracturing modeling (Appendices E.13, F.3, F.4.11) using the Revised ESD on Chemicals Used in Hydraulic Fracturing, which has since gone through review by the OECD. The updates include the addition of a release point from spills, and the alteration of the percentages of produced water that remains underground or returns to the surface as flowback water. Associated text edits in the report have also been completed. Additionally, the Agency will continue to use reasonably available data for risk evaluation which at this time, does not include the initiation of on-site visits to perform monitoring.

SUMMARY: In response to charge question 1d, the SACC noted that 411 sites reported emissions of 1,4-dioxane during hydraulic fracturing, and inquired what fraction of all hydraulic fracturing operations this represents. The SACC then recommended that EPA, "consider calculating the fraction of wells reporting 1,4-dioxane in hydraulic fracturing waters and expanding that to all wells in the United States." Public comment 63 also discussed uncertainty in the extent in which the FracFocus data represents operations across the country.
EPA RESPONSE: EPA added a discussion to Appendix E.13.3 to discuss why 411 sites were used over an industry-wide estimate, and that this may not capture the full number of sites that potentially use 1,4-D. The assessment is not intended to represent all fracturing sites, but to represent sites specifically using 1,4-dioxane.

SUMMARY: In response to charge question 1b, the SACC noted that the use rate of fracturing fluids containing 1,4-dioxane and the mass fraction of 1,4-dioxane in fracturing fluid were modeled discretely, and commented that, "the use of a few discrete values does not seem representative of such a large industry (according to the US Energy Information Administration there were >900,000 hydraulic fracturing wells in the US as of 2021)…". The SACC made the recommendation that "A triangular distribution informed by the discrete values may better reflect the variability of this large industry."
EPA RESPONSE: The discrete distributions are based on data from 411 sites from FracFocus that report the use of 1,4-dioxane. Since EPA seeks to estimate releases and exposures from 1,4-dioxane specifically at sites that use the chemical, the use of the data from these 411 sites is preferable to using general data for the entire hydraulic fracturing industry.

2.4 Surface Water Pathway

2.4.1 Use of NHDPlus to Estimate 1,4-Dioxane Concentrations in Surface Water

SUMMARY: In response to Charge question 2.1a, the SACC noted that NHDPlus V2.1 is a "highly robust moeling representation of river and stream flows and geometry and the US" and that "Its application for the current modeling purpose is appropriate" The SACC recommended that "Consideration should be given to using the more robust version of NHDPlus V2.1 called NHD High Resolution and an evaluation of the uncertainty in modeling flows introduced by climate change should be considered given that the NHDPlus V2.1 database is populated by historic flow data that is from 1971 to 2000. Consideration should be given to incorporating the variability in flow data at particular locations into a Monte Carlo framework that takes into account such climate-related impacts."

In response to charge question 2.1b, the SACC also offered comments on assumptions made in cases where specific release amounts and locations are unknown, including the assumption of 500 lb/year of releases to surface water for facilities reporting to TRI via Form A. This choice was supported as "reasonable" and having "an appropriate level of conservatism." Where receiving waterbodies were not listed on NPDES permits, or flow data were missing, the SACC supported spatial analysis to identify the nearest reaches and substitutions of the lowest non-zero flow within a TSCA Condition of Use (COU) as a surrogate flow, respectively.

The SACC recommended evaluating the impact of assuming high-end releases for the Form A facilities through sensitivity testing, and that EPA address the selection of the facilities included in the surface water analysis. Additionally, SACC asked about the reliability of, and agreement between, the TRI and DMR reported release values.

The SACC also recommended assessing the impact of using the mean flow among multiple stream segments (COMIDs) within the NHDPlus dataset assigned the same reach code.

EPA RESPONSE: EPA is continually incorporating new datasets and methodologies and evaluating their utility to improve TSCA REs, and as such may consider using NHD HR in a future assessment as appropriate.

EPA added acknowledgement of uncertainties in modeled flows related to the years of data collection compared to current flow conditions in Section 2.3.1.5 of the revised supplement, and EPA notes that this is the most up-to-date version of the NHDPlus flow dataset.

EPA incorporated additional flow variability in the probabilistic surface water modeling described in Section 2.3.1.2.1 and Appendix G.2.3 of the revised supplement.

EPA conducted some sensitivity testing of the assumptions made for releasing facilities with less available data, shown in Figure 5-1 and Figure 5-2, and agrees with the SACC's characterization that the impact of these assumptions is likely to be small, regarding the conclusions of the assessment and its impact on risk management. EPA utilizes TRI and DMR reporting as the most readily available and complete public records of discharges to surface water. The TSCA RE process is open to additional submissions of more refined release data from facilities to assist in improving estimations if the data are available. While TRI and DMR records are generally observed to agree with one another, differences in the estimation and reporting process can lead to differences in the annual loadings estimated in each system. Due to these uncertainties and variations, the highest release value for each facility was selected for analysis in the individual facility release modeling, regardless of the system of origin. The probabilistic surface water release modeling incorporated all available annual release estimates from both systems.

EPA did not observe dramatic differences in flows for adjacent stream segments assigned the same reach code within the NHDPlus V2.1 dataset and does not expect modifications to this approach to impact the conclusions of this analysis. EPA will consider alternative methods for assigning flows, such as pulling the minimum flow from a group of segments, for future analyses.

2.4.2 Evaluation of Down-the-Drain Releases to Surface Water

SUMMARY: In response to charge question 2.2, the SACC made a series of specific recommendations on EPA's approach to evaluating down-the-drain releases of 1,4-dioxane, including recommendations about the 1,4-dioxane concentrations in products used for modeling. The SACC recommended including more information about the product categories used in modeling and the variability and uncertainty associated with the source data, and better documentation of the input data. The SACC additionally recommended sources for 1,4-dioxane concentration data in products, especially for dish soap and surface cleaners. One public comment (51) recommended consideration of NY product data limits in estimation of 1,4-dioxanes in consumer dish soaps and detergents.
EPA RESPONSE: EPA has added the product weight fractions of 1,4-dioxane included in modeled products in the SHEDS-HT estimation of down-the-drain loading to the supplemental EWISRD-XL supplemental file ("EWISRDXL BunswickCountyNC Case Study"), for clarity and reproducibility. These values are based on those developed from the systematic review and engineering analyses associated with this revised supplement.

SUMMARY: The SACC recommended refinement and clarity on parameterizing the down-the-drain loading assessment in SHEDS-HT, including the exclusion of the paint COU from commercial releases, the exclusion of modeling releases from septic systems to groundwater, and the behavioral/usage patterns for the dishwashing COU.
EPA RESPONSE: The zero contribution from paint in the commercial down-the-drain loading is an artifact of how the SHEDS-HT model was applied, resulting in a higher consumer loading than commercial loading for this particular COU. EPA did not model down-the-drain releases to ground water via septic tanks due to limited data availability and high uncertainty regarding this pathway. EPA notes that while some COUs may be over-represented and others under-represented in the down-the-drain loading, the readily available opportunities to compare monitoring data show a trend of overestimation of average waterbody concentrations based on the methodology applied. EPA added further acknowledgement of the uncertainties associated with the commercial component of the DTD analysis, particularly paint and dishwashing, to Section 3.3.2.1.

SUMMARY: The SACC recommended comparison of model estimates with measured values to improve confidence in the down-the-drain estimation and recommended an additional dataset of surface water monitoring of 1,4-dioxane concentrations in North Carolina.
EPA RESPONSE*:* EPA includes three case studies comparing monitored concentrations to modeled estimates of 1,4-dioxane, including down-the-drain loading, in Appendix G.2.3.2. In prominent examples from the North Carolina database, elevated 1,4-dioxane concentrations had been attributed to unregulated facility discharges to publicly owned treatment works (POTWs), and could not be directly captured in this consumer/commercial down-the-drain modeling.

SUMMARY: In addition, SACC members offered a range of additional comments on the down-the-drain approach. The use of SHEDS-HT was described as "appropriate to estimate per capita DTD loading and has been validated for similar uses as part of its development." However, it was noted that a beta version of the SHEDS-HT model had been used that was not yet available to the public, so the analysis could not be replicated. The SACC reflected on uncertainty inherent in the method of estimating the proportion of the population within various occupations and offered suggestions for additional analysis. A discrepancy between the values reported in Apx_Table G-2 and Apx_Table G-4 was also pointed out.
EPA RESPONSE: A correction has been made to the commercial loading per capita values in Table_Apx G-2. Additional clarification has been added to the description of the data sources for SHEDS-HT product usage information, and EPA is in the process of publicly releasing the version of SHEDS-HT applied in this RE.

2.4.3 Probabilistic Modeling of Water Concentrations Resulting from Releases

SUMMARY: In response to charge questions 2.3a to 2.3d, the SACC offered a range of comments on EPA's approach to probabilistic surface water modeling, including the appropriateness of the probabilistic model to be a more nationally-representative than individual facility modeling, and the flexibility of incorporating additional input data, while noting the uncertainties with the down-the-drain component of the probabilistic model, and the limited opportunities for thorough model validation. Overall, the SACC stated that "The goal of developing a national scale model is appreciated as worthwhile, and new data will continue to become available to support this in coming years." The SACC also commented that "The case studies are valuable as a means of 'ground truthing' but it is noted that they overestimated measured values at the low end of the measured range, and it is unclear if this would be the case at higher levels."

The SACC made a series of recommendations, including to "Discuss plans to obtain more measured data so that models can be refined, and "Validate model assumptions to the extent possible and perform a sensitivity analysis to assess the influence of input data.

***EPA RESPONSE*:** EPA acknowledges the limited opportunities to validate the probabilistic model. As described for the individual facility release modeling, EPA did not find surface water monitoring data located immediately downstream of facilities reporting releases of 1,4-dioxane to TRI, to confirm the point-of-release estimates. The aggregate scenarios evaluated in the case studies then rely on down-the-drain loading estimates, combined with diluted release estimates from facilities, to compare with monitoring data. While the bulk of the monitoring data may be quarterly or one-time sampling events, the modeled concentrations are more representative of annual average concentrations (as shown by the Brunswick County case study in Appendix G.2.3.2. At the distances further downstream where monitoring data are available, greater uncertainty from this approach stems from the down-the-drain component. EPA will continue to assess opportunities to improve the down-the-drain estimations for future analyses of other chemicals, including the incorporation of additional monitoring data, where available, and considering commercial contributions to POTWs with more refined assumptions. For the sake of conservatism where there was uncertainty, EPA parameterized the SHEDS-HT modeling of down-the-drain loading to assume higher-end concentrations and contributions to POTWs, where refinement would likely result in reduced estimates of down-the-drain loading.

SUMMARY: In response to charge question 2.3.b the SACC recommended clarifying whether TRI air release data was utilized to estimate groundwater concentrations.

EPA RESPONSE: Deposition from air to soil, surface water, or groundwater were not accounted for in this assessment. This is due to the physical chemical and fate properties of 1,4-dioxane described in the 2020 Final Risk Evaluation. The air modeling applied in the supplement to the risk evaluation is described in Appendix J.

SUMMARY: In addition, in response to charge question 2.3.c, the recommended clarifying the word "conservative" in the following sentence (lines 2005–2007) … "These additional scenarios with lower numbers of days of operation provide more *conservative* estimates of resulting surface water concentrations and are intended to evaluate the full range of possible facility release patterns based on the best available information…". The SACC stated that "it seems this is a low-release estimate which in hazard and risk parlance is not conservative."

EPA RESPONSE: Lower days of operation were considered more conservative, because in these scenarios the total annual release remained the same but was spread out over fewer days. These scenarios capture shorter term but higher-end release rates. EPA added the following equation to Appendix G.2.2 for clarity:

$$Daily\ Load\ \left(\frac{kg}{day}\right) = \frac{Annual\ Load\ \left(\frac{kg}{year}\right)}{Days\ of\ Release\ (\frac{day}{year})}$$

SUMMARY: The SACC noted that on line 2039, "distributions of total concentrations resulting from combinations of facility releases and background concentrations were used for calculations." – is this facility releases plus background? Please clarify in the text.
EPA RESPONSE: Correct, this refers to aggregated facility release and background concentrations to produce a "total concentration." This sentence is updated for clarity.

SUMMARY: One SACC comment spoke specifically to the consideration of releases of raw or only partially treated sewage from combined sewer overflows regarding the down-the-drain releases from POTWs. In addition, SACC members offered additional specific comments about figure labels and text throughout the draft document that could be improved for clarity.
EPA RESPONSE: The EPA appreciates this feedback has adjusted the text to add additional clarity, including the replacement of the term "concordance" when referring to the agreement between the monitored and modeled concentration data, with "general consistency" or "agreement." Regarding consideration for combined sewer overflows: because of the assumption of zero removal of 1,4-dioxane via wastewater treatment throughout the surface water assessment, the conditions of these scenarios already account for releases of potentially untreated wastewater (with respect to 1,4-dioxane concentrations). EPA notes the prevalence and importance of these conditions and will consider them for future analyses where they may have a greater impact on release estimations.

SUMMARY: One public comment (66) also recommended that EPA provide more context on how it arrived at average daily dose estimates for surface water that correspond to water concentrations higher than those reported in the monitoring data cited in the assessment
EPA RESPONSE: In the comparison between modeled and monitored concentrations in Section 3.3.2.1, EPA discusses how the ambient surface water monitoring data are generally not located downstream from releasing facilities or representative of the high-end relevant release scenarios at the point of release targeted in the modeling. Where a small subset of ambient surface water monitoring data are flagged by the collectors as representing a waterbody receiving effluent from a facility, concentrations are orders of magnitude greater than the typical ambient surface water samples.

SUMMARY: One public comment (67) suggested relying on the analysis conducted in Dawson, et al 2020, which applied SHEDS-HT to calculate exposures to 1,4-dioxane, rather than additional modeling.
EPA RESPONSE*:* While the SHEDS-HT model was applied for both the analysis in this cited study, and the down-the-drain analysis in the supplement to the 1,4-dioxane RE, the model was applied in different ways to answer different questions. While the cited study primarily focuses on modeled direct exposures to consumer products, and drinking water (with concentrations from the UCMR3 monitoring data), the supplement to the 1,4-dioxane risk evaluation applied SHEDS-HT to estimate how down-the-drain loading of consumer products can impact drinking water. Additionally, the supplement considers surface water exposures from industrial facility releases, and hydraulic fracturing.

2.4.4 Consideration of Concentrations at Drinking Water Intake Locations

SUMMARY: In response to charge question 2.4, the SACC made several specific recommendations on EPA's approach to accounting for additional dilution that may occur between the point of release and the location of drinking water intakes. Specifically, the SACC recommended that EPA "Use more rigorous methods for inclusion of "non-detects" in monitoring data analysis."

EPA RESPONSE: EPA appreciates that sample data below detection limits are important to the characterization of the prevalence of a chemical and help to demonstrate that 1,4-dioxane is not universally present in surface water throughout the United States. For the drinking water monitoring data included in the probabilistic surface water modeling, EPA applied the Kaplan-Meier method when constructing empirical cumulative distribution functions so that the censored data were accounted for in the resulting input distributions (Gillespie et al., 2010).

SUMMARY: The SACC recommended that EPA "Provide test statistics that describe the "accordance" between measured and predicted 1,4-dioxane concentrations."
EPA RESPONSE: EPA does not apply statistical tests to describe the agreement between observed and modeled values in the case studies due to data limitations. For the Brunswick County case study, only summary data (min, average, max) are available for comparison, and in the other case studies only up to four co-located samples are available.

SUMMARY: The SACC recommended that "To the best extent possible determine how climate change impacts on precipitation and stream flow will impact predicted 1,4-dioxane concentrations."
EPA RESPONSE*:* EPA added acknowledgement of uncertainties in modeled flows related to the years of data collection compared to current and future flow conditions in Section 2.3.1.5. Nationally there is uncertainty about the impacts of climate change on stream flows, they be may be lower in some locations and higher in others. There is also uncertainty around the extent to which other factors such as release amounts may change in the future.

SUMMARY: The SACC recommended that EPA "evaluate the DRINCs model (Rice et al., 2015) for use in evaluating dilution of 1,4-dioxane following POTW discharge to stream and rivers and transport to PWS intakes."
EPA RESPONSE: EPA has not developed specific approaches for applying the DRINCs model in the context of the 1,4-dioxane risk evaluation. In the future, EPA may consider the utility of the DRINCs model and other relevant models for other chemicals.

SUMMARY: The SACC recommended that EPA "conduct Monte-Carlo simulations that provide probabilistic estimates of 1,4-dioxane concentration at drinking water intakes."
EPA RESPONSE: EPA has considered the addition of additional components to the probabilistic model, including dilution factors, and may assess additional parameters for future applications of the probabilistic surface water modeling approach. EPA notes that in the current probabilistic modeling scenarios, no downstream dilution factors are incorporated, and no removal due to drinking water treatment is included. The addition of these components would be expected to result in distributions with similar high-end concentrations, while spreading lower quantiles toward lower values.

SUMMARY: Additionally, one public comment (52), provided comments and suggested refinement on several components of the surface water analysis, including the assumption of no 1,4-dioxane removal during wastewater or drinking water treatment, the application of a 30Q5 flow, and no assumed dilution for drinking water.
EPA RESPONSE: EPA assumed zero wastewater and drinking water removal in the absence of data showing consistent implementation of technologies that reliably remove 1,4-dioxane. EPA notes that the individual facility release estimates are reported to TRI as the amounts released to the environment after any wastewater treatment has taken place. EPA used a harmonic mean streamflow, rather than a 30Q5 (*i.e.,* the lowest 30-day average flow that occurs in a 5-year period) flow, for the concentrations used in the lifetime drinking water exposure scenario, which is more of a central tendency flow metric. While the exposure is modeled for the initial point of release from facilities, additional consideration of

dilution (both in a generic condition and in a location-specific analysis) is considered and presented in Section 5.2.2.1.2.

2.4.5 Exposure Factors for Assessing Drinking Water Exposure to 1,4-Dioxane in Surface Water

SUMMARY: In response to charge question 4b, the SACC noted that use of central tendency estimates for drinking water intake estimates was inconsistent with EPA approaches for deriving lifetime health advisory levels, drinking water equivalent levels, and maximum contaminant levels. The SACC made a specific recommendation to use alternate exposure factors for calculating acute and chronic exposure to 1,4-dioxane through drinking water exposures, stating, "EPA should use upper bound drinking water intake rates from the Exposure Factors Handbook for both the acute and chronic scenarios involving 1,4-dioxane ingestion."

EPA RESPONSE: EPA has retained risk estimates based on central tendency ingestion rates but has revised the narrative to describe the magnitude of impact higher drinking water intakes would have on exposure and risk estimates. Specifically, EPA added clarification to Section 5 that, "While most cancer risk estimates summarized in this section are based on exposures resulting from 33-year exposure durations and mean drinking water ingestion rates, longer exposure durations or higher drinking water ingestion rates would result in greater exposure and risk… Lifetime cancer risk estimates based on 95th percentile drinking water ingestion rates could result in 3-4 times higher exposures and risks than those based on mean ingestion rates, depending on the age groups exposed (described in Appendix I)."

2.4.6 Revisions to Surface Water Pathway Resulting from Revised Release Assessments

SUMMARY: As described above throughout Sections 2.1 and 2.3, the SACC and public commenters made several specific comments on Monte Carlo modeling approaches and input assumptions used in the surface water release assessment. EPA used some of these release assessments to estimate exposure and risk for the surface water pathway. Specific recommendations from the SACC and public commenters included using alternate model distributions, alternate temperature assumptions for industrial and commercial laundries, and consideration of additional data sources.

EPA RESPONSE: As described above in Sections 2.1 and 2.3, EPA revised release assessments for surface water for a range of COUs in response to SACC and public comments. Among the release assessments that were revised in response to comments, the only one directly contributing to surface water exposure and risk estimates was the release assessment for hydraulic fracturing. In Sections 2.3.1, 3.2.2, and 5.2.2.1 of the revised supplement, EPA updated exposure and risk estimates for hydraulic fracturing based on the revised release assessment.

2.5 Groundwater Pathway

2.5.1 Scope and Clarity of the Groundwater Assessment

SUMMARY: In response to charge question 3a, the SACC commended EPA for considering groundwater exposure via private drinking water wells and offered several comments, including suggestions to provide a lengthier discussion of the DRAS model, a more detailed discussion of monitoring data, and extensive discussion of uncertainties for groundwater contamination from hydraulic fracturing operations and disposal to RCRA subtitle D landfills. In addition, the SACC made a series of specific comments on the scope of the groundwater pathway analysis, including

- EPA did not evaluate acute risks from groundwater;
- EPA did not consider vaporization from household water (for example, through use of the Agency for Toxic Substances and Disease Registry (ATSDR)'s Shower and Household Water-

use Exposure (SHOWER) Model v3.0) and from unique exposure pathways such as steam rooms and sweat lodges; and

- The hydraulic fracturing assessment is "incomplete" in that it is limited to surface impoundment of produced water and does not assess water injected into Class II disposal wells, spills, or casing failures.

EPA RESPONSE: EPA provided access to the technical support documents for DRAS on line 11587 in the Draft Supplement for the 1,4-Dioxane Risk Evaluation. Most methods for this supplement to the 1,4-dioxane risk evaluation are provided in appendices to reduce the length of the main body of the document as previously requested by the SACC. Calculations are provided in the *1,4-Dioxane Supplemental Information File: Drinking Water Exposure and Risk Estimates for 1,4-Dioxane Land Releases to Landfills*.

EPA appreciates the request to discuss monitoring data more thoroughly. Based on currently available information on releases from TSCA COUs, EPA could not characterize the source of every contamination in the contiguous United States. Similarly, releases of chemical substances should be tied to a TSCA COU. As such, disposal was the most likely condition of use for 1,4-dioxane that could lead to groundwater contamination. Down-the-drain release of 1,4-dioxane to groundwater may be possible when homeowners rely on septic systems with drainfields; however, this assessment did not characterize this scenario. The assessment considered underground injection, but EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) does not have a peer-reviewed model for considering groundwater contamination from that practice.

EPA recognizes the lack of assessment of vaporization of 1,4-dioxane as a source of uncertainty. EPA will explore potential to apply ATSDR's shower model or similar models for vaporization in future assessments where relevant to chemical fate properties and use patterns. Similarly, for future assessments on other chemicals, EPA will continue to explore models that are fit for purpose when considering groundwater contamination and subsequent exposure.

SUMMARY: One comment (55) indicated that EPA should conduct an acute analysis of consuming drinking water contaminated with 1,4-dioxane and consider land application of wastewater effluent, further consider underground injection, and evaluate ongoing disposals where cases of groundwater contamination of been detected.
EPA RESPONSE: Because available models allow EPA to estimate average exposures over long durations but do not provide information on potential acute exposures, EPA did not assess acute exposures.

SUMMARY: One comment (47) expressed concern that the groundwater assessment did not consider contamination from down-the-drain releases of commercial and consumer products to residential and commercial septic systems and urged EPA to consider these pathways.
EPA RESPONSE: EPA does not currently have access to tools or models to assess this potential contribution of 1,4-dioxane to aquifers via septic systems. However, the contribution of landfills to potential contamination of local aquifers gives some insight into how much volume and contributing concentrations would lead to potential risks to the general population. Only at the highest loading rates and the highest leachate concentrations are groundwater concentrations high enough to cause risk from oral exposure. It reasonable to expect that concentrations released down the drain to local aquifer to be substantially smaller and lower in concentration than those identified at the high end of the landfill analysis. Thus, EPA anticipates that any consideration of landfills would be similarly protective of releases from septic systems. EPA will continue to consider any new information in the future that can further bolster its confidence in such an assessment.

SUMMARY: One comment (66) expressed "The oil and gas industry benefits from a number of exemptions in federal statutes, enabling the industry to handle and dispose of its waste and operational fluids in a different manner than EPA analyzed for this draft risk assessment. For instance, the hazardous exemption for oil and gas exploration and production wastes results in UIC Class II disposal practices not analyzed under this draft assessment." [The Agency]...should assess disposals of hydraulic fracturing produced water to class II wells, which are less regulated than class I.
EPA RESPONSE: EPA does not currently have tools or models that can assess disposal of hydraulic fracturing produced water to class II wells. Similarly OCSPP does not have access to the location and information to confidently characterize how release of 1,4-dioxane in produced waters may impact those aquifers. EPA will continue to consider any new information in the future that can further bolster its confidence in such an assessment.

2.5.2 Groundwater Monitoring Data

SUMMARY: In response to charge question 3b, the SACC also commented on the range of sources of 1,4-dioxane considered in the groundwater analysis and made the following recommendation: **"**The difference in the basic engineering, geospatial factors, landfill use and maintenance…just to name a few real factors…make it necessary to separate databases of leachate values into sections unique for the type of landfill under consideration. (*e.g.,* Communities with sophisticated and well-maintained landfills should have information relevant to their community situation…not based on statistics that include open dump scenarios.) Not only will the resulting calculations be more representative, but chances are also that future data collection will provide information for at least some of these landfill categories. Such scientific analyses will be more useful to Agency and community decision-makers."

In addition, public comments (54, 55) suggest that EPA consider available monitoring data, noting that there are multiple sites with groundwater contamination where groundwater is the primary drinking water sources.
EPA RESPONSE: EPA/OCSPP does not have access to monitoring data for all landfills or data on groundwater concentrations associated with specific TSCA COUs. Similarly, OCSPP cannot conduct assessments on the future availability of data. Lastly, OCSPP used this assessment to identify the range of potential groundwater concentrations that could occur given different leachate concentrations and loading rates for a poorly managed landfill. The model, as noted in the technical support document, considers multiple geospatial and geophysical factors that influence groundwater migration and contamination.

2.5.3 Characterization of Groundwater Exposure Scenarios

SUMMARY: In response to charge question 3b, the SACC commented on EPA's characterization of the groundwater exposure scenarios considered by EPA as 'sentinel' exposures, stating that "Assuming a point on any distribution (no matter the input to making the distribution) can represent PESS exposure would be difficult to defend scientifically unless the distribution is constructed from the full array of exposure opportunities relevant to the population experiencing the exposure. The SACC noted that "It would be more accurate to note that this is an upper-bound value but because of the input data uncertainties, it may not represent "sentinel exposure values" The SACC made several major recommendations on this point:

- Recommendation 1: "The calculations above be retained as they are important and useful but should not be defined as "sentinel." The discussion for these can be improved for clarity, transparency and to characterize the calculated values as "levels of concern" within highly variable landfill scenarios, but not inferring the existing data can describe a distribution of potential values from which a sentinel value can be extracted."
- Recommendation 2: **"**The concept of sentinel should be used with consistency throughout the document (and across all other documents). Notably, if a particular cohort is missing or under-

represented among the data used to construct the distribution, the value at the 95th percentile (nor any other percentile) does not necessarily represent that “missing/underrepresented” cohort. In this case, assessments should specifically address risks to communities where the landfills exist and water/contaminants from those landfills may contaminate the groundwater and surface water.”

EPA RESPONSE: In the revised supplement, EPA has rephrased the characterization of the groundwater exposure scenario evaluated. Rather than classifying these scenarios as sentinel, the revised supplement describes that scenario as potentially exposed or susceptible subpopulation. It is worth noting that EPA did not select a point on a distribution and define that population as sentinel. EPA classified the scenario as a potential sentinel exposure for communities living within one mile of a poorly managed landfill who may be exposed to a range of drinking water concentrations based on a range of loading rates and leachate concentrations.

In addition, EPA revised discussion of sentinel exposures in Section 5.2.2.1.4 of the revised supplement to clarify that “Where possible, EPA focused on assessing exposure scenarios where the greatest exposures are likely to occur” and that “While the analysis is intended to capture the exposure scenarios and populations likely to result in the greatest exposures, EPA acknowledges that there may be additional groups with sentinel exposures that are not captured in this analysis”

2.5.4 Model Inputs and Assumptions

SUMMARY: In response to Charge question 3c, the SACC made several specific recommendations including, **“**EPA should provide additional details that describe these default loading rates in the Risk Assessment itself or in the relevant Appendix” and **“**EPA should ensure that matrix diffusion and 1,4-dioxane concentrations in saturated and unsaturated zones are properly included in models.”

EPA RESPONSE: EPA did not use default loading rates. It is an input for the DRAS model. EPA used default chemical properties that are pre-loaded into the DRAS model and these aligned with those selected for the risk evaluation. Likewise, OCSPP did not generate the DRAS model and cannot modify the model for matrix diffusion.

2.5.5 Revisions to Groundwater Pathway Resulting from Revised Release Assessments

SUMMARY: As described above throughout Sections 2.1 and 2.3, the SACC and public commenters made several specific comments on Monte Carlo modeling approaches and input assumptions used in the release assessment. EPA used the release assessments to estimate potential loading rates and subsequent risk estimates for the groundwater pathway. Specific recommendations from the SACC and public commenters included using alternate model distributions, alternate temperature assumptions for industrial and commercial laundries, and consideration of additional data sources.

EPA RESPONSE: As described above in Sections 2.1 and 2.3, EPA revised release assessments for a range of COUs in response to SACC and public comments. Among the revised release assessments, the release assessment for hydraulic fracturing was the only one used to inform COU-specific exposure and risk estimates for the groundwater pathway. For hydraulic fracturing, the revised release assessment values were lower than those originally evaluated. As such, the bounding assessment that looked at the potential distribution of groundwater concentrations would be lower, and no risk would be identified. Because risk was only identified at the highest potential release estimates, EPA concludes that while exposure and risk estimates presented in the revised supplement (based on the original release assessment) may be greater than those expected based on the revised release assessments, the overall risk conclusions would not be expected to change.

2.6 Air Pathway

2.6.1 Approaches to Air Modeling and Aggregate Analysis

SUMMARY: In response to charge question 4a, SACC members made several comments on the air pathway analysis. SACC members "agreed that considering calculations for both grouped and individual facilities represents a strength of the aggregate analysis. SACC members also suggested that future assessments consider aggregate exposures that could occur over larger distances (*i.e.*, facilities within 15 or 20 km buffers rather than 10 km) or justify the choice of 10 km. SACC members also suggested several points of clarification and editorial comments for EPA to consider.
EPA RESPONSE: For the air pathway, EPA generally focused on areas closest to release locations because that is where exposures and risks are expected to be highest. EPA appreciates the suggestion to consider aggregate exposures over greater distances and may consider distances farther out than 10 km in future risk evaluations. EPA also appreciates editorial comments and suggestions from the SACC to improve the clarity and has revised the narrative where appropriate.

SUMMARY: Some public comments (52, 55, 58, 74) commented on aspects of the use of IIOAC and AERMOD for various parts of the air pathway, suggesting that EPA should do multi-year analysis with AERMOD. Some public comments appear to reflect confusion about the order of analyses using a lower tier model (IIOAC) for multi-year after using the higher tier model (AERMOD) for single year.
EPA RESPONSE: EPA has revised the narrative in Sections 1.3.1.3.2 and 2.3.3 to clarify that the single year analysis using AERMOD was conducted as part of the 2022 fenceline effort, which was prior to EPA's receipt of SACC comments and recommendations to use multiple years of data. Therefore, the multi-year analysis for 1,4-dioxane represents integration of SACC's recommendation during fenceline to consider multiple years of data but was conducted after the original single-year fenceline work. Nonetheless, EPA will continue to expand the fenceline methodologies for future chemicals where applicable, as the Agency gains more experience incorporating the methodologies and associated revisions into ongoing and future risk evaluations and rulemaking.

SUMMARY: One comment (67) states that the model has not been sufficiently validated and suggests consideration of terrain and meteorology
EPA RESPONSE: As described in Section 2.3.3.3 and J.1.1, the IIOAC model does not include an option for terrain and local meteorology inputs. It includes pre-run scenarios using AERMOD and uses 14 real meteorological stations selected to represent regional meteorology (*e.g.*, South Coastal). Although detailed modeling considering terrain, local meteorology, building dimensions, other highly site-specific inputs (etc.) can be done using AERMOD, it was not conducted in the 1,4-dioxane supplemental RE because the fit-for-purpose, lower tier analyses did not indicate the need for additional, more detailed modeling or analysis to characterize exposures or associated risks.

SUMMARY: One comment (55) recommended that EPA include fugitive emissions from hydraulic fracturing in the analysis of aggregate exposures from multiple facilities.
EPA RESPONSE: The analysis of fugitive emissions from hydraulic fracturing operations is based on a distribution of conditions that are possible based on available information and it is not tied to specific sites. Due to the difficulty in determining the exact locations of a particular site, the fugitive releases resulting from hydraulic fracturing sites, and where these emissions may overlap with other sources, EPA did not include the modeled fugitive releases from hydraulic fracturing in the aggregate analysis.

The statement in comment 55 that "EPA did not consider fugitive emissions from hydraulic fracturing as part of the fenceline risk analysis" is not accurate. All releases evaluated and modeled for hydraulic fracturing were fugitive emissions. EPA modeled those fugitive emissions with IIOAC to evaluate exposure to fenceline communities that could be present within the distances evaluated.

SUMMARY: One comment (55) recommended that EPA use NEI and state data in addition to TRI data for the air pathway
EPA RESPONSE: For all seven chemicals evaluated using the fenceline methodologies EPA only presented results from releases reported to TRI because a cursory review of maximum releases reported to both TRI and NEI indicated that TRI tended to be more conservative (higher releases). In addition, as described in several technical support memoranda associated with the first 10 risk evaluations and associated rulemakings, consideration of some NEI data did not change the overall risk profile and therefore EPA carried its use and presentation of only the TRI dataset into the revised supplement for 1,4-Dioxane. Nonetheless, EPA continues to receive recommendations from both SACC and the public that it should consider NEI data (while SACC also recognizes NEI has its own data issues) in future risk evaluations for a more comprehensive assessment. In response to the ongoing recommendation, as EPA looks to expand the fenceline methodologies for future chemicals where applicable, and as the Agency gains more experience incorporating the methodologies and associated revisions into ongoing and future risk evaluations and rulemakings, EPA may consider and model releases reported to either or both TRI and NEI datasets. EPA also may expand its outreach efforts earlier in the risk evaluation process to try and obtain state data on chemicals undergoing risk evaluation in the future.

SUMMARY: One comment (73) recommends that EPA prioritize and use existing data from published evaluations over novel modeling approaches.
EPA RESPONSE: EPA does consider data and information from other published risk evaluations which, when published and readily available, is captured by EPA's systematic review process and integrated into TSCA risk evaluations as described in Appendix C. Additionally, other published risk evaluations also often rely upon modeled data using the same models EPA uses in its risk evaluations. However, if information on a given chemical is limited or unavailable, the only option to assess exposures is using existing or newly developed modeling approaches/methodologies.

2.6.2 Revisions to Air Pathway Resulting from Revised Release Assessments

SUMMARY: As described above throughout Sections 2.1 and 2.3, the SACC and public commenters made several specific comments on Monte Carlo modeling approaches and input assumptions used in the release assessment. EPA used some of these release assessments to estimate exposure and risk for the ambient air pathway. Specific recommendations from the SACC and public commenters included using alternate model distributions, alternate temperature assumptions for industrial and commercial laundries, corrections to an error in fugitive release calculations for hydraulic fracturing, and consideration of additional data sources.
EPA RESPONSE: As described in Sections 2.1 and 2.3, EPA revised release assessments for a range of COUs in response to SACC and public comments. Release assessments were revised for textile dyes, industrial and institutional laundries, hydraulic fracturing, and dish soaps and detergents. Among these, the release assessments for hydraulic fracturing and industrial and institutional laundries are the only ones used to inform the COU-specific exposure and risk estimates for the air pathway. EPA considered the magnitude of impact of these revisions on estimated releases to determine whether revisions are also warranted for corresponding exposure and risk estimates.

For both hydraulic fracturing and for laundries, EPA concluded that the shift in release estimates based on alternate assumptions, inputs, or model distributions are not expected to shift exposure and risk estimates sufficiently to alter the risk conclusions. For those COUs, EPA has therefore retained the original exposure and risk estimates based on the original release assessments published in the draft risk evaluation supplement. The Agency revised the narrative to acknowledge the magnitude of effect the revised release estimates could have on exposure and risk estimates and to describe this as a source of uncertainty. In the case of hydraulic fracturing, the revised release assessment values were lower than those originally evaluated. EPA concludes that although exposure and risk estimates presented in the revised supplement (based on the original release assessment) may be greater than those expected based on the revised release assessments, the overall risk conclusions would not be expected to change. In the case of institutional and industrial laundries, the revised release assessments based on alternate temperature assumptions increased release estimates by up to 10-fold. However, given the very low exposures and risks originally estimated, revising risks to incorporate these higher release estimates would not be expected to increase risk sufficiently to alter risk conclusions.

2.7 Hazard Assessment and Dose-Response Analysis

SUMMARY: In response to charge question 4b, the SACC recommended that EPA "utilize the approaches described in publications produced by the National Research Council (NRC, 2009), the World Health Organization (WHO) and others to expand the probabilistic assessment from the hazard and exposure assessments to the dose- response assessment."

In addition, several public comments (51, 53, 55, 57, 58, 61, 64, 66, 67, 68, 71, 72) commented on aspects of the hazard characterization and dose-response analysis, including the basis for the cancer slope factor, the mode of action for liver tumors and use of a linear non-threshold approach for estimating cancer risk, application of uncertainty factors for non-cancer PODs, and the potential to apply a probabilistic approach for assessment of non-cancer risks.

EPA RESPONSE: In this supplement, EPA is relying on the hazard and dose-response analysis that was published in the final risk evaluation for 1,4-dioxane and the subsequent correction memo following consideration of previous SACC peer-review and public comment. Similar comments were previously addressed in the response to comment on the final risk evaluation. EPA made revisions to the hazard characterization and dose-response in the original 2020 risk evaluation based on those comments where appropriate. EPA has reviewed all of the comments on hazard, including an additional recent publication, and concluded that this new information does not alter the overall hazard conclusions and dose-response analysis presented in the 2020 risk evaluation. No further edits are being made to hazard characterization or dose-response analysis in this supplement. EPA may explore opportunities to apply probabilistic methods for dose-response analysis (such as those proposed by NRC and recommended by the SACC) for future assessments.

SUMMARY: Several public commenters (51, 53, 57, 64, 66, 67, 68, 71) focus on the mode of action (MOA) for liver tumors, arguing that the MOA evidence supports a threshold approach for evaluating cancer risk. Several of these commenters cite a recently published review paper on the cancer MOA for 1,4-dioxane (Lafranconi et al, 2023).

EPA RESPONSE: As described in the 2020 risk evaluation and corresponding response to comment, EPA has previously performed a MOA analysis for liver tumors (Appendix J of the 2020 risk evaluation). Based on evidence that cytotoxicity is not a necessary key event, the lack of consistent dose-response concordance between key events in the MOA and carcinogenicity, data gaps in support of specific key events, and the plausibility of alternate MOAs that would also be consistent with experimental observations, EPA determined that existing evidence is not sufficient to support the MOA for liver tumors. Furthermore, EPA has concluded that there is insufficient MOA information for other tumor locations that also contribute to cancer risk for 1,4-dioxane (Section 3.2.4 of the 2020 risk evaluation). In 2019, SACC reviewers noted that the rare nasal tumor types associated with 1,4-D exposure indicate that the MOA for nasal tumors is unlikely to be a generic cytotoxic/regenerative repair response. The 2019 SACC reviewers also provided input that nasal tumors were unlikely to be a cytotoxic portal entry effect because of their occurrence in oral studies.

EPA's inhalation unit risk (IUR) for 1,4-dioxane (used to assess cancer risk following inhalation exposure) is based on multiple systemic tumor locations, including liver, nasal, kidney, peritoneal, mammary gland, zymbal gland or subcutis tumors. In the 2020 risk evaluation, EPA used an MS-Combo model to derive an IUR based on multiple tumor sites. To determine the impact of alternate MOA conclusions for liver tumors on overall cancer risk estimates, the MS-Combo model was run both with and without liver tumors. The IUR estimate derived without liver tumors is very similar to the IUR including liver tumors (within a rounding error). To further characterize the sensitivity of 1,4-dioxane cancer models to assumptions about liver tumor MOA, EPA also provided dose-response analysis for both linear and threshold cancer models for liver tumors (see Appendix K in the 2020 risk evaluation).

EPA's cancer slope factor for 1,4-dioxane (used to assess cancer risk following oral or dermal exposure) is based on liver tumors following drinking water exposure using individual animal data for a time-to-tumor analysis. While liver tumors were the most sensitive, the MS-combo model for multiple tumor sites indicates cancer slope factors derived with and without liver tumors included are within 2-fold.

EPA considered the information submitted in the current public comments and concluded that commenters did not provide information that alters the overall conclusions described in the 2020 risk evaluation. Specifically, EPA considered the information presented in the Lafranconi et al (2023) review paper. This paper was previously submitted to EPA in 2023 as part of a request for correction to the 2020 risk evaluation for 1,4-dioxane. In response to that request, EPA concluded that the issues raised in the request were "duplicative with comments and submissions received and addressed in the public comment opportunities associated with the development of the 2020 Risk Evaluation for 1,4-Dioxane." The Lafranconi et al (2023) review paper does not provide novel data and relies primarily on studies that were already considered by the EPA in the MOA analysis published in 2020. The paper cites some studies published since 2020 (Chen et al, 2022, LaFranconi et al, 2021, Chappell et al 2021, and Charkoftaki et al 2021). Some of these more recently published data were previously available to EPA through public comment during finalization of the 2020 risk evaluation. While these more recent papers provide evidence that is consistent with a cytotoxic MOA, they do not rule out other modes of action and do not sufficiently address the critical data gaps EPA identified in the MOA analysis. After consideration of information submitted through the most recent public comments, EPA maintains its conclusion that there is insufficient evidence to determine a threshold MOA for cancer. In addition, the recent papers shared in public comments are focused on evidence related to liver tumors and do not provide MOA information for other tumor types that contribute to cancer risk for 1,4-dioxane.

2.8 Exposure and Risk Calculations

SUMMARY: At several points throughout the report, the SACC discussed assumptions embedded in exposure and risk estimates with implications for PESS and environmental justice. SACC members recommended considering the potential for general population exposures to continue over the course of a full lifetime rather than being limited to 33 years (the duration of exposure assumed in the draft based on 95th percentile of time spent living at a single residence). Specifically, in response to charge question 1d, the report states, "The homeowner mobility value (33 years) … is inadequate for PESS communities and arguably invalid for the general population as well, as discussed previously. More explanation [line 3281] would be helpful for the implications of "33 years of exposure over a 78-year lifetime for those not very familiar with risk assessment practices." Similarly, in response to question 3b, the report states "the Committee emphasized the need for real world assessments with respect to environmental justice and fence-line communities for the entire lifespan (78 years, not 33)." Public commenters made similar comments on the exposure assumptions EPA used for general population exposures pathways. Several comments (55, 56, 58, 62, 72) recommended if exposure may continue over the course of a full lifetime rather than being limited to 33 years.

In response to charge question 4b, the SACC made another recommendation to use alternate exposure factors, stating that "EPA should use upper bound drinking water intake rates from the Exposure Factors Handbook for both the acute and chronic scenarios involving 1,4-dioxane ingestion."

EPA RESPONSE: EPA agrees that some people may live in a community near releases for longer durations and agrees with the SACC recommendation to utilize a full lifetime of exposure for assessing lifetime exposure and cancer risks for fenceline communities. For surface water, groundwater and ambient air exposure pathways, EPA has retained the original exposure and risk estimates provided in the draft supplement based on the assumption of 33 years of exposure but has modified the narrative and discussion of uncertainty to describe how a lifetime (78-year) exposure duration would increase risk. Specifically, EPA has modified the narrative to note that exposure and risk estimates presented in the supplement may underestimate cancer risk (by roughly 2.4-fold for air and 2.3-fold for water once accounting for age differences in drinking water intakes) for people who are exposed over a full 78-year lifetime. As discussed above in Section 2.4.5, EPA also modified the narrative to describe the extent to which higher drinking water ingestion rates would increase exposure and risk estimates.

2.9 Aggregate

SUMMARY: In response to charge question 4c, the SACC discussed the potential to quantitatively characterize aggregate exposure and risk across exposure routes (dermal and inhalation) while recognizing uncertainties. Some committee members recommended that EPA quantify aggregate risk across routes while other reviewers support limiting the analysis to a qualitative discussion of aggregate risks with additional language to support the decision. Reviewers suggested additional language to incorporate into qualitative discussion. In related comments in response to charge question 4a, some committee members "also stated that when considering aggregate risk, it would be warranted to consider synergistic effects (as opposed to just additive), in order to not underestimate exposures and impacts to susceptible subpopulations."

In addition, several public comments (55, 56, 58, 62, 74, 76) recommend calculating aggregate exposures across routes. Some commenters further recommend aggregating occupational exposures and risks with consumer and general population exposures and risks for individuals who may have exposure through multiple scenarios. In addition, some noted that aggregate exposure should look across COUs.

EPA RESPONSE: EPA has expanded on the quantitative analysis of aggregate exposure and risk across routes in the occupational risk calculator. As stated in Section 5.2.2.5 of the revised supplement, "EPA assessed the potential impact of aggregation across routes by summing risks from dermal and exposures for each COU in the occupational risk calculator. Given the uncertainty around the additive nature of cancer risk across routes, EPA is not relying on these quantitative aggregate risk estimates as the basis for risk conclusions in this assessment. However, the aggregate estimates illustrate the potential magnitude of the impact on risk estimates if risks are assumed to be additive across routes." As noted by some SACC members, it is possible that some combinations of co-exposures may act synergistically. However, EPA does not have data to suggest that aggregate exposure to 1,4-dioxane through multiple routes of exposure results in synergistic, rather than additive effects.

In response to comments that aggregate analysis should look across COUs, EPA notes that aggregate analysis within the air pathway focuses on all facilities in proximity and is not limited to facilities within a single COU. Given the uncertainty around the degree to which individuals may be exposed through multiple scenarios, EPA is not further quantifying aggregate exposure across occupational, consumer and general population exposures. As stated in Section 5.2.2.5 of the revised supplement, "In most potential combinations of exposures scenarios, the exposures and risks from one scenario are much greater than from the other scenarios that may be aggregated with it (*e.g.*, occupational risks for a particular COU may be an order of magnitude greater than risks from 1,4-dioxane in drinking water in the community where the worker lives). When this is the case, aggregate risk would be very similar to risk from the scenario with the highest risk. In more rare cases where risks from a particular combination of exposure scenarios are similar (*e.g.*, occupational risks for a particular COU are equal to risks from drinking water), aggregate risks could theoretically be double the risk from each pathway in isolation."

2.10 PESS

SUMMARY: In response to charge question 3b, the SACC offered a range of specific comments on PESS with relevance for other parts of the assessment, including the following:

- The groundwater assessment "would better represent the potential for sentinel exposure and PESS" by addressing higher drinking water intakes for lactating people and people of childbearing age, susceptibility of unborn children, scenarios for people drinking water from their domestic water supply every day.
- The Committee "recommended expanding consideration of susceptible sub-populations to include those with pre-existing conditions, not just sensitive life-stages.
- The Committee "emphasized the need for real world assessments with respect to environmental justice and fence-line communities for the entire lifespan (78 years, not 33), prioritizing multiple exposures, exposures across pathways, pre-existing conditions, vulnerable sub-groups, and during sensitive life stages including pregnancy, in utero, childhood and adolescent exposures."
- "EPA should formally consider how to apply the amassing evidence that chemical and non-chemical "stressors" are a part of risk assessment… the Committee recommended that EPA should at least estimate exposures to these additional scenarios (identified and discussed above) and apply some reasonable safety factor or slope adjustment to be utilized as PESS risk assessments, pending further global policy and science changes."

In addition, several public comments (56, 58, 60, 76) provided comments on EPA's assessment of PESS, including suggestions to consider additional exposure pathways resulting in high exposure, and to consider additional exposure pathways and exposure factors that are unique to tribes.

EPA RESPONSE: As summarized in Section 5.2.2.4 and Table 5-11 of the supplement, EPA considered a range of factors that may increase exposure or biological susceptibility to 1,4-dioxane. The Agency considered PESS throughout exposure assessments for the occupational and general population exposures evaluated in the supplement. Exposure scenarios were designed to focus on populations expected to have the greatest exposures. For example, for the surface water pathway, EPA focused on drinking water exposure scenarios for communities sourcing water downstream of releases sites and calculated lifetime cancer risks based on exposure at different lifestages. As described above in Section 2.7, EPA estimated risks based on an assumption of 33 years of exposure, but also estimated how risk would increase for people who are exposed for a full 78-year lifetime.

EPA considered PESS throughout hazard characterization and dose-response used to derive the hazard values presented in the 2020 risk evaluation and applied in the supplement. The resulting hazard values are intended to be protective of sensitive subpopulations. While there are many factors that may influence biological susceptibility to 1,4-dioxane, quantitative information on how these factors influence susceptibility is limited. EPA discusses these factors qualitatively and acknowledges them as a source of uncertainty. For example, given the likely role of the liver in metabolism of 1,4-dioxane and the effect of 1,4-dioxane on the liver, it is very plausible that people with chronic liver disease may be more biologically susceptible to 1,4-dioxane. However, EPA did not identify any specific information quantifying the extent to which chronic disease may influence susceptibility. As discussed in Section 3.2.6.1 of the 2020 Risk Evaluation, "Pre-existing conditions affecting the liver may also impair metabolism in some individuals. For example, fatty liver disease has been associated with reduced CYP function. Other pre-existing conditions affecting the kidneys, upper respiratory system and other organs targeted by 1,4-dioxane could make some individuals more susceptible."

Similarly, EPA agrees with the SACC that characterizing susceptibility due to chemical and non-chemical stressors is limited by lack of quantitative data on particular co-exposures may interact with 1,4-dioxane. As noted in Table 5-11 of the final supplement, "There is insufficient data to quantitatively address potential increased susceptibility due to chemical or nonchemical stressors and this is a remaining source of uncertainty." In Section 4 and 5.2.2.4 of the supplement, EPA summarizes these potential sources of susceptibility originally noted in the 2020 risk evaluation. In both the 2020 risk evaluation and the supplement, EPA applied a 10× uncertainty factor to non-cancer hazard values to account for these sources of human variability.

SUMMARY: One commenter (56) noted that tribal communities often have unique exposure pathways that were not directly considered in the supplement, including stream bathing, subsistence fishing, steam bathing, indoor air, higher frequency of exposure to outdoor air, and dermal exposures.
EPA RESPONSE: While these unique exposure pathways are not directly addressed in the assessment, EPA focused on assessing general population exposure scenarios expected to be representative of the greatest exposures. For example, to assess exposures and risks from 1,4-dioxane in outdoor air, EPA calculated risks based on continuous exposure (24 hours/day, 7 days/week) to modeled concentrations in outdoor air. While that scenario was not specific to tribal communities, tribal communities who spend more time outside would be represented by that scenario. EPA assessed exposure and risks from swimming in surface water associated with frequent swimming in the 2020 risk evaluation. While that scenario is not specific to tribal communities, it is expected to represent a similarly high level of dermal contact and incidental ingestion. The current supplement focuses the analysis of risks from surface water on drinking water ingestion because that is expected to be a much greater source of exposure.

EPA did not assess exposures to 1,4-dioxane through subsistence fishing because, as discussed in Section 2.4.2 of the 2020 risk evaluation, 1,4-dioxane's bioaccumulation factor (BAF) indicates that concentrations in fish tissues are expected to be lower than aqueous concentrations and supports the expectation that fish ingestion is not a primary pathway of human exposure for 1,4-dioxane. Given its hydrophilic properties and short half-life, 1,4-dioxane is not expected to accumulate in tissue.

SUMMARY: Several commenters recommended that EPA perform a demographic analysis for communities near release sites (62, 76).
EPA RESPONSE: The final supplement does not include any demographic analysis, but EPA expects to consider potential disproportionate impacts into economic analysis during risk management.

SUMMARY: One comment (58) suggested that EPA develop a comprehensive methodology to identify PESS and quantify risks to those groups consistently across assessments.
EPA RESPONSE: The Agency appreciates the advice to develop a comprehensive methodology for assessing PESS consistently across assessments. In each assessment, EPA aims to iteratively improve on approaches to assessing PESS and clearly communicating those approaches.

2.11 Risk Determination

SUMMARY: The SACC was not asked to comment on the risk determination for 1,4-dioxane. Several commenters offered comments on unreasonable risk findings for specific COUs. For example, one comment (62) expresses confusion that EPA determined no unreasonable risk for air releases of 1,4 dioxane even though their risk calculations exceeded the 1 to 1,000,000 benchmark for cancer risk in fenceline communities, and offered no explanation as to why this was done. Other comments (47, 58) suggest EPA should reconsider the finding of no unreasonable risk from down-the-drain releases from consumer and commercial uses of surface cleaner, dish soap, and detergents.
EPA RESPONSE: EPA appreciates these comments on the Draft Revised Unreasonable Risk Determination for 1,4-Dioxane and has responded to them along with others that EPA received. See the *Response to Public Comments on the 1,4-Dioxane Draft Revised Unreasonable Risk Determination.*

SUMMARY: The SACC was not asked to comment on risk management options for 1,4-dioxane. Several commenters offered comments that may be relevant to risk management. For example, several public comments (50, 57, 68) noted assessment of 1,4-dioxane under TSCA may duplicate work being done under the Clean Air Act or Safe Drinking Water Act. Another comment (52) notes that EPA has not indicated how it "shall coordinate actions" under TSCA section 9(b). Another comment (47) sought clarification of the term "unreasonable risk" and further explanation on the "whole chemical substance approach," as well as the hazards, exposures, risks, and uses or COUs associated with a "whole chemical" approach.

Other commenters (54, 60, and 61) made specific risk management recommendations:

- propose an additional rule under TSCA 6(a) that addresses all unreasonable risk including drinking water contamination from down the drain releases of consumer and commercial products containing 1,4 dioxane (54);
- develop ambient water criteria under Section 304(a) of the CWA for state considerations for future triennial reviews (61); and
- use authority to ban use of 1,4-dioxane in hydraulic fracturing (60).

EPA RESPONSE: The development of this supplement to the risk evaluation and the 2020 risk evaluation has been coordinated with other EPA offices, including the Office of Air and Radiation, the Office of Land and Emergency Management, and the Office of Water. More information on how EPA makes a determination of unreasonable risk, and on the whole chemical approach, can be found in EPA's 2024 *Final Revised Unreasonable Risk Determination for 1,4-Dioxane*. Finally, EPA appreciates the commenters' risk management suggestions and expects to consider a variety of approaches for addressing the unreasonable risk presented by 1,4-dioxane. As part of risk management, EPA will consider, consistent with TSCA section 9, whether all or part of such unreasonable risk might be more appropriately managed under another regulatory program implemented by EPA or another federal agency (see further discussion on this point in the memo on *Coordinated Risk Management Action on 1,4-Dioxane under Section 9(b) of the Toxic Substances Control Act* authored jointly by EPA's OCSPP and Office of Water, posted to the 1,4-dioxane docket: EPA-HQ-OPPT-2016-0723).

2.11.1 ECEL

SUMMARY: Some commenters made recommendations related to the occupational exposure values to be considered during risk management. Two comments (66, 67) suggested that the non-cancer exposure values would be sufficiently protective of cancer risks and should be the basis for levels set for risk management. Another comment (68) notes that the draft value calculated with the supplement is set to eliminate any appreciable risk while the requirement under TSCA is to prevent "unreasonable risks." Another comment requested additional time for industry to review/develop methods to allow them detect levels below the draft exposure value.

EPA RESPONSE: The draft exposure value is derived through a hazard-based calculation and does not account for non-risk factors. As shown in Appendix A to the Draft Existing Chemical Exposure Limit (ECEL) for Occupational Use of 1,4-Dioxane memorandum, the calculated ECEL based on non-cancer risks is an order of magnitude higher than the ECEL based on lifetime cancer risk calculated using linear extrapolation (as discussed in Section 2.7 above). Thus, an ECEL based on non-cancer risks will not be protective of cancer risks.

2.11.2 De Minimus Levels

SUMMARY: One comment (68) suggests EPA consider establishing a *de minimus* level of exposure to account for 1,4-dioxane that is produced inadvertently during certain manufacturing processes.

EPA RESPONSE: EPA appreciates the commenter's risk management suggestion and expects to consider a variety of approaches for addressing the unreasonable risk presented by 1,4-dioxane.

2.12 Other Topics

EPA received public comments on a range of other topics that were not the subject of charge questions to the SACC.

2.12.1 Scope

SUMMARY: One comment (47) requests clarification of the scope of the supplement. Specifically, the comment requests scope clarity to guarantee all general population pathways and COUs are fully considered, "especially those general population exposures in which consumer and commercial use of cleansing products containing 1,4-dioxane as a byproduct contribute to elevated concentrations of 1,4-dioxane in the waters of the State, particularly on Long Island. It is essential that EPA makes very clear the hazards, exposures, risks, and uses or COUs covered in the final Supplement to the 1,4-Dioxane Risk Evaluation (pg. 1)."

EPA RESPONSE: As clarified in Section 1.2 of the revised supplement, the scope of the supplement includes new COUs and new exposure pathways. New COUs include 1,4-dioxane present as a byproduct in commercial products (corresponding to consumer products considered in the 2020 risk evaluation and 1,4-dioxane produced or present as a byproduct in additional industrial COUs—including ethoxylation processing, polyethylene terephthalate (PET) manufacturing, and hydraulic fracturing. New exposure pathways include 1,4-dioxane present in drinking water sourced from surface water as a result of direct and indirect industrial releases and down-the-drain releases of consumer and commercial products, 1,4-dioxane present in drinking water sourced from groundwater contaminated as a result of disposals, and 1,4-dioxane released to air from industrial and commercial sources.

To the extent commenters are interested in the topic of preemption, EPA notes that the Agency recently explained: "Permanent preemption is triggered under [TSCA] Section 18(a)(1)(B)(ii) if EPA issues first a scope of the risk evaluation under section 6(b)(4)(D) and then a section 6(a) final rule or section 6(i)(1) determination based on the risk evaluation. The scope of this preemption is addressed in section 18(c)(3) and EPA reads this provision to apply permanent preemption to any condition of use within the scope of the risk evaluation which is the support document for any resulting section 6(a) rule or section 6(i)(1) determination. In the context of a section 6(a) rule, this is the case irrespective of whether those uses contribute to the unreasonable risk and/or are targeted for risk management." (see Section 3.6.1 of the April 2024 EPA Response to Public Comments on the *Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act*). In the case of 1,4-dioxane, EPA understands the scope of the risk evaluation to consist of the combined scope of both the 2020 risk evaluation and the 2024 supplement to the risk evaluation.

2.12.2 Communication and Accessibility

SUMMARY: One comment (55) suggests that EPA provide a non-technical summary to summarize scope of the assessment, unreasonable risk findings, and identifying facilities for which risk exceeds a certain threshold. This comment also recommended disclosing all non-cancer risk calculations and identifying which facilities pose a greater risk for cancer without requiring the reader to read through additional attachments and spreadsheets. Another similar comment (61) requested that EPA identify "all potential sources of 1,4-dioxane vapor that results in human exposure," even those lacking quantification, to allow states to better identify possible sources and locations of 1,4-dioxane contamination.

Another comment (51) suggested EPA offer training on Monte Carlo models, SHEDS-HT, and other models used in the assessment.

***EPA RESPONSE*:** EPA provides non-technical summaries with final TSCA risk evaluations and has provided one with the final supplement and revised risk determination for 1,4-dioxane (available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-14-dioxane). The Agency provides all exposure and risk estimate results in supplemental material. In supplemental appendices and risk calculator files, EPA aims to present a full range of results, including what-if scenarios and sensitivity analyses. In an effort to keep the main body of the document as concise and clear as possible, EPA focuses on key findings rather than presenting the full range of results. The Agency therefore focuses on presenting cancer risk in the main body of the supplement because cancer risk appears to be the primary risk driver for 1,4-dioxane for the exposure scenarios evaluated.

In addition, the results of the analysis should not be interpreted as a definitive characterization of the level of risk present at specific locations. The supplement presents a national scale analysis. While it may explore potential risk expected at a particular facility under certain conditions, a national scale assessment does not provide site-specific granularity to offer definitive information about the risks associated with specific facilities. Rather, it offers information about the range of conditions under which risk may reach specific levels.

The risk evaluation presents risk estimates but does not define a specific "bright line" at which risk estimates would be determined to be unreasonable. Unreasonable risk determinations are policy decisions based on a broader set of factors and are beyond the scope of the analysis presented in the risk evaluation. *The Final Revised Risk Determination for 1,4-Dioxane* identifies the COUs that contribute to unreasonable risk and subsequent policy choices about how to address the unreasonable risk presented by 1,4-dioxane will be handled in risk management.

EPA has not provided training on models used for this assessment. However, as described in 2.1, 2.2, 2.3, and 2.4 above, EPA has updated the revised supplement to provide greater clarity around the models and inputs used. In addition, EPA's Office of Research and Development has publicly released the version of SHEDS-HT applied in this risk evaluation supplement (at https://github.com/HumanExposure/SHEDS_OPPT_1_4Dioxane_RE).Appendix A

2.12.3 Peer Review Process

SUMMARY: Several comments (64, 66) raised concerns that novel approaches for the assessment of groundwater, surface water, and air pathways have not been peer-reviewed by the SACC.
EPA RESPONSE: The charge questions posed to the SACC specifically solicited input on all of the novel approaches used in this assessment. SACC review of the draft supplement constitutes peer review of the application of these novel methods in the context of this assessment.

2.12.4 Risk Evaluation Process

SUMMARY: Several comments (33, 34, 41, 51, 52, 64, 75) made observations about the process used to develop and review the supplement, including that there was not sufficient time to provide comment on the draft supplement and revised risk determination and that the review process is not sustainable and needs to be streamlined. One comment (75) notes that many analyses lack of framework for determining when further analysis is warranted.
EPA RESPONSE: EPA will consider whether a longer comment period is warranted for future draft risk evaluations. With each new assessment, EPA aims to make iterative process improvements that further clarify frameworks and decision logic applied for each aspect of the analysis. The Agency aims to further refine frameworks and decision logic applied to each pathway and improve communication around those frameworks with future assessments.

SUMMARY: In response to charge question 1f on any scientific considerations that EPA should contemplate when considering Monte Carlo methods in release and occupational assessments for future risk evaluations under TSCA, the SACC recommended that EPA, "consider the use of artificial intelligence (AI) for future TSCA evaluations."
EPA RESPONSE*:* EPA will consider the utility of artificial intelligence for future risk evaluation processes.

Appendix A SACC CHARGE QUESTIONS

Charge Question 1a: Comment on EPA's method for developing Monte Carlo modeling simulations and use of those methods in the 1,4-dioxane draft supplement. Specifically, please provide detailed comments on the strengths, uncertainties, and the incorporation of variability.

Charge Question 1b: For the exposure and release assessments, EPA assigned statistical distributions based on available literature data or standard probability distribution assumptions appropriate for limited datasets to address the variability in several parameters. Please comment on the distribution selection and if EPA should consider any additional parameters for inclusion in the model equations.

Charge Question 1c: EPA relied on reasonably available information to identify model input parameters. For these parameters, there is uncertainty in whether the input data adequately captures the variability in the true distribution. Please provide additional sources of reasonably available data that may improve the parameter distributions for consideration in the development of distributions.

Charge Question 1d: In the 2023 draft supplement, EPA used Monte Carlo modeled releases to estimate general population exposures and risks. For example, the Agency used Monte Carlo modeled releases to water, land, and air from hydraulic fracturing as the basis for general population exposure estimates in Sections 3.2.2.1.3, 3.2.2.2.2, and 3.2.3.2. Please comment on the strengths and uncertainties of using Monte Carlo modeled releases as the basis for modeling air or water concentrations intended to inform nationally generalizable exposure and risk estimates for general population exposures.

Charge Question 1e: Please comment on the application of the Monte Carlo method taken by EPA in the 1,4-dioxane 2023 draft supplement. Sections 2.1.1 and 3.1.1 are general overviews of the assessment approaches. Appendix E.9 is an overview of Monte-Carlo methods as applied specifically to this risk evaluation and will be applied generally to subsequent risk evaluations. Appendix F.4 includes occupational exposure scenarios where Monte-Carlo methods were used to develop distributions for certain 1,4 dioxane occupational exposure scenarios.

Charge Question 1f: Please provide feedback on any scientific considerations that EPA should contemplate when considering Monte Carlo methods in release and occupational assessments for future risk evaluations under TSCA.

Charge Question 2.1a: As described in Appendix G.2.1, EPA used the NHDPlus V2.1 flowline data for receiving water body flows, including the use of modeled annual and monthly average flows from this database as well as geospatial techniques used to assign facilities and intakes to reaches when necessary. Please comment on the strengths and uncertainties of applying this data set.

Charge Question 2.1b: As described in Appendix G.2.1, EPA, in the absence of data, relied on assumptions for specific release amounts and locations. For example, for facilities reporting releases via Form A, EPA assumed 500 lb/year of releases; for facilities without reach codes in NPDES permits, EPA used the nearest NHDPlus flowline within 2 km as the receiving water body. EPA compared the impact on the overall analysis when facilities requiring these assumptions were included (Figure 5-1 in Section 5.2.2.1) or excluded (Figure 5-2 in Section 5.2.2.1). Please comment on the strengths and uncertainties of these assumptions.

Charge Question 2.2: EPA applied novel approaches to estimate DTD releases of 1,4-dioxane in consumer and commercial products as described in Appendix G.2.3. Please comment on the strengths and uncertainties of the novel estimation methods and validation of the DTD modeling in the case studies presented in Appendix G.2.3.2. In addition, please comment on the application of SHEDS-HT to develop per capita DTD loading, which may be applicable for other chemicals with relevant product and usage data within SHEDS-HT. Finally, please comment on how SHEDS-HT outputs are incorporated into the novel DTD modeling approaches applied in this assessment.

Charge Question 2.3a: EPA developed an aggregate probabilistic model to estimate surface water concentrations, as described in Section 2.3.1 and Appendix G.2.3. Please comment on the strengths and uncertainties of the aggregate probabilistic model.

Charge Question 2.3b: While the aggregated probabilistic model is informed by site-specific release information, the Agency aims to develop and utilize methods for national scale risk evaluations that estimate risks for a nationally representative distribution of exposures. Please comment on the strengths and uncertainties in this approach for providing a nationally representative distribution of chemical concentrations that is suitable for informing a national scale risk evaluation.

Charge Question 2.3c: As described in Appendix G.2.3, EPA included multiple years of release data for each facility reporting releases as inputs into the probabilistic model. The Agency used available surface water monitoring data to provide an input distribution of background surface water concentration. Please comment on the strengths and uncertainties of the specific inputs and source data EPA used to run the model, including EPA's approach to incorporating multiple years and multiple sources (*i.e.,* facility releases and background concentrations) in this methodology.

Charge Question 2.3d: To evaluate the performance of probabilistic model, EPA used site-specific case studies to compare modeled concentrations to available co-located monitoring concentrations. Based on the case study comparisons presented in Section 2.3.1.4 and Appendix G.2.3.2, EPA concluded that there is strong concordance between monitoring data and modeled concentrations. Please comment on the strengths and uncertainties of the comparisons between modeling and monitored concentrations, including the case studies described in Appendix G.2.3.2. Specifically, describe the relevance of the monitored data and its relevance to the modeled concentrations and comment on EPA's interpretation of the case study results.

Charge Question 2.4a: EPA estimated the impact of generic assumptions about the degree of dilution on the overall distribution of concentrations and risks from individual facility releases. Please comment on the strengths and uncertainties of the generalized dilution estimates presented in Figure 5-4. As part of this discussion, please comment on the strengths and uncertainties around EPA's assumption that, in some locations, minimal dilution may occur between the point of 1,4-dioxane release and the location of drinking water intakes.

Charge Question 2.4b: The EPA estimated site-specific concentrations and risks beyond the point of release by including a downstream dilution factor estimated from a downstream tracing analysis described in Section 5.2.2.1.2 and Appendix G.2.4. Please comment on the downstream tracing analysis and the use of the NHDPlus V2.1 flow network to identify drinking water intakes downstream of facility releases and to estimate dilution from the point of release. Specifically, discuss the strengths and uncertainties in the methodology used to inform risk characterization for a nationally representative assessment.

Charge Question 3a: EPA applied the DRAS model to estimate groundwater concentrations associated with releases from municipal solid waste landfills and disposal of hydraulic fracturing waste, as described in Section 2.3.2. and Appendix H. Please comment on the strengths and uncertainties and assumptions associated with use of the DRAS model to estimate groundwater concentrations in this context.

Charge Question 3b: The Agency aims to develop and utilize methods for national scale risk evaluations that provide risk estimates for a range of reasonably foreseeable exposure scenarios, including sentinel exposures and PESS. Please include in your comments the extent to which this groundwater assessment reasonably represents the potential for sentinel exposure for a potentially exposed susceptible subpopulation in a national assessment.

Charge Question 3c: Throughout Section 2.3.2, EPA made several assumptions about drinking water exposure scenarios for groundwater. For example, EPA assumed that groundwater concentrations predicted using the DRAS model may reflect average concentrations in untreated private drinking water wells over 33 years. Please comment on the assumptions underlying drinking water exposure scenarios for groundwater.

Charge Question 4a: EPA quantitatively aggregated exposures and risks resulting from multiple sources releasing to air (Appendix J.4.). Please comment on the strengths and uncertainties of EPA's approach, including the approaches used to group facilities, combined releases by overlaying, and other components of the aggregate methodologies, as well as alternative/improved approaches.

Charge Question 4b: EPA quantitatively characterized surface water concentrations as well as exposure and risks resulting from multiple sources of 1,4-dioxane released to water (Section 2.3.1.2.1, Section 2.3.1.3.4, Section 5.2.2.1.5, and Appendix G.2.3). Please comment on the strengths and uncertainties of EPA's approach for estimating aggregate exposure and risk from multiple sources in surface sourced drinking water.

Charge Question 4c: EPA qualitatively characterized aggregate exposure and risk across routes and across pathways. While EPA recognizes the importance of identifying and characterizing these aggregate exposures, they were not quantified due to substantial uncertainties associated with aggregating 1,4-dioxane exposures and risks across routes. Please comment on EPA's approach to assessing aggregate exposures across routes qualitatively rather than quantitatively in this assessment, and on the strengths and uncertainties identified in this qualitative characterization.